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News Release

AMGEN REPORTS FIRST QUARTER 2021 FINANCIAL RESULTS

THOUSAND OAKS, Calif. (April 27, 2021) - Amgen (NASDAQ:AMGN) today announced financial results for the first quarter of 2021. Key results include:

- Total revenues decreased 4% to $5.9 billion in comparison to the first quarter of 2020, driven by lower net selling prices, partially offset by volume growth. These results reflect the cumulative, continuing negative effect of COVID-19 on patient visits and new patient diagnoses.
  - Although product sales decreased 5%, volumes grew double digits or better for a number of products including Repatha® (evolocumab), Prolia® (denosumab), MVASI® (bevacizumab-awwb) and KANJINTI® (trastuzumab-anns).
- GAAP earnings per share (EPS) decreased 8% to $2.83 driven by decreased revenues, partially offset by lower weighted-average shares outstanding.
  - GAAP operating income decreased 10% to $2.1 billion and GAAP operating margin decreased 1.9 percentage points to 38.1%.
- Non-GAAP EPS decreased 12% to $3.70 driven by decreased revenues and our share of BeiGene's net loss, partially offset by lower weighted-average shares outstanding.
  - Non-GAAP operating income decreased 10% to $2.9 billion and non-GAAP operating margin decreased 2.7 percentage points to 51.2%.
- The Company generated $1.9 billion of free cash flow in the first quarter versus $2.0 billion in the first quarter of 2020.
- 2021 total revenues guidance reaffirmed at $25.8-$26.6 billion; EPS guidance revised to $9.11-$10.71 on a GAAP basis, and reaffirmed at $16.00-$17.00 on a non-GAAP basis.

"While our business continued to be impacted by the COVID-19 pandemic particularly in the first two months of the quarter, we are encouraged by strong volume trends in many of our newer products and remain confident in the outlook for the full year," said Robert A. Bradway, chairman and chief executive officer. "We also continue to advance key pipeline opportunities, including three late-stage assets that have earned Breakthrough Therapy Designation from the U.S. Food and Drug Administration."

$Millions, except EPS, dividends paid per share and percentages	Q1 '21	Q1 '20	YOY Δ
Total Revenues	$ 5,901	$ 6,161	(4%)
GAAP Operating Income	$ 2,129	$ 2,355	(10%)
GAAP Net Income	$ 1,646	$ 1,825	(10%)
GAAP EPS	$ 2.83	$ 3.07	(8%)
Non-GAAP Operating Income	$ 2,864	$ 3,176	(10%)
Non-GAAP Net Income	$ 2,150	$ 2,506	(14%)
Non-GAAP EPS	$ 3.70	$ 4.22	(12%)
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

Consistent with prior years, we expect first quarter sales in 2021 to be the lowest quarter as a percentage of the full year.

COVID-19 update: As noted earlier, the cumulative missed patient visits and diagnoses since the start of the pandemic continue to impact our business, slowing treatment and new patient starts. In the quarter, demand was most negatively affected in January and February as COVID-19 cases and hospitalizations surged in the U.S. and Europe, with demand improvement seen across most brands in March and continuing into April. While patient visits and diagnoses remain below pre-COVID-19 levels, both are showing improvement from the early days of the pandemic. We remain hopeful that the global vaccination rollout will support a steady recovery going forward. However, we expect to see continuing disruption from COVID-19 in the second quarter and, to a lesser degree, in the second half of the year.

Total product sales decreased 5% for the first quarter of 2021 versus the first quarter of 2020. Unit volumes grew 4% while net selling price declined 7%. Year-over-year growth was negatively impacted by 2% due to a benefit in Q1 2020 from ~$150M of changes to estimated sales deductions that did not recur to the same magnitude in Q1 2021. In addition, in Q1 2021, Enbrel® (etanercept), Otezla® (apremilast) and Aimovig® (erenumab-aooe) followed the historic pattern of lower Q1 sales relative to the remainder of the year due to the impact of benefit plan changes, insurance reverifications and increased co-pay expenses as U.S. patients work through deductibles.

