



## Amgen Reports Second Quarter 2021 Financial Results

August 3, 2021

THOUSAND OAKS, Calif., Aug. 3, 2021 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced financial results for the second quarter of 2021. Key results include:

- Total revenues increased 5% to \$6.5 billion in comparison to the second quarter of 2020, driven by higher unit demand, partially offset by lower net selling prices.
  - Product sales increased 3% globally, driven by double digit volume growth across a number of our products including Prolia® (denosumab), Repatha® (evolocumab) and our biosimilar products MVASI® (bevacizumab-awwb) and KANJINTI® (trastuzumab-anns).
- GAAP earnings per share (EPS) decreased 73% to \$0.81 driven by the write-off of \$1.5 billion in acquired in-process research & development (acquired IPR&D) associated with our acquisition of Five Prime Therapeutics, partially offset by increased revenues.
  - GAAP operating income decreased 64% to \$0.8 billion and GAAP operating margin decreased 25.8 percentage points to 13.5%.
- Non-GAAP EPS increased 4% to \$4.38 driven by increased revenues and the impact of fewer weighted average shares outstanding.
  - Non-GAAP operating income decreased 4% to \$3.1 billion and non-GAAP operating margin decreased 4.1 percentage points to 50.9%.
- The Company generated \$1.7 billion of free cash flow in the second quarter versus \$2.7 billion in the second quarter of 2020 driven by a difference in the timing of tax payments.
- 2021 total revenues guidance reaffirmed at \$25.8-\$26.6 billion; EPS guidance revised to \$8.84-\$9.90 on a GAAP basis, and reaffirmed at \$16.00-\$17.00 on a non-GAAP basis.

***"We achieved solid, volume-driven growth in the quarter as our business recovered from the effects of the pandemic," said Robert A. Bradway, chairman and chief executive officer. "As we look to the balance of the year, we are excited to be launching LUMAKRAS™, a first-in-class lung cancer treatment, and advancing a robust pipeline of potential new medicines to meet the demands of patients around the world."***

| \$Millions, except EPS, dividends paid per share and percentages | Q2 '21  | Q2 '20  | YOY Δ |
|--|---------|---------|-------|
| Total Revenues   | \$6,526 | \$6,206 | 5%    |
| GAAP Operating Income  | \$ 828  | \$2,323 | (64%) |
| GAAP Net Income  | \$ 464  | \$1,803 | (74%) |
| GAAP EPS   | \$ 0.81 | \$ 3.05 | (73%) |
| Non-GAAP Operating Income  | \$3,111 | \$3,247 | (4%)  |
| Non-GAAP Net Income  | \$2,522 | \$2,484 | 2%    |
| Non-GAAP EPS   | \$ 4.38 | \$ 4.20 | 4%    |
| Dividends Paid Per Share   | \$ 1.76 | \$ 1.60 | 10%   |

References in this release to "non-GAAP" measures, measures presented "on a non-GAAP basis" and to "free cash flow" (computed by subtracting capital expenditures from operating cash flow) refer to non-GAAP financial measures. Adjustments to the most directly comparable GAAP financial measures and other items are presented on the attached reconciliations. For comparability of results to the prior year, non-GAAP net income and non-GAAP EPS amounts for 2020 have been revised to reflect the update to our non-GAAP policy that excludes gains and losses on certain equity investments. Refer to Non-GAAP Financial Measures below for further discussion.

### Product Sales Performance

**COVID-19 update:** Compared to the first quarter of 2021, we have seen gradual recovery from the impacts of the COVID-19 pandemic. Patient visits and lab test procedure trends continued to improve but remained below pre-COVID-19 levels. The cumulative decrease in diagnoses over the course of the pandemic has suppressed the volume of new patients starting treatment, which we expect to continue to impact our business during the second half of the year.

**Total product sales** increased 3% for the second quarter of 2021 versus the second quarter of 2020. Unit volumes grew 8% while net selling price declined 5%. On a sequential basis, product sales grew 9% quarter-over-quarter, driven by 6% volume growth.

Results for individual products are as follows:

- **Prolia** sales increased 24% year-over-year for the second quarter, driven by 20% volume growth as new and repeat patient volumes continued to recover from the pandemic. With osteoporosis diagnosis rates remaining at approximately 90% of pre-COVID-19 levels in the quarter, we are focused on driving patient growth and are optimistic about Prolia's continued strength in the second half of the year.
- **EVENITY® (romosozumab-aqqg)** sales increased 30% year-over-year for the second quarter, driven by 32% volume

growth. U.S. sales nearly doubled year-over-year, driven by 97% volume growth as we continued to focus on new patient activation. Rest of world (ROW) sales decreased 15% year-over-year due in part to the timing of purchases by our partner Astellas during the first half of 2020.

- **Repatha** sales increased 43% year-over-year for the second quarter, driven by 49% volume growth. In the U.S., volumes grew 37% year-over-year, and outside the U.S. volumes grew 66% year-over-year. Volume growth in the quarter was partially offset by lower net selling price as a result of an increase in the number of U.S. Medicare Part D patients receiving Repatha and entering the coverage gap. We expect further reduction in the net selling price on a sequential basis as the number of Medicare Part D patients receiving Repatha increases. Repatha has now been prescribed for more than one million patients.
- **Aimovig (erenumab-aooe)** sales decreased 16% year-over-year for the second quarter. Unit volume growth of 11% was offset by lower net selling price and unfavorable changes to estimated sales deductions. Aimovig retains strong payer coverage and remains the segment leader within the preventive calcitonin gene-related peptide (CGRP) class. To date, more than 500,000 patients worldwide have been prescribed Aimovig for the preventive treatment of migraine.
- **Otezla (apremilast)** sales decreased 5% year-over-year for the second quarter, primarily driven by unfavorable changes to estimated sales deductions and lower net selling price, partially offset by 5% volume growth. In the U.S., Otezla continued to maintain first-line share leadership in psoriasis. New-to-brand prescription (NBRx) volumes grew 10% year-over-year, even as patient visits to dermatologists remained 15% below pre-pandemic levels. The number of new patients that started treatment with Otezla in Q2 was near pre-pandemic levels, but those gains were largely offset by a lower percentage of 90-day prescriptions and lower prescription refill rates. We expect that recovery in the dermatology segment will continue to progress over the coming quarters. Looking forward, we are preparing for the anticipated approval of the mild-to-moderate psoriasis indication in the U.S., and continued geographic expansion, including the launch in China.
- **Enbrel (etanercept)** sales decreased 8% year-over-year for the second quarter, primarily driven by lower net selling price and unfavorable changes in estimated sales deductions. On a year-over-year basis volumes declined 1%. Going forward, we expect net selling price to continue to decline year-over-year.
- **AMGEVITA™ (adalimumab)** sales increased 73% year-over-year for the second quarter, primarily driven by volume growth. AMGEVITA continued to be the most prescribed adalimumab biosimilar in Europe.
- **LUMAKRAS™ (sotorasib)** has been well received by the oncology community. LUMAKRAS has been added to the National Comprehensive Cancer Network (NCCN) guidelines and unaided awareness among oncologists has increased significantly since launch. KRAS testing of patients with metastatic non-small cell lung cancer (NSCLC) now stands at approximately 70%, driven by increased next generation sequencing (NGS) utilization and KRAS G12C educational efforts, and 46 of the 50 top testing laboratories are now identifying the KRAS G12C mutation as actionable in their lab reports.
- **KYPROLIS® (carfilzomib)** sales increased 11% year-over-year for the second quarter, primarily driven by volume growth and net selling price. For the remainder of the year, we expect continued growth from Kyprolis use in combination with CD38 antibodies.
- **XGEVA® (denosumab)** sales increased 12% year-over-year for the second quarter, driven by volume growth as the segment recovered from the earlier effects of the pandemic.
- **Vectibix® (panitumumab)** sales increased 23% year-over-year for the second quarter, driven by 20% volume growth that benefited from increased shipments to Takeda, our partner in Japan. We expect lower demand from Takeda in the third quarter.
- **Nplate® (romiplostim)** sales increased 27% year-over-year for the second quarter, driven by 17% volume growth and higher inventory levels.
- **BLINCYTO® (blinatumomab)**, our BiTE® immunotherapy, sales increased 16% year-over-year for the second quarter, driven by 18% volume growth as we benefited from broader adoption in the community hospital setting.
- **MVASI** sales increased 71% year-over-year for the second quarter, driven by strong volume growth, partially offset by lower net selling price. In the U.S., MVASI continued to hold leading volume share with 50% of the bevacizumab segment in the quarter. Sales were flat quarter-over-quarter as volume growth was offset by unfavorable changes to estimated sales deductions. Going forward on a sequential basis, we expect continued worldwide volume growth to be more than offset by declines in net selling price due to increased competition.
- **KANJINTI** sales increased 27% year-over-year for the second quarter, primarily driven by volume growth, partially offset by lower net selling price. In the U.S., KANJINTI continued to hold leading volume share with 42% of the trastuzumab segment in the quarter. Sales decreased 3% quarter-over-quarter, primarily driven by unfavorable changes to estimated sales deductions. Going forward, we expect sales to decline sequentially in the second half of the year driven by net selling price.
- **Neulasta® (pegfilgrastim)** sales decreased 18% year-over-year for the second quarter, driven by declines in both net selling price and volume, partially offset by a \$75 million year-over-year benefit from favorable changes in reimbursement mix, resulting from the comparison of a \$39 million favorable adjustment to estimated sales deductions in the quarter to a \$36 million unfavorable adjustment in the second quarter last year. In the long-acting granulocyte colony-stimulating factor (G-CSF) segment, Neulasta Onpro® continued to be the preferred choice for physicians and patients with volume share of 52% in the quarter. The most recent published Average Selling Price for Neulasta in the U.S. declined 35% year-over-year

and 12% quarter-over-quarter. Going forward, we expect increased competition to result in further declines in net selling price.

- **NEUPOGEN® (filgrastim)** sales increased 4% year-over-year for the second quarter, driven by favorable changes in estimated sales deductions, partially offset by volume declines.
- **EPOGEN® (epoetin alfa)** sales decreased 19% year-over-year for the second quarter, driven by volume declines and lower net selling price resulting from our contractual commitment with DaVita.
- **Aranesp® (darbepoetin alfa)** sales decreased 5% year-over-year for the second quarter, driven by lower net selling price due to competition.
- **Parsabiv® (etelcalcetide)** sales decreased 62% year-over-year for the second quarter, driven by volume declines. With Parsabiv's inclusion in the U.S. end-stage renal disease (ESRD) bundled payment system, dialysis clinics rapidly implemented new treatment protocols, switching patients from Parsabiv to generic oral cinacalcet. As a result, we expect a 50-60% year-over-year Parsabiv sales decline in 2021. For patients on hemodialysis, Parsabiv is the only IV-administered calcimimetic that treats secondary hyperparathyroidism and provides the opportunity to reduce patient pill burden.
- **Sensipar®/Mimpara™ (cinacalcet)** sales decreased 70% year-over-year for the second quarter, primarily driven by volume declines in response to generic competition.

#### Product Sales Detail by Product and Geographic Region

| \$Millions, except percentages | Q2 '21   |          |          | Q2 '20   | YOY Δ |
|--------------------------------|----------|----------|----------|----------|-------|
|                                | US       | ROW      | TOTAL    | TOTAL    | TOTAL |
| Prolia®                        | \$ 538   | \$ 276   | \$ 814   | \$ 659   | 24%   |
| EVENITY®                       | 79       | 52       | 131      | 101      | 30%   |
| Repatha®                       | 143      | 143      | 286      | 200      | 43%   |
| Aimovig®                       | 82       | —        | 82       | 98       | (16%) |
| Otezla®                        | 423      | 111      | 534      | 561      | (5%)  |
| Enbrel®                        | 1,113    | 31       | 1,144    | 1,246    | (8%)  |
| AMGEVITA™                      | —        | 107      | 107      | 62       | 73%   |
| KYPROLIS®                      | 190      | 90       | 280      | 253      | 11%   |
| XGEVA®                         | 355      | 133      | 488      | 435      | 12%   |
| Vectibix®                      | 92       | 147      | 239      | 195      | 23%   |
| Nplate®                        | 136      | 109      | 245      | 193      | 27%   |
| BLINCYTO®                      | 62       | 46       | 108      | 93       | 16%   |
| MVASI®                         | 206      | 88       | 294      | 172      | 71%   |
| KANJINTI®                      | 132      | 24       | 156      | 123      | 27%   |
| Neulasta®                      | 434      | 52       | 486      | 593      | (18%) |
| NEUPOGEN®                      | 36       | 15       | 51       | 49       | 4%    |
| EPOGEN®                        | 130      | —        | 130      | 161      | (19%) |
| Aranesp®                       | 135      | 232      | 367      | 387      | (5%)  |
| Parsabiv®                      | 37       | 34       | 71       | 186      | (62%) |
| Sensipar®/Mimpara™             | 4        | 20       | 24       | 81       | (70%) |
| Other**                        | 47       | 30       | 77       | 60       | 28%   |
| Total product sales            | \$ 4,374 | \$ 1,740 | \$ 6,114 | \$ 5,908 | 3%    |

\*\* Other includes Corlanor®, GENSENTA, IMLYGIC®, LUMAKRAS™, AVSOLA®, Bergamo, and RIABNI®

#### Operating Expense, Operating Margin and Tax Rate Analysis

On a GAAP basis:

- **Total Operating Expenses** increased 47% primarily driven by the recent acquisition of Five Prime Therapeutics. **Cost of Sales** margin increased 1.6 percentage points primarily due to product mix, including COVID-19 antibody shipments to Eli Lilly and Company (Lilly) that began this quarter, profit share and royalties, partially offset by lower amortization expense from acquisition-related assets. **Research & Development (R&D)** expenses increased 12% primarily due to higher research and early pipeline spend and late-stage development program spend, including our recent business development activities. **Acquired IPR&D** expenses in 2021 were driven by the Five Prime Therapeutics acquisition. **Selling, General & Administrative (SG&A)** expenses increased 7% driven by marketed product support due to increased customer engagement in response to the pandemic recovery and investment in new product launches.
- **Operating Margin** as a percentage of product sales decreased 25.8 percentage points to 13.5%.
- **Tax Rate** increased 5.6 percentage points primarily driven by the non-deductible acquired IPR&D expense arising from the acquisition of Five Prime Therapeutics.