Results for individual products are as follows:

- **Prolia** sales increased 16% year-over-year for the first quarter, driven by 13% volume growth as new and repeat patient volumes continue to recover from the pandemic. With a large proportion of osteoporosis patients likely having received COVID-19 vaccinations and diagnosis rates reaching ~90% of pre-COVID-19 levels, we are confident in Prolia's continued growth in 2021.
- **EVENITY®** (romosozumab-aqqg) sales increased 7% year-over-year for the first quarter, driven by volume growth. U.S. sales increased 54% year-over-year driven by 67% volume growth. Rest of world (ROW) sales decreased 21% year-over-year partially due to the timing of purchases by our partner Astellas during the first half of 2020. We expect strong volume growth for Evenity to continue in 2021.

- **Repatha** sales increased 25% year-over-year for the first quarter to record quarterly sales of $286 million, driven by 36% volume growth, partially offset by lower net selling price and the effect of favorable changes to estimated sales deductions in the prior year. We continue to see strong sales growth internationally with 42% volume growth in ROW regions. In the U.S., total prescription (TRx) volumes grew 32% year-over-year. Repatha new-to-brand prescriptions (NBRx) in the U.S. grew 54% quarter-over-quarter, partially benefited by improved formulary coverage. Given the increase in U.S. Medicare Part D patients receiving Repatha, we expect some additional reduction in global net price on a sequential basis.
- **Aimovig** sales decreased 7% year-over-year for the first quarter. Unit volume growth of 20% 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, with 45% average TRx share and 38% average NBRx share in the quarter.
- **Otezla** sales decreased 1% year-over-year for the first quarter, driven by declines in net selling price and inventory, substantially offset by volume growth. In the U.S., TRx volumes grew 11% year-over-year. Otezla remains the segment-leading branded systemic medication for psoriasis with approximately 30% share of first-line treatment. However, NBRx volumes remained flat as COVID-19 continued to suppress the diagnosis and treatment of psoriasis patients. Looking forward, we see attractive growth opportunities for Otezla as the pandemic recovery continues, as well as the anticipated approval of the mild-to-moderate psoriasis indication in the U.S. and continued geographic expansion.
- **Enbrel** sales decreased 20% year-over-year for the first quarter, driven by unfavorable changes in estimated sales deductions, volume declines and lower net selling price. Of the ~$255 million in favorable changes to estimated sales deductions realized in 2020 related to Enbrel, ~$115M of these changes occurred in Q1 2020 and did not repeat this quarter. Going forward, we expect volume and net selling price trends to continue. With its long-established record of safety and efficacy, we continue to invest in Enbrel along with our broader inflammation portfolio.
- **AMGEVITA**™ (adalimumab) increased 23% year-over-year for the first quarter, driven by volume growth as we expand geographically outside the U.S., partially offset by lower net selling price. AMGEVITA continues to be the most prescribed adalimumab biosimilar in Europe.
- **KYPROLIS®** (carfilzomib) sales decreased 10% year-over-year for the first quarter, primarily as a result of slower growth in the multiple myeloma segment as fewer patients were diagnosed and treated due to COVID-19. For the remainder of the year, we expect the new patient growth headwinds from the pandemic to be offset by the growth of KYPROLIS® from its recently approved indication for use in combination with DARZALEX® (daratumumab) plus dexamethasone (DKd).
- **XGEVA®** (denosumab) sales decreased 3% year-over-year for the first quarter, as volume growth in Asia was offset by lower net selling price in that region. U.S. unit volumes declined year-over-year driven by demand impacts from COVID-19 in January and February, with recovery beginning in March and into April.
- **Vectibix®** (panitumumab) sales decreased 5% year-over-year for the first quarter, primarily driven by the timing of shipments to Takeda, our partner in Japan, in Q1 2020.
- **Nplate®** (romiplostim) sales increased 4% year-over-year for the first quarter, driven by volume growth of 23% in ROW, partially offset by declines in U.S. sales.
- **BLINCYTO®** (blinatumomab) sales increased 14% year-over-year for the first quarter, driven by volume growth due to broader adoption in the community hospital setting.