On a non-GAAP basis:

- **Total Operating Expenses** increased 15%. **Cost of Sales** margin increased 4.1 percentage points primarily due to product mix, including COVID-19 antibody shipments to Lilly that began this quarter, profit share and royalties. **R&D** expenses increased 11% primarily due to higher research and early pipeline spend and late-stage development program spend, including our recent business development activities. **SG&A** expenses increased 6% driven by marketed product support due to increased customer engagement in response to the pandemic recovery and investment in new product launches.
- **Operating Margin** as a percentage of product sales decreased 4.1 percentage points to 50.9%.
- **Tax Rate** decreased 1.0 percentage points primarily driven by a prior year change in foreign loss utilization.

| \$Millions, except percentages         | GAAP           |                |                | Non-GAAP       |                |                  |
|--|----------------|----------------|----------------|----------------|----------------|------------------|
|  | Q2 '21         | Q2 '20         | YOY Δ          | Q2 '21         | Q2 '20         | YOY Δ            |
| Cost of Sales                          | \$1,637        | \$1,488        | 10%            | \$1,034        | \$ 758         | 36%              |
| % of product sales                     | 26.8%          | 25.2%          | 1.6 pts        | 16.9%          | 12.8%          | 4.1 pts          |
| Research & Development                 | \$1,082        | \$ 964         | 12%            | \$1,036        | \$ 936         | 11%              |
| % of product sales                     | 17.7%          | 16.3%          | 1.4 pts        | 16.9%          | 15.8%          | 1.1 pts          |
| Acquired IPR&D                         | \$1,505        | \$ —           | *              | \$ —           | \$ —           | —%               |
| % of product sales                     | 24.6%          | —%             | 24.6 pts       | —%             | —%             | 0 pts            |
| Selling, General & Administrative      | \$1,384        | \$1,295        | 7%             | \$1,345        | \$1,265        | 6%               |
| % of product sales                     | 22.6%          | 21.9%          | 0.7 pts        | 22.0%          | 21.4%          | 0.6 pts          |
| Other                                  | \$ 90          | \$ 136         | (34%)          | \$ —           | \$ —           | —%               |
| <b>Total Operating Expenses</b>        | <b>\$5,698</b> | <b>\$3,883</b> | <b>47%</b>     | <b>\$3,415</b> | <b>\$2,959</b> | <b>15%</b>       |
| Operating Margin                       |                |                |                |                |                |                  |
| operating income as % of product sales | 13.5%          | 39.3%          | (25.8) pts     | 50.9%          | 55.0%          | (4.1) pts        |
| <b>Tax Rate</b>                        | <b>16.8%</b>   | <b>11.2%</b>   | <b>5.6 pts</b> | <b>12.6%</b>   | <b>13.6%</b>   | <b>(1.0) pts</b> |

pts: percentage points  
\* Change in excess of 100%

#### Cash Flow and Balance Sheet

- The Company generated \$1.7 billion of free cash flow in the second quarter of 2021 versus \$2.7 billion in the second quarter of 2020, driven by a difference in the timing of tax payments.
- The Company's second quarter 2021 dividend of \$1.76 per share was declared on March 3, 2021, and was paid on June 8, 2021, to all stockholders of record as of May 17, 2021, representing a 10% increase from 2020.
- During the second quarter, the Company repurchased 6.5 million shares of common stock at a total cost of \$1.6 billion. At the end of the second quarter, the Company had \$3.9 billion authorization remaining under its stock repurchase program.
- Cash and investments totaled \$8.1 billion and debt outstanding totaled \$32.8 billion as of June 30, 2021.

| \$Billions, except shares         | Q2 '21 | Q2 '20 | YOY Δ   |
|-----------------------------------|--------|--------|---------|
| Operating Cash Flow               | \$ 1.9 | \$ 2.8 | \$(0.9) |
| Capital Expenditures              | \$ 0.2 | \$ 0.2 | \$ 0.0  |
| Free Cash Flow                    | \$ 1.7 | \$ 2.7 | \$(0.9) |
| Dividends Paid                    | \$ 1.0 | \$ 0.9 | \$ 0.1  |
| Share Repurchases                 | \$ 1.6 | \$ 0.6 | \$ 1.0  |
| Average Diluted Shares (millions) | 576    | 592    | (16)    |

Note: Numbers may not add due to rounding

| \$Billions           | 6/30/21 | 12/31/20 | YTD Δ   |
|----------------------|---------|----------|---------|
| Cash and Investments | \$ 8.1  | \$ 10.6  | \$(2.6) |
| Debt Outstanding     | \$ 32.8 | \$ 33.0  | \$(0.2) |

Note: Numbers may not add due to rounding

#### 2021 Guidance

For the full year 2021, the Company now expects:

- **Total revenues** in the range of \$25.8 billion to \$26.6 billion, unchanged from previous guidance.
- On a **GAAP basis**, **EPS** in the range of \$8.84 to \$9.90 and a **tax rate** in the range of 13.0% to 14.5%.
  - Previously, the Company expected GAAP EPS in the range of \$9.11 to \$10.71 and a tax rate in the range of 14.0%

to 15.5%.

- On a **non-GAAP basis**, **EPS** in the range of \$16.00 to \$17.00, unchanged from previous guidance and a **tax rate** in the range of 13.5% to 14.5%, also unchanged from previous guidance.
- **Capital expenditures** to be approximately \$900 million.
- **Share repurchases** at the upper end of our previous guidance of \$3.0 billion to \$5.0 billion.

## Second Quarter Product and Pipeline Update

The Company provided the following updates on selected product and pipeline programs:

### LUMAKRAS

- In May, the U.S. Food and Drug Administration (FDA) approved LUMAKRAS for the treatment of adult patients with *KRAS* G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy. LUMAKRAS received accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Regulatory reviews continue in Europe, Japan and other jurisdictions.
- Top-line results from the event-driven confirmatory Phase 3 study comparing LUMAKRAS to docetaxel in patients with *KRAS* G12C-mutated advanced NSCLC are expected in H1 2022.
- Primary results from the Phase 2 monotherapy study in patients with advanced *KRAS* G12C-mutated colorectal cancer (CRC) have been submitted for publication.
- Additional data from the Phase 1/2 CodeBreak 100 monotherapy study in advanced NSCLC have been accepted for presentation at the World Conference on Lung Cancer in September, including biomarker analyses and post hoc analyses of efficacy and safety in patients with stable brain metastases. Enrollment continues in a cohort of patients with active brain metastases in the CodeBreak 101 study.
- Exploration of LUMAKRAS in multiple Phase 1b combination cohorts continues to progress.
  - Initial data from LUMAKRAS in combination with Vectibix in patients with advanced *KRAS* G12C-mutated CRC have been accepted for presentation at the European Society for Medical Oncology Congress in September.
  - Initial data from LUMAKRAS in combination with a mitogen-activated protein kinase kinase (MEK) inhibitor and LUMAKRAS in combination with an oral EGFR inhibitor are planned to be submitted for presentation at a Q4 2021 medical conference.
  - The Company is collaborating with Novartis on a LUMAKRAS combination study with their SHP-2 inhibitor TNO155. A cohort is expected to initiate in the CodeBreak 101 study in Q3 2021. Enrollment continues in a combination cohort with Revolution Medicine's SHP-2 inhibitor RMC-4630.
- Initiation of a Phase 2 study is planned for Q3 2021 in first-line patients with *KRAS* G12C mutated NSCLC whose tumors express < 1% programmed death-ligand 1 (PD-L1) and/or serine/threonine kinase 11 (STK11) mutations.
- Data from the Phase 2 monotherapy study in patients with *KRAS* G12C-mutated solid tumors other than NSCLC and CRC are expected in H1 2022.