- **MVASI** sales increased 156% year-over-year for the first quarter, driven by volume growth and favorable changes to estimated sales deductions, partially offset by lower net selling price. In the U.S., MVASI continues to hold leading volume share of 50% of the bevacizumab segment in the quarter. Going forward, MVASI will continue to launch across multiple markets driving worldwide volume growth. However, we expect this to be offset by declines in net selling price due to increased competition.
- **KANJINTI** sales increased 35% year-over-year for the first quarter, driven by volume growth, partially offset by lower net selling price. In the U.S., KANJINTI continues to hold leading volume share of 43% of the trastuzumab segment in the quarter. Sales increased 2% quarter-over-quarter as favorable changes to estimated sales deductions were offset by price declines due to increased competition. Going forward, we expect net selling price to continue to decline quarter-over-quarter.
- **Neulasta®** (pegfilgrastim) sales decreased 21% year-over-year for the first quarter, driven by declines in both net selling price and unit volumes due to increased biosimilar competition, partially offset by favorable changes to estimated sales deductions. Within the long-acting granulocyte colony-stimulating factor (G-CSF) segment, Neulasta Onpro® maintained 54% volume share in the quarter and continues to be the preferred choice for physicians and patients, with over one million patients treated with Onpro. The most recent published Average Selling Price for Neulasta in the U.S. declined 30% year-over-year and 9% quarter-over-quarter. Going forward, we expect increased competition to result in additional net price erosion.
- **NEUPOGEN®** (filgrastim) sales decreased 48% year-over-year for the first quarter, primarily driven by volume declines due to competition.
- **EPOGEN®** (epoetin alfa) sales decreased 19% year-over-year for the first quarter, primarily driven by volume declines and lower net selling price resulting from our existing contractual commitment with DaVita.
- **Aranesp®** (darbepoetin alfa) sales decreased 16% year-over-year for the first quarter, driven by volume declines and lower net selling price due to competition.
- **Parsabiv®** (etelcalcetide) sales decreased 55% year-over-year for the first quarter, driven by 65% volume declines. With Parsabiv's inclusion in the end-stage renal disease (ESRD) bundled payment system in the U.S., we expect declining year-over-year sales trends to continue through 2021 as numerous dialysis centers update their treatment protocols due to the reimbursement change. 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 81% year-over-year for the first quarter, driven by volume declines in response to generic competition. Sales in Europe declined 74% year-over-year due to the expiration of supplemental patent protection in major European markets in April 2020.

Product Sales Detail by Product and Geographic Region

$Millions, except percentages	Q1 '21			Q1 '20	YOY Δ
	US	ROW	TOTAL	TOTAL	TOTAL
Prolia®	$ 501	$ 257	$ 758	$ 654	16%
EVENITY®	57	50	107	100	7%
Repatha®	139	147	286	229	25%
Aimovig®	66	—	66	71	(7%)
Otezla®	366	110	476	479	(1%)
Enbrel®	894	30	924	1,153	(20%)
AMGEVITA™	—	106	106	86	23%
KYPROLIS®	159	92	251	280	(10%)
XGEVA®	334	134	468	481	(3%)
Vectibix®	79	112	191	202	(5%)
Nplate®	112	115	227	218	4%
BLINCYTO®	65	42	107	94	14%
MVASI®	224	70	294	115	*
KANJINTI®	130	31	161	119	35%
Neulasta®	421	61	482	609	(21%)
NEUPOGEN®	18	16	34	65	(48%)
EPOGEN®	125	—	125	155	(19%)
Aranesp®	125	230	355	422	(16%)
Parsabiv®	46	33	79	175	(55%)
Sensipar®/Mimpara™	—	23	23	123	(81%)
Other**	42	30	72	64	13%
Total product sales	$ 3,903	$ 1,689	$ 5,592	$ 5,894	(5%)

* Change in excess of 100%

** Other includes GENSENTA, IMLYGIC®, Corlanor®, Bergamo, AVSOLA® and RIABNI®.

Operating Expense, Operating Margin and Tax Rate Analysis

On a GAAP basis:

- **Total Operating Expenses** decreased 1%. We expect total operating expenses to grow for the year as we invest in internal and external innovation, launches and long-term growth. **Cost of Sales** margin increased 0.9 percentage points primarily driven by product mix, profit share and royalties, partially offset by lower amortization expense from acquisition-related assets. **Research & Development (R&D)** expenses increased 2% primarily due to higher research and early pipeline spend, including the acquisition of Rodeo Therapeutics, partially offset by lower late-stage development program spend. **Selling, General & Administrative (SG&A)** expenses decreased 5% driven by lower spend on general and administrative activities as well as favorable adjustments to estimated U.S. healthcare reform federal excise fees.
- **Operating Margin** as a percentage of product sales decreased 1.9 percentage points to 38.1%.
- **Tax Rate** increased 1.7 percentage points primarily driven by changes in jurisdictional mix of earnings.

On a non-GAAP basis:

- **Total Operating Expenses** increased 2%. We continue to expect total operating expenses to grow for the year as we invest in internal and external innovation, launches and long-term growth. **Cost of Sales** margin increased 2.4 percentage points primarily due to product mix, profit share and royalties. **R&D** expenses increased 2% primarily due to higher research and early pipeline spend, including the acquisition of Rodeo Therapeutics, partially offset by lower late-stage development program spend. **SG&A** expenses decreased 5% driven by lower spend on general and administrative activities as well as favorable adjustments to estimated U.S. healthcare reform federal excise fees.
- **Operating Margin** as a percentage of product sales decreased 2.7 percentage points to 51.2%.
- **Tax Rate** increased 0.6 percentage points primarily driven by changes in jurisdictional mix of earnings.

$Millions, except percentages	GAAP			Non-GAAP		
	Q1 '21	**Q1 '20**	**YOY Δ**	**Q1 '21**	**Q1 '20**	**YOY Δ**
Cost of Sales	$ 1,490	$ 1,513	(2%)	$ 867	$ 771	12%
% of product sales	26.6 %	25.7 %	0.9 pts.	15.5 %	13.1 %	2.4 pts.
Research & Development	$ 967	$ 952	2%	$ 944	$ 927	2%
% of product sales	17.3 %	16.2 %	1.1 pts.	16.9 %	15.7 %	1.2 pts.
Selling, General & Administrative	$ 1,254	$ 1,316	(5%)	$ 1,226	$ 1,287	(5%)
% of product sales	22.4 %	22.3 %	0.1 pts.	21.9 %	21.8 %	0.1 pts.
Other	$ 61	$ 25	*	$ —	$ —	—%
Total Operating Expenses	**$ 3,772**	**$ 3,806**	**(1%)**	**$ 3,037**	**$ 2,985**	**2%**
Operating Margin						
operating income as % of product sales	38.1 %	40.0 %	(1.9) pts.	51.2 %	53.9 %	(2.7) pts.
Tax Rate	**11.4 %**	**9.7 %**	**1.7 pts.**	**13.6 %**	**13.0 %**	**0.6 pts.**

pts: percentage points
* Change in excess of 100%

Cash Flow and Balance Sheet

- The Company generated $1.9 billion of free cash flow in the first quarter of 2021 versus $2.0 billion in the first quarter of 2020.
- The Company's first quarter 2021 dividend of $1.76 per share was declared on December 16, 2020, and was paid on March 8, 2021, to all stockholders of record as of February 15, 2021, representing a 10% increase from 2020.
- During the first quarter, the Company repurchased 3.7 million shares of common stock at a total cost of $865 million. At the end of the first quarter, the Company had $5.5 billion remaining under its stock repurchase authorization.
- Cash and investments totaled $10.6 billion and debt outstanding totaled $32.7 billion at the end of Q1 2021.