### BLINCYTO

- In June, the European Commission approved an expanded indication for the use of BLINCYTO in the treatment of pediatric patients aged 1 year or older with high-risk first relapsed Philadelphia chromosome negative CD19 positive B-precursor acute lymphoblastic leukemia as part of the consolidation therapy.

### Bemarituzumab

- The Company has initiated discussions with regulators on the Phase 3 study design for bemarituzumab, a first-in-class anti-fibroblast growth factor receptor 2b (FGFR2b) antibody for the treatment of patients with human epidermal growth factor receptor 2 (HER2) negative, FGFR2b-positive gastric and gastroesophageal junction cancer. Initiation of the registrational program is planned for Q4 2021.
- Bemarituzumab has been granted Breakthrough Therapy Designation by the FDA as first-line treatment for patients with at least 10% FGFR2b overexpression and HER2-negative metastatic and locally advanced gastric and gastroesophageal adenocarcinoma in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin).
- Planning is underway for bemarituzumab clinical studies in other solid tumors, including squamous NSCLC.

### Acapatamab (AMG 160)

- A dose expansion cohort of acapatamab, a half-life extended (HLE) BiTE molecule targeting prostate-specific membrane antigen (PSMA), has completed enrollment of patients with metastatic castrate resistant prostate cancer (mCRPC). Enrollment of acapatamab is ongoing in cohorts with reduced levels of monitoring during cycle one to explore outpatient administration.

- An acapatamab dose escalation study has initiated for patients with NSCLC expressing PSMA.
- A master protocol evaluating combinations of acapatamab with AMG 404, an anti-programmed cell death 1 (PD-1) antibody, or the novel hormone therapies enzalutamide or abiraterone, continues to enroll patients with earlier-line mCRPC.

#### **Tarlatamab (AMG 757)**

- The Company has begun planning a potentially pivotal Phase 2 study and will initiate discussions with regulators for tarlatamab, an HLE BiTE molecule targeting delta-like ligand 3 (DLL3), in patients with relapsed or refractory small cell lung cancer.
- A Phase 1b study of tarlatamab has begun recruiting patients with neuroendocrine prostate cancer.
- A Phase 1b study of tarlatamab in combination with AMG 404 is planned to initiate in Q3 2021 for patients with small cell lung cancer.

#### **Additional Phase 1 Oncology Programs**

- AMG 509, a bivalent T-cell engager XmAb<sup>®</sup> 2+1 antibody targeting six transmembrane epithelial antigen of the prostate 1 (STEAP1) was recently granted Fast Track designation by the FDA and continues to enroll patients with mCRPC.
- Pavurutamab (AMG 701), an HLE BiTE<sup>®</sup> molecule targeting B-cell maturation antigen (BCMA), has resumed enrolling patients with relapsed or refractory multiple myeloma.
- AMG 330, a BiTE<sup>®</sup> molecule targeting CD33, continues to enroll patients with acute myeloid leukemia.
- Enrollment has been paused in the Phase 1 study of AMG 427, a BiTE<sup>®</sup> molecule targeting fms-like tyrosine kinase 3 (FLT3) for patients with acute myeloid leukemia.
- HLE BiTE<sup>®</sup> molecules AMG 199 and AMG 910, targeting mucin 17 (MUC17) and claudin 18.2 (CLDN18.2), respectively, continue to enroll patients with gastric and gastroesophageal junction cancer.
- AMG 176, a small molecule inhibitor of myeloid cell leukemia 1 (MCL-1), continues to enroll patients with hematologic malignancies.
- AMG 256, a multispecific interleukin-21 receptor agonist, continues to enroll patients with PD-1 positive solid tumors.

#### **Tezepelumab**

- In July, the FDA accepted the Biologics License Application and granted Priority Review for tezepelumab for the treatment of asthma. Regulatory reviews are also underway in the EU and Japan.
- A Phase 3 study has begun enrolling patients with chronic rhinosinusitis with nasal polyps.
- A Phase 2b study continues to enroll patients with chronic spontaneous urticaria.
- A Phase 2 study continues to enroll patients with chronic obstructive pulmonary disease.

#### **Otezla**

- In May, the Company announced that the FDA accepted the supplemental New Drug Application for Otezla for the treatment of adults with mild-to-moderate plaque psoriasis who are candidates for phototherapy or systemic therapy. The FDA has assigned a Prescription Drug User Fee Act action date of December 19, 2021.
- Phase 3 planning is underway for Otezla for the treatment of Japanese patients with palmoplantar pustulosis.
- The Company has stopped enrollment in the Otezla arms of ongoing platform trials designed to evaluate the efficacy and safety of potential treatments for patients hospitalized with COVID-19.

#### **AMG 451 / KHK4083**

- The Company expects to commence discussions with regulators soon for AMG 451, an anti-OX40 monoclonal antibody, for the treatment of atopic dermatitis, with Phase 3 development anticipated to begin in H1 2022.

#### **Rozibafusp alfa (AMG 570)**

- A Phase 2b study of rozibafusp alfa, a multispecific antibody-peptide conjugate that simultaneously blocks inducible T-cell costimulatory ligand (ICOSL) and B-cell activating factor (BAFF) activity, continues to enroll patients with systemic lupus erythematosus (SLE).

#### **Efavaleukin alfa (AMG 592)**

- A Phase 2b study of efavaleukin alfa, an interleukin-2 mutein Fc fusion protein, is enrolling patients with SLE.
- Data from a Phase 1b SLE study have been submitted to a Q4 2021 medical conference.
- A Phase 2 study of efavaleukin alfa is planned to initiate in H2 2021 for patients with ulcerative colitis.

#### **AMG 714 / PRV-015**

- A Phase 2b study of AMG 714, a monoclonal antibody that binds interleukin-15, continues to enroll patients with non-responsive celiac disease.

#### **Repatha**

- A Phase 3 cardiovascular outcomes study (VESALIUS-CV) continues to enroll patients at high cardiovascular risk without prior myocardial infarction or stroke.

#### **Olpasiran (AMG 890)**

- Results from a Phase 2 study in patients with elevated lipoprotein(a) are expected in H1 2022 with publication expected in H2 2022.

#### **Aimovig**

- In June, the Japanese Ministry of Health, Labour and Welfare granted marketing approval for Aimovig for the suppression of onset of migraine attacks in adults.

#### **Biosimilars**

- A Phase 3 study of ABP 654, a biosimilar candidate to STELARA<sup>®</sup> (ustekinumab), has completed enrollment.
- A Phase 3 study of ABP 938, a biosimilar candidate to EYLEA<sup>®</sup> (aflibercept) continues to enroll patients.
- A Phase 3 study of ABP 959, a biosimilar candidate to SOLIRIS<sup>®</sup> (eculizumab), is ongoing.