$Billions, except shares	Q1 '21	Q1 '20	YOY Δ
Operating Cash Flow	$ 2.1	$ 2.1	$ 0.0
Capital Expenditures	0.2	0.1	0.0
Free Cash Flow	1.9	2.0	(0.1)
Dividends Paid	1.0	0.9	0.1
Share Repurchases	0.9	0.9	(0.1)
Average Diluted Shares (millions)	581	594	(13)

Note: Numbers may not add due to rounding

$Billions	3/31/21	12/31/20	YTD Δ
Cash and Investments	10.6	10.6	(0.1)
Debt Outstanding	32.7	33.0	(0.3)

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 $9.11 to $10.71 and a **tax rate** in the range of 14.0% to 15.5%.
    - Previously, the Company expected GAAP EPS in the range of $12.12 to $13.17 and a tax rate in the range of 11.0% to 12.5%.
- 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%.
    - Previously, the Company expected a tax rate in the range of 13.0% - 14.0%.
- **Capital expenditures** to be approximately $900 million.
- **Share repurchases** in the range of $3.0 billion to $5.0 billion, versus previous guidance of $3.0 billion to $4.0 billion.

First Quarter Product and Pipeline Update

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

LUMAKRAS™ (sotorasib)

- In February, the U.S. Food and Drug Administration (FDA) granted Priority Review for LUMAKRAS, a first in class, once-daily oral small molecule $KRAS^{G12C}$ inhibitor, for the treatment of patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), following at least one prior systemic therapy. Based on the Priority Review designation, the Prescription Drug User Fee Action date for LUMAKRAS is Aug. 16, 2021, which is four months earlier than the standard review cycle. LUMAKRAS has received Breakthrough Therapy Designation and is being reviewed under the Real-Time Oncology Review pilot program in the U.S.
- Regulatory submissions have also been completed in other jurisdictions, including the EU, Switzerland, the United Kingdom, Canada, Brazil and Australia, with submission in Japan planned for later today.

- Enrollment completed in a Phase 3 study (CodeBreaK 200) comparing LUMAKRAS to docetaxel in patients with *KRAS G12C*-mutated advanced NSCLC. Based on the efficacy results in NSCLC from the pivotal Phase 2 monotherapy study (CodeBreaK 100) and guidance from the FDA, we have reduced the Phase 3 CodeBreaK 200 sample size to reflect the statistical power necessary for the progression free survival primary endpoint.
- The Company expects to present updates on the pivotal Phase 2 monotherapy study in patients with NSCLC including subgroup analyses, overall survival data and biomarker analyses on mechanisms of resistance at upcoming medical conferences beginning this quarter.
- The Company recently initiated a sub-study within CodeBreaK trial that will evaluate LUMAKRAS dosed at 240 mg once-daily vs. 960 mg once-daily in patients with advanced NSCLC, with enrollment expected to begin in the coming weeks. The results in the pivotal Phase 2 NSCLC study demonstrated that the 960 mg once-daily dose was safe and effective in this setting, and the intent of the dose comparison study is to evaluate whether a lower dose is also safe and efficacious. The Company does not anticipate any impact on the timelines of the ongoing FDA Priority Review of LUMAKRAS.
- Mature data from the Phase 2 monotherapy study in patients with *KRAS G12C*-mutated advanced colorectal cancer (CRC) are expected in Q2 2021, with submission for publication expected by the end of the year.
- A Phase 2 monotherapy study in patients with KRAS G12C-mutated solid tumors other than NSCLC and CRC has completed enrollment with data expected in H1 2022.
- Exploration of LUMAKRAS in multiple Phase 1b combination cohorts continues to progress with more than 10 combinations now underway. We are initiating triplet cohorts of LUMAKRAS and standard of care chemotherapy in combination with either an EGFR antibody or bevacizumab in patients with advanced colorectal cancer. Expansion cohorts to assess efficacy of LUMAKRAS in combination with a mitogen-activated protein kinase kinase (MEK) inhibitor, an oral epidermal growth factor (EGFR) inhibitor or an EGFR Ab are underway, with initial data from these programs to be submitted for presentation in H2 2021.

Bemarituzumab

- The Company has begun Phase 3 planning and expects to commence discussions with regulators 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.
- In April, the FDA granted Breakthrough Therapy Designation for investigational bemarituzumab as first-line treatment for patients with FGFR2b-overexpressing and HER2-negative metastatic and locally advanced gastric and gastroesophageal adenocarcinoma in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin), based on an FDA-approved companion diagnostic assay showing at least 10% of tumor cells overexpressing FGFR2b.
- The Company is also planning to investigate bemarituzumab in other solid tumors, including squamous cell NSCLC.

Acapatamab (AMG 160)

- A dose expansion cohort of acapatamab a half-life extended (HLE) BiTE molecule targeting prostate-specific membrane antigen (PSMA), continues to enroll 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 NSCLC-expressing PSMA.

- A master protocol evaluating combinations of acapatamab with AMG 404, an anti-programmed cell death ligand 1 (PD-1) antibody, or the novel hormone therapies enzalutamide or abiraterone, is enrolling patients with earlier-line mCRPC.

AMG 757

- The Company has completed dose escalation for AMG 757, an HLE BiTE molecule targeting delta-like ligand 3 (DLL3), in patients with relapsed or refractory small cell lung cancer and expects to initiate the expansion phase by H2 2021.
- A Phase 1b study of AMG 757 has initiated for patients with neuroendocrine prostate cancer expressing DLL3.
- A Phase 1b study of AMG 757 in combination with AMG 404 is planned to initiate in Q3 2021 for patients with small cell lung cancer.

Pavurutamab (AMG 701)

- Enrollment is anticipated to resume in May in the dose escalation study of pavurutamab, an HLE BiTE molecule targeting B-cell maturation antigen (BCMA) for patients with relapsed or refractory multiple myeloma.

Additional oncology programs

- The following programs continue to enroll patients in dose escalation studies:
  - BiTE® molecules AMG 330 and AMG 427, targeting CD33 and fms-like tyrosine kinase 3 (FLT3), respectively, for acute myeloid leukemia.
  - AMG 176, a small molecule inhibitor of myeloid cell leukemia 1 (MCL-1) for hematologic malignancies.
  - HLE BiTE molecules AMG 199 and AMG 910, targeting mucin 17 (MUC17) and claudin 18.2 (CLDN18.2), respectively, for gastric and gastroesophageal junction cancer.
  - AMG 509, a bivalent T-cell engager XmAb® 2+1 antibody targeting six transmembrane epithelial antigen of the prostate 1 (STEAP1) for prostate cancer.
  - AMG 256, a bifunctional interleukin-21 agonist for PD-1 positive solid tumors.

Tezepelumab

- Results from the pivotal Phase 3 NAVIGATOR study demonstrating significant reductions in exacerbations in a broad population of patients with severe uncontrolled asthma were presented at the American Academy of Allergy, Asthma and Immunology Virtual Annual Meeting in February. Additional NAVIGATOR data will be presented at the American Thoracic Society International Conference in May 2021.
- Regulatory submissions in the U.S. and EU are expected in Q2 2021.
- A Phase 2 study continues to enroll patients with chronic obstructive pulmonary disease.
- A Phase 2b study is enrolling patients with chronic spontaneous urticaria.
- A Phase 3 chronic rhinosinusitis with nasal polyps study has initiated.

Otezla

- In February, a supplemental New Drug Application for the treatment of adults with mild-to-moderate plaque psoriasis was submitted to the FDA based on the results of the Phase 3 ADVANCE study. Data from the ADVANCE study were presented at the American Academy of Dermatology Virtual Experience in April.

- A Phase 2 study of Otezla for the treatment of Japanese patients with palmoplantar pustulosis successfully completed and planning for a Phase 3 trial in Japan is underway. Data from the Phase 2 study will be submitted to an upcoming medical conference.
- In Q1, the Otezla arm of the Phase 2 open-label I-SPY COVID adaptive platform trial being conducted in critically ill COVID-19 patients who are receiving high-flow oxygen or mechanical ventilation was stopped for futility upon recommendation from the Data Monitoring Committee. COMMUNITY, an adaptive placebo-controlled, double-blind, Phase 3 platform study evaluating adult patients hospitalized with COVID-19, is ongoing.