#### **[Amgenpipeline.com](http://Amgenpipeline.com)**

- A listing of additional ongoing clinical programs can be found at [Amgenpipeline.com](http://Amgenpipeline.com)

*Tezepelumab is being developed in collaboration with AstraZeneca  
AMG 451 (also known as KHK4083) is being developed in collaboration with Kyowa Kirin  
AMG 714 (also known as PRV-015) is being developed in collaboration with Provention Bio  
DARZALEX and STELARA are a registered trademarks of Janssen Pharmaceutica NV  
EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.  
SOLIRIS is a registered trademark of Alexion Pharmaceuticals, Inc.  
XmAb is a registered trademark of Xencor, Inc.*

#### **U.S. Manufacturing Facilities**

In anticipation of future demand for our medicines, we will invest approximately \$1 billion to build two new manufacturing facilities – a packaging plant in Ohio and a drug substance plant in North Carolina. Both of these facilities will be built faster and at a lower cost than traditional plants, and both also will utilize cutting-edge technologies to be more efficient and environmentally friendly than traditional plants.

#### **U.S. Tax Petition**

In July 2021, we filed a petition in the U.S. Tax Court to contest notices of deficiencies received from the IRS during the quarter for 2010, 2011 and 2012. These notices seek to increase our U.S. taxable income by an amount that would result in additional federal tax of approximately \$3.6 billion, plus interest. Any additional tax that could be imposed would be reduced by up to approximately \$900 million of repatriation tax previously accrued on our foreign earnings. We firmly believe that the IRS's positions in the notices are without merit and we will vigorously contest the notices through the judicial process.

#### **Non-GAAP Financial Measures**

In this news release, management has presented its operating results for the second quarters of 2021 and 2020, in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and on a non-GAAP basis. In addition, management has presented its full year 2021 EPS and tax rate guidance in accordance with GAAP and on a non-GAAP basis. These non-GAAP financial measures are computed by excluding certain items related to acquisitions, restructuring and certain other items from the related GAAP financial measures. Reconciliations for these non-GAAP financial measures to the most directly comparable GAAP financial measures are included in the news release. Management has also presented Free Cash Flow (FCF), which is a non-GAAP financial measure, for the second quarters of 2021 and 2020. FCF is computed by subtracting capital expenditures from operating cash flow, each as determined in accordance with GAAP.

The Company believes that its presentation of non-GAAP financial measures provides useful supplementary information to and facilitates additional analysis by investors. The Company uses certain non-GAAP financial measures to enhance an investor's overall understanding of the financial performance and prospects for the future of the Company's ongoing business activities by facilitating comparisons of results of ongoing business operations among current, past and future periods. The Company believes that FCF provides a further measure of the Company's liquidity.

Beginning January 1, 2021, we began to exclude the gains and losses on our investments in equity securities from our non-GAAP measures that are recorded to Other income (expense). This exclusion will not apply to our share of the earnings and losses of our strategic investments in corporations accounted for under the equity method of accounting, such as our investment in BeiGene. The Company will be excluding gains and losses from equity investments for the purpose of calculating the non-GAAP financial measures presented because the Company believes the results of such gains and losses are not representative of our normal business operations. We are making this change beginning in 2021 because, as we have increased our investments in these companies, we recognized that the resulting variability can impede comparability between periods of our financial performance for our ongoing business operations. For comparability of results to the prior year, non-GAAP net income and non-GAAP EPS amounts

for 2020 have been revised to reflect the update to our non-GAAP policy that excludes gains and losses on certain equity investments.

The Company uses the non-GAAP financial measures set forth in the news release in connection with its own budgeting and financial planning internally to evaluate the performance of the business, including to allocate resources and to evaluate results relative to incentive compensation targets. The non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

## **About Amgen**

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit [www.amgen.com](http://www.amgen.com) and follow us on [www.twitter.com/amgen](http://www.twitter.com/amgen).

## **Forward-Looking Statements**

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd. or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), or the Five Prime Therapeutics, Inc. acquisition, as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

CONTACT: Amgen, Thousand Oaks  
Trish Rowland, 805-447-5631 (media)  
Arvind Sood, 805-447-1060 (investors)



**Amgen Inc.**  
**Consolidated Statements of Income - GAAP**  
(In millions, except per-share data)  
(Unaudited)

|  | Three months ended |                 | Six months ended |                 |
|--|--------------------|-----------------|------------------|-----------------|
|  | June 30,           |                 | June 30,         |                 |
|  | 2021               | 2020            | 2021             | 2020            |
| Revenues:  |                    |                 |                  |                 |
| Product sales  | \$ 6,114           | \$ 5,908        | \$ 11,706        | \$ 11,802       |
| Other revenues   | 412                | 298             | 721              | 565             |
| Total revenues   | <u>6,526</u>       | <u>6,206</u>    | <u>12,427</u>    | <u>12,367</u>   |
| Operating expenses:  |                    |                 |                  |                 |
| Cost of sales  | 1,637              | 1,488           | 3,127            | 3,001           |
| Research and development   | 1,082              | 964             | 2,049            | 1,916           |
| Acquired in-process research and development                       | 1,505              | —               | 1,505            | —               |
| Selling, general and administrative                                | 1,384              | 1,295           | 2,638            | 2,611           |
| Other  | 90                 | 136             | 151              | 161             |
| Total operating expenses   | <u>5,698</u>       | <u>3,883</u>    | <u>9,470</u>     | <u>7,689</u>    |
| Operating income   | 828                | 2,323           | 2,957            | 4,678           |
| Other income (expense):  |                    |                 |                  |                 |
| Interest expense, net  | (281)              | (296)           | (566)            | (642)           |
| Other income, net  | 11                 | 3               | 24               | 14              |
| Income before income taxes   | 558                | 2,030           | 2,415            | 4,050           |
| Provision for income taxes   | 94                 | 227             | 305              | 422             |
| Net income   | <u>\$ 464</u>      | <u>\$ 1,803</u> | <u>\$ 2,110</u>  | <u>\$ 3,628</u> |
| Earnings per share:  |                    |                 |                  |                 |
| Basic  | \$ 0.81            | \$ 3.07         | \$ 3.67          | \$ 6.16         |
| Diluted  | \$ 0.81            | \$ 3.05         | \$ 3.65          | \$ 6.12         |
| Weighted-average shares used in calculation of earnings per share: |                    |                 |                  |                 |
| Basic  | 573                | 588             | 575              | 589             |
| Diluted  | 576                | 592             | 578              | 593             |

**Amgen Inc.**  
**Consolidated Balance Sheets - GAAP**  
(In millions)

|  | June 30, December 31, |                  |
|--|-----------------------|------------------|
|  | 2021                  | 2020             |
|  | <b>(Unaudited)</b>    |                  |
| <b>Assets</b>                                    |                       |                  |
| Current assets:                                  |                       |                  |
| Cash, cash equivalents and marketable securities | \$ 8,082              | \$ 10,647        |
| Trade receivables, net                           | 4,479                 | 4,525            |
| Inventories                                      | 4,115                 | 3,893            |
| Other current assets                             | 2,423                 | 2,079            |
| Total current assets                             | <u>19,099</u>         | <u>21,144</u>    |
| Property, plant and equipment, net               | 4,906                 | 4,889            |
| Intangible assets, net                           | 15,308                | 16,587           |
| Goodwill   | 14,676                | 14,689           |
| Other noncurrent assets                          | 5,784                 | 5,639            |
| Total assets                                     | <u>\$ 59,773</u>      | <u>\$ 62,948</u> |
| <b>Liabilities and Stockholders' Equity</b>      |                       |                  |
| Current liabilities:                             |                       |                  |
| Accounts payable and accrued liabilities         | \$ 10,261             | \$ 11,562        |
| Current portion of long-term debt                | 4,324                 | 91               |
| Total current liabilities                        | <u>14,585</u>         | <u>11,653</u>    |
| Long-term debt                                   | 28,458                | 32,895           |

|  |                  |                  |
|--|------------------|------------------|
| Long-term tax liabilities                  | 6,428            | 6,968            |
| Other noncurrent liabilities               | 2,055            | 2,023            |
| Total stockholders' equity                 | 8,247            | 9,409            |
| Total liabilities and stockholders' equity | <u>\$ 59,773</u> | <u>\$ 62,948</u> |
| Shares outstanding                         | 570              | 578              |