Rozibafusp alfa (AMG 570)

- Rozibafusp alfa (AMG 570), an 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) in a Phase 2b study.

Efavaleukin alfa (AMG 592)

- A Phase 2b study of efavaleukin alfa (AMG 592), an interleukin-2 mutein, has been initiated, and enrollment of patients with SLE is expected to begin in Q2 2021. Data from the Phase 1b SLE study will be submitted to a medical conference in H2 2021.

AMG 714 / PRV-015

- A Phase 2b study of AMG 714 / PRV-015, a monoclonal antibody that binds interleukin-15, continues to enroll patients with non-responsive celiac disease.

Repatha

- In February, a variation to the marketing application was submitted to the European Medicines Agency for a new indication for pediatric patients with heterozygous familial hypercholesterolemia and to include additional results in the label for pediatric patients with homozygous familial hypercholesterolemia.

Olpasiran (AMG 890)

- Enrollment of a Phase 2 study in patients with elevated lipoprotein(a) has completed, with data expected in H1 2022.

Biosimilars

- Phase 3 studies of ABP 654, a biosimilar candidate to STELARA® (ustekinumab), and ABP 938, a biosimilar candidate to EYLEA® (aflibercept), continue to enroll patients. A Phase 3 study of ABP 959, a biosimilar candidate to SOLIRIS® (eculizumab), is ongoing.

Amgenpipeline.com

- A listing of additional ongoing clinical programs can be found at Amgenpipeline.com

The trade name LUMAKRAS™ is provisionally approved for use by the U.S. FDA

Tezepelumab is being developed in collaboration with AstraZeneca

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.

Non-GAAP Financial Measures

In this news release, management has presented its operating results for the first 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 first 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 and follow us on 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.

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

	Three months ended March 31,	
	2021	**2020**
Revenues:		
Product sales	$ 5,592	$ 5,894
Other revenues	309	267
Total revenues	5,901	6,161
Operating expenses:		
Cost of sales	1,490	1,513
Research and development	967	952
Selling, general and administrative	1,254	1,316
Other	61	25
Total operating expenses	3,772	3,806
Operating income	2,129	2,355
Other income (expense):		
Interest expense, net	(285)	(346)
Other income, net	13	11
Income before income taxes	1,857	2,020
Provision for income taxes	211	195
Net income	$ 1,646	$ 1,825
Earnings per share:		
Basic	$ 2.85	$ 3.09
Diluted	$ 2.83	$ 3.07
Weighted-average shares used in calculation of earnings per share:		
Basic	577	590
Diluted	581	594

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

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 10,566	$ 10,647
Trade receivables, net	4,423	4,525
Inventories	4,017	3,893
Other current assets	2,293	2,079
Total current assets	21,299	21,144
Property, plant and equipment, net	4,855	4,889
Intangible assets, net	15,947	16,587
Goodwill	14,673	14,689
Other assets	5,765	5,639
Total assets	$ 62,539	$ 62,948
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 11,313	$ 11,562
Current portion of long-term debt	1,556	91
Total current liabilities	12,869	11,653
Long-term debt	31,129	32,895
Long-term tax liabilities	7,037	6,968
Other noncurrent liabilities	2,170	2,023
Total stockholders’ equity	9,334	9,409
Total liabilities and stockholders’ equity	$ 62,539	$ 62,948
Shares outstanding	575	578