**Amgen Inc.**  
**GAAP to Non-GAAP Reconciliations**  
(Dollars in millions)  
(Unaudited)

**Three months ended June 30,**  
**Six months ended June 30,**

| <b>2021</b> | <b>2020*</b> | <b>2021</b> | <b>2020*</b> |
|-------------|--------------|-------------|--------------|
| \$ 1,637    | \$ 1,488     | \$ 3,127    | \$ 3,001     |

**GAAP cost of sales**

**Adjustments to cost of sales:**

Acquisition-related expenses (a)

Other

**Total adjustments to cost of sales**

|                 |               |                 |                 |
|-----------------|---------------|-----------------|-----------------|
| (598)           | (730)         | (1,221)         | (1,472)         |
| (5)             | —             | (5)             | —               |
| <u>(603)</u>    | <u>(730)</u>  | <u>(1,226)</u>  | <u>(1,472)</u>  |
| <u>\$ 1,034</u> | <u>\$ 758</u> | <u>\$ 1,901</u> | <u>\$ 1,529</u> |

**Non-GAAP cost of sales**

**GAAP cost of sales as a percentage of product sales**

Acquisition-related expenses (a)

Other

**Non-GAAP cost of sales as a percentage of product sales**

|              |              |              |              |
|--------------|--------------|--------------|--------------|
| 26.8%        | 25.2%        | 26.7%        | 25.4%        |
| (9.8)        | (12.4)       | (10.4)       | (12.4)       |
| (0.1)        | 0.0          | (0.1)        | 0.0          |
| <u>16.9%</u> | <u>12.8%</u> | <u>16.2%</u> | <u>13.0%</u> |

**GAAP research and development expenses**

**Adjustments to research and development expenses:**

Acquisition-related expenses (a)

**Non-GAAP research and development expenses**

|                 |               |                 |                 |
|-----------------|---------------|-----------------|-----------------|
| \$ 1,082        | \$ 964        | \$ 2,049        | \$ 1,916        |
| (46)            | (28)          | (69)            | (53)            |
| <u>\$ 1,036</u> | <u>\$ 936</u> | <u>\$ 1,980</u> | <u>\$ 1,863</u> |

**GAAP research and development expenses as a percentage of product sales**

Acquisition-related expenses (a)

**Non-GAAP research and development expenses as a percentage of product sales**

|              |              |              |              |
|--------------|--------------|--------------|--------------|
| 17.7%        | 16.3%        | 17.5%        | 16.2%        |
| (0.8)        | (0.5)        | (0.6)        | (0.4)        |
| <u>16.9%</u> | <u>15.8%</u> | <u>16.9%</u> | <u>15.8%</u> |

**GAAP acquired IPR&D**

**Adjustments to acquired IPR&D:**

Five Prime acquisition IPR&D expense

**Non-GAAP acquired IPR&D**

|             |             |             |             |
|-------------|-------------|-------------|-------------|
| \$ 1,505    | \$ —        | \$ 1,505    | \$ —        |
| (1,505)     | —           | (1,505)     | —           |
| <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> |

**GAAP acquired IPR&D expenses as a percentage of product sales**

Five Prime acquisition IPR&D expense

**Non-GAAP acquired IPR&D expenses as a percentage of product sales**

|           |           |           |           |
|-----------|-----------|-----------|-----------|
| 24.6%     | —%        | 12.9%     | —%        |
| (24.6)    | 0.0       | (12.9)    | 0.0       |
| <u>—%</u> | <u>—%</u> | <u>—%</u> | <u>—%</u> |

**GAAP selling, general and administrative expenses**

**Adjustments to selling, general and administrative expenses:**

Acquisition-related expenses (a)

Other

**Total adjustments to selling, general and administrative expenses**

**Non-GAAP selling, general and administrative expenses**

|                 |                 |                 |                 |
|-----------------|-----------------|-----------------|-----------------|
| \$ 1,384        | \$ 1,295        | \$ 2,638        | \$ 2,611        |
| (39)            | (30)            | (51)            | (59)            |
| —               | —               | (16)            | —               |
| <u>(39)</u>     | <u>(30)</u>     | <u>(67)</u>     | <u>(59)</u>     |
| <u>\$ 1,345</u> | <u>\$ 1,265</u> | <u>\$ 2,571</u> | <u>\$ 2,552</u> |

**GAAP selling, general and administrative expenses as a percentage of product sales**

Acquisition-related expenses (a)

Other

**Non-GAAP selling, general and administrative expenses as a percentage of product sales**

|              |              |              |              |
|--------------|--------------|--------------|--------------|
| 22.6%        | 21.9%        | 22.5%        | 22.1%        |
| (0.6)        | (0.5)        | (0.4)        | (0.5)        |
| 0.0          | 0.0          | (0.1)        | 0.0          |
| <u>22.0%</u> | <u>21.4%</u> | <u>22.0%</u> | <u>21.6%</u> |

**GAAP operating expenses**

**Adjustments to operating expenses:**

Adjustments to cost of sales

Adjustments to research and development expenses

Adjustments to acquired IPR&D

Adjustments to selling, general and administrative expenses

Certain charges pursuant to our cost savings initiatives

Certain other expenses (b)

**Total adjustments to operating expenses**

**Non-GAAP operating expenses**

|                 |                 |                 |                 |
|-----------------|-----------------|-----------------|-----------------|
| \$ 5,698        | \$ 3,883        | \$ 9,470        | \$ 7,689        |
| (603)           | (730)           | (1,226)         | (1,472)         |
| (46)            | (28)            | (69)            | (53)            |
| (1,505)         | —               | (1,505)         | —               |
| (39)            | (30)            | (67)            | (59)            |
| (76)            | 2               | (128)           | 4               |
| (14)            | (138)           | (23)            | (165)           |
| <u>(2,283)</u>  | <u>(924)</u>    | <u>(3,018)</u>  | <u>(1,745)</u>  |
| <u>\$ 3,415</u> | <u>\$ 2,959</u> | <u>\$ 6,452</u> | <u>\$ 5,944</u> |

|                                   |                 |                 |                 |                 |
|-----------------------------------|-----------------|-----------------|-----------------|-----------------|
| <b>GAAP operating income</b>      | \$ 828          | \$ 2,323        | \$ 2,957        | \$ 4,678        |
| Adjustments to operating expenses | 2,283           | 924             | 3,018           | 1,745           |
| <b>Non-GAAP operating income</b>  | <u>\$ 3,111</u> | <u>\$ 3,247</u> | <u>\$ 5,975</u> | <u>\$ 6,423</u> |

|   | Three months ended<br>June 30, |              | Six months ended<br>June 30, |              |
|---|--------------------------------|--------------|------------------------------|--------------|
|   | 2021                           | 2020*        | 2021                         | 2020*        |
| <b>GAAP operating income as a percentage of product sales</b>     | 13.5%                          | 39.3%        | 25.3%                        | 39.6%        |
| Adjustments to cost of sales                                      | 9.9                            | 12.4         | 10.5                         | 12.5         |
| Adjustments to research and development expenses                  | 0.8                            | 0.5          | 0.6                          | 0.4          |
| Acquired IPR&D  | 24.7                           | 0.0          | 12.9                         | 0.0          |
| Adjustments to selling, general and administrative expenses       | 0.6                            | 0.5          | 0.5                          | 0.5          |
| Certain charges pursuant to our cost savings initiatives          | 1.2                            | 0.0          | 1.1                          | 0.0          |
| Certain other expenses (b)  | 0.2                            | 2.3          | 0.1                          | 1.4          |
| <b>Non-GAAP operating income as a percentage of product sales</b> | <u>50.9%</u>                   | <u>55.0%</u> | <u>51.0%</u>                 | <u>54.4%</u> |

|   |              |             |                |             |
|---|--------------|-------------|----------------|-------------|
| <b>GAAP other income, net</b>                           | \$ 11        | \$ 3        | \$ 24          | \$ 14       |
| <b>Adjustments to other income (expense), net:</b>      |              |             |                |             |
| Equity method investment basis difference amortization  | 42           | 36          | 84             | 36          |
| Net (gains)/losses from equity investments              | 1            | (44)        | (144)          | (5)         |
| Gain from legal judgment proceeds                       | —            | (72)        | —              | (72)        |
| <b>Total adjustments to other income (expense), net</b> | <u>43</u>    | <u>(80)</u> | <u>(60)</u>    | <u>(41)</u> |
| <b>Non-GAAP other income (expense), net</b>             | <u>\$ 54</u> | <u>(77)</u> | <u>\$ (36)</u> | <u>(27)</u> |

|  |                 |                 |                 |                 |
|--|-----------------|-----------------|-----------------|-----------------|
| <b>GAAP income before income taxes</b>                 | \$ 558          | \$ 2,030        | \$ 2,415        | \$ 4,050        |
| <b>Adjustments to income before income taxes</b>       |                 |                 |                 |                 |
| Adjustments to operating expenses                      | 2,283           | 924             | 3,018           | 1,745           |
| Adjustments to other income, net                       | 43              | (80)            | (60)            | (41)            |
| <b>Total adjustments to income before income taxes</b> | <u>2,326</u>    | <u>844</u>      | <u>\$ 2,958</u> | <u>\$ 1,704</u> |
| <b>Non-GAAP income before income taxes</b>             | <u>\$ 2,884</u> | <u>\$ 2,874</u> | <u>\$ 5,373</u> | <u>\$ 5,754</u> |

|  |               |               |               |               |
|--|---------------|---------------|---------------|---------------|
| <b>GAAP provision for income taxes</b>                 | \$ 94         | \$ 227        | \$ 305        | \$ 422        |
| <b>Adjustments to provision for income taxes:</b>      |               |               |               |               |
| Income tax effect of the above adjustments (c)         | 277           | 154           | 408           | 334           |
| Other income tax adjustments (d)                       | (9)           | 9             | (12)          | 8             |
| <b>Total adjustments to provision for income taxes</b> | <u>268</u>    | <u>163</u>    | <u>396</u>    | <u>342</u>    |
| <b>Non-GAAP provision for income taxes</b>             | <u>\$ 362</u> | <u>\$ 390</u> | <u>\$ 701</u> | <u>\$ 764</u> |

|  |              |              |              |              |
|--|--------------|--------------|--------------|--------------|
| <b>GAAP tax as a percentage of income before taxes</b>     | 16.8%        | 11.2%        | 12.6%        | 10.4%        |
| <b>Adjustments to provision for income taxes:</b>          |              |              |              |              |
| Income tax effect of the above adjustments (c)             | (4.0)        | 2.1          | 0.6          | 2.7          |
| Other income tax adjustments (d)                           | (0.2)        | 0.3          | (0.2)        | 0.2          |
| <b>Total adjustments to provision for income taxes</b>     | <u>(4.2)</u> | <u>2.4</u>   | <u>0.4</u>   | <u>2.9</u>   |
| <b>Non-GAAP tax as a percentage of income before taxes</b> | <u>12.6%</u> | <u>13.6%</u> | <u>13.0%</u> | <u>13.3%</u> |

|   |                 |              |                 |                 |
|---|-----------------|--------------|-----------------|-----------------|
| <b>GAAP net income</b>  | \$ 464          | \$ 1,803     | \$ 2,110        | \$ 3,628        |
| <b>Adjustments to net income:</b>                                       |                 |              |                 |                 |
| Adjustments to income before income taxes, net of the income tax effect | 2,049           | 690          | 2,550           | 1,370           |
| Other income tax adjustments (d)  | 9               | (9)          | 12              | (8)             |
| <b>Total adjustments to net income</b>                                  | <u>2,058</u>    | <u>681</u>   | <u>2,562</u>    | <u>1,362</u>    |
| <b>Non-GAAP net income</b>  | <u>\$ 2,522</u> | <u>2,484</u> | <u>\$ 4,672</u> | <u>\$ 4,990</u> |

Note: Numbers may not add due to rounding

**Amgen Inc.**  
**GAAP to Non-GAAP Reconciliations**  
(In millions, except per-share data)  
(Unaudited)

The following table presents the computations for GAAP and non-GAAP diluted earnings per share:

|            | Three months ended<br>June 30, 2021 |          | Three months ended<br>June 30, 2020* |          |
|------------|-------------------------------------|----------|--------------------------------------|----------|
|            | GAAP                                | Non-GAAP | GAAP                                 | Non-GAAP |
| Net income | \$ 464                              | \$ 2,522 | \$ 1,803                             | \$ 2,484 |

|   |   |                 |  |                 |
|---|---|-----------------|--|-----------------|
| Weighted-average shares for diluted EPS | 576                                       | 576             | 592  | 592             |
| Diluted EPS                             | <u>\$ 0.81</u>                            | <u>\$ 4.38</u>  | <u>\$ 3.05</u>                             | <u>\$ 4.20</u>  |
|   | <b>Six months ended<br/>June 30, 2021</b> |                 | <b>Six months ended<br/>June 30, 2020*</b> |                 |
|   | <b>GAAP</b>                               | <b>Non-GAAP</b> | <b>GAAP</b>                                | <b>Non-GAAP</b> |
| Net income                              | \$ 2,110                                  | \$ 4,672        | \$ 3,628                                   | \$ 4,990        |
| Weighted-average shares for diluted EPS | 578                                       | 578             | 593  | 593             |
| Diluted EPS                             | <u>\$ 3.65</u>                            | <u>\$ 8.08</u>  | <u>\$ 6.12</u>                             | <u>\$ 8.41</u>  |

\*Effective January 2021, we began to exclude the gains and losses on our investments in equity securities from our non-GAAP measures that are recorded to Other income, net pursuant to an update to our non-GAAP policy. For comparability of results to the prior year, non-GAAP Other income, net, non-GAAP Net income and non-GAAP EPS amounts for 2020 have been revised to reflect the update to our non-GAAP policy.

- (a) The adjustments related primarily to noncash amortization of intangible assets from business acquisitions.
- (b) For the three and six months ended June 30, 2021, the adjustments related primarily to the change in fair values of contingent consideration liabilities. For the three months ended June 30, 2020, the adjustment related primarily to legal settlement expenses. For the six months ended June 30, 2020, the adjustment related primarily to legal settlement expenses and an impairment charge associated with an in-process research and development asset.
- (c) The tax effect of the adjustments between our GAAP and non-GAAP results takes into account the tax treatment and related tax rate(s) that apply to each adjustment in the applicable tax jurisdiction(s). Generally, this results in a tax impact at the U.S. marginal tax rate for certain adjustments, including the majority of amortization of intangible assets, whereas the tax impact of other adjustments, including restructuring initiatives, depends on whether the amounts are deductible in the respective tax jurisdictions and the applicable tax rate(s) in those jurisdictions. Acquired IPR&D expense from the Five Prime acquisition was not tax deductible. Due to these factors, the effective tax rates for the adjustments to our GAAP income before income taxes, for the three and six months ended June 30, 2021, were 11.9% and 13.8%, compared to 18.2% and 19.6% for the corresponding periods of the prior year.
- (d) The adjustments related to certain acquisition items, prior period and other items excluded from GAAP earnings.

**Amgen Inc.**  
**Reconciliations of Cash Flows**  
(In millions)  
(Unaudited)

|   | <b>Three months ended<br/>June 30,</b> |                 | <b>Six months ended<br/>June 30,</b> |                 |
|---|--|-----------------|--------------------------------------|-----------------|
|   | <b>2021</b>                            | <b>2020</b>     | <b>2021</b>                          | <b>2020</b>     |
| Net cash provided by operating activities           | \$ 1,931                               | \$ 2,842        | \$ 4,035                             | \$ 4,976        |
| Net cash provided by (used in) investing activities | 1,209                                  | (2,159)         | 890                                  | (2,389)         |
| Net cash (used in) provided by financing activities | (2,622)                                | 775             | (4,561)                              | 521             |
| Increase in cash and cash equivalents               | 518                                    | 1,458           | 364                                  | 3,108           |
| Cash and cash equivalents at beginning of period    | 6,112                                  | 7,687           | 6,266                                | 6,037           |
| Cash and cash equivalents at end of period          | <u>\$ 6,630</u>                        | <u>\$ 9,145</u> | <u>\$ 6,630</u>                      | <u>\$ 9,145</u> |

|   | <b>Three months ended<br/>June 30,</b> |                 | <b>Six months ended<br/>June 30,</b> |                 |
|---|--|-----------------|--------------------------------------|-----------------|
|   | <b>2021</b>                            | <b>2020</b>     | <b>2021</b>                          | <b>2020</b>     |
| Net cash provided by operating activities | \$ 1,931                               | \$ 2,842        | \$ 4,035                             | \$ 4,976        |
| Capital expenditures                      | (185)                                  | (158)           | (351)                                | (300)           |
| Free cash flow                            | <u>\$ 1,746</u>                        | <u>\$ 2,684</u> | <u>\$ 3,684</u>                      | <u>\$ 4,676</u> |

**Amgen Inc.**  
**Reconciliation of GAAP EPS Guidance to Non-GAAP  
EPS Guidance for the Year Ending December 31, 2021**  
(Unaudited)

|  |         |          |
|--|---------|----------|
| <b>GAAP diluted EPS guidance</b>                 | \$ 8.84 | —\$ 9.90 |
| <b>Known adjustments to arrive at non-GAAP*:</b> |         |          |
| Acquisition-related and licensing expenses (a)   | 4.46    | — 4.52   |
| Acquired IPR&D (b)                               |         | 2.62     |

|  |                |                 |
|--|----------------|-----------------|
| Certain charges pursuant to our cost savings initiatives | 0.20           |                 |
| Net gains from equity investments                        | (0.20)         |                 |
| Legal proceedings  | 0.02           |                 |
| Non-GAAP diluted EPS guidance                            | <u>\$16.00</u> | <u>-\$17.00</u> |

\* The known adjustments are presented net of their related tax impact, which amount to approximately \$1.18 per share.

(a) The adjustments relate primarily to noncash amortization of intangible assets acquired in business acquisitions.

(b) The adjustment relates to in-process research & development (IPR&D) expense as a result of acquiring Five Prime Therapeutics in April 2021. The acquired IPR&D is not tax deductible.

Our GAAP diluted EPS guidance does not include the effect of GAAP adjustments triggered by events that may occur subsequent to this press release such as acquisitions, asset impairments, litigation, changes in the fair value of our contingent consideration and changes in fair value of our equity investments. The GAAP adjustments from the recently announced acquisition of Teneobio (expected to close in the second half of 2021) are included in the GAAP diluted EPS guidance.

**Reconciliation of GAAP Tax Rate Guidance to Non-GAAP  
Tax Rate Guidance for the Year Ending December 31, 2021  
(Unaudited)**

|   |                      |
|---|----------------------|
| GAAP tax rate guidance                        | 13.0% — 14.5%        |
| Tax rate of known adjustments discussed above | <u>0.0% — 0.5%</u>   |
| Non-GAAP tax rate guidance                    | <u>13.5% — 14.5%</u> |

**Reconciliation of 2020 Non-GAAP Financial Information As Reported to Updated Non-GAAP Policy  
2020 Non-GAAP Financial Results - Excluding gains and losses from equity investments  
(Unaudited)**

Effective January 2021, we began to exclude the gains and losses on our investments in equity securities from our non-GAAP measures that are recorded to Other income, net pursuant to an update to our non-GAAP policy. This policy update excludes our share of the earnings and losses of our strategic investments in corporations accounted for under the equity method of accounting, such as our investment in BeiGene. This updated non-GAAP policy is the basis for our comparisons starting in 2021 and is reflected in our 2021 guidance. The reconciliations below show the effects of the application of the new policy as if it had been adopted at the beginning of 2020.

| \$Millions, except EPS           | Q1 '20         | Q2 '20         | Q3 '20         | Q4 '20         | FY '20         |
|----------------------------------|----------------|----------------|----------------|----------------|----------------|
| Net income (as reported)         | \$2,476        | \$2,518        | \$2,572        | \$2,229        | \$9,795        |
| Equity securities losses (gains) | 39             | (44)           | (134)          | (265)          | (404)          |
| Tax impact                       | (9)            | 10             | 29             | 58             | 88             |
| Net income (adjusted)            | <u>\$2,506</u> | <u>\$2,484</u> | <u>\$2,467</u> | <u>\$2,022</u> | <u>\$9,479</u> |
| Diluted shares                   | 594            | 592            | 589            | 585            | 590            |
| Diluted EPS (as reported)        | \$4.17         | \$4.25         | \$4.37         | \$3.81         | \$16.60        |
| Diluted EPS (adjusted)           | \$4.22         | \$4.20         | \$4.19         | \$3.46         | \$16.07        |



View original content to download multimedia: <https://www.prnewswire.com/news-releases/amgen-reports-second-quarter-2021-financial-results-301347523.html>

SOURCE Amgen