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

	Three months ended March 31,	
	2021	**2020***
GAAP cost of sales	$ 1,490	$ 1,513
Adjustments to cost of sales:		
Acquisition-related expenses (a)	(623)	(742)
Non-GAAP cost of sales	$ 867	$ 771
GAAP cost of sales as a percentage of product sales	26.6 %	25.7 %
Acquisition-related expenses (a)	-11.1	-12.6
Non-GAAP cost of sales as a percentage of product sales	15.5 %	13.1 %
GAAP research and development expenses	$ 967	$ 952
Adjustments to research and development expenses:		
Acquisition-related expenses (a)	(23)	(25)
Non-GAAP research and development expenses	$ 944	$ 927
GAAP research and development expenses as a percentage of product sales	17.3 %	16.2 %
Acquisition-related expenses (a)	-0.4	-0.5
Non-GAAP research and development expenses as a percentage of product sales	16.9 %	15.7 %
GAAP selling, general and administrative expenses	$ 1,254	$ 1,316
Adjustments to selling, general and administrative expenses:		
Acquisition-related expenses (a)	(12)	(29)
Other	(16)	—
Total adjustments to selling, general and administrative expenses	(28)	(29)
Non-GAAP selling, general and administrative expenses	$ 1,226	$ 1,287
GAAP selling, general and administrative expenses as a percentage of product sales	22.4 %	22.3 %
Acquisition-related expenses (a)	-0.2	-0.5
Other	-0.3	0.0
Non-GAAP selling, general and administrative expenses as a percentage of product sales	21.9 %	21.8 %
GAAP operating expenses	$ 3,772	$ 3,806
Adjustments to operating expenses:		
Adjustments to cost of sales	(623)	(742)
Adjustments to research and development expenses	(23)	(25)
Adjustments to selling, general and administrative expenses	(28)	(29)
Certain charges pursuant to our cost savings initiatives	(52)	2
Certain other expenses (b)	(9)	(27)
Total adjustments to operating expenses	(735)	(821)
Non-GAAP operating expenses	$ 3,037	$ 2,985
GAAP operating income	$ 2,129	$ 2,355
Adjustments to operating expenses	735	821
Non-GAAP operating income	$ 2,864	$ 3,176

	Three months ended March 31,	
	2021	2020*
GAAP operating income as a percentage of product sales	38.1 %	40.0 %
Adjustments to cost of sales	11.1	12.6
Adjustments to research and development expenses	0.4	0.5
Adjustments to selling, general and administrative expenses	0.5	0.5
Certain charges pursuant to our cost savings initiatives	0.9	-0.1
Certain other expenses (b)	0.2	0.4
Non-GAAP operating income as a percentage of product sales	51.2 %	53.9 %
GAAP other income, net	$ 13	$ 11
Adjustments to other income, net:		
Equity method investment basis difference amortization	42	—
Net (gains)/losses from equity investments	(145)	39
Total adjustments to other income, net	(103)	39
Non-GAAP other income, net	$ (90)	50
GAAP income before income taxes	$ 1,857	$ 2,020
Adjustments to income before income taxes		
Adjustments to operating expenses	735	821
Adjustments to other income, net	(103)	39
Total adjustments to income before income taxes	632	860
Non-GAAP income before income taxes	$ 2,489	$ 2,880
GAAP provision for income taxes	$ 211	$ 195
Adjustments to provision for income taxes:		
Income tax effect of the above adjustments (c)	131	180
Other income tax adjustments (d)	(3)	(1)
Total adjustments to provision for income taxes	128	179
Non-GAAP provision for income taxes	$ 339	$ 374
GAAP tax as a percentage of income before taxes	11.4 %	9.7 %
Adjustments to provision for income taxes:		
Income tax effect of the above adjustments (c)	2.3	3.3
Other income tax adjustments (d)	-0.1	0.0
Total adjustments to provision for income taxes	2.2	3.3
Non-GAAP tax as a percentage of income before taxes	13.6 %	13.0 %
GAAP net income	$ 1,646	$ 1,825
Adjustments to net income:		
Adjustments to income before income taxes, net of the income tax effect	501	680
Other income tax adjustments (d)	3	1
Total adjustments to net income	504	681
Non-GAAP net income	$ 2,150	2,506

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 March 31, 2021		Three months ended March 31, 2020*	
	GAAP	Non-GAAP	GAAP	Non-GAAP
Net income	$ 1,646	$ 2,150	$ 1,825	$ 2,506
Weighted-average shares for diluted EPS	581	581	594	594
Diluted EPS	$ 2.83	$ 3.70	$ 3.07	$ 4.22

*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 months ended March 31, 2020, the adjustments related primarily to an impairment charge associated with a nonkey 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 and other cost savings initiatives, depends on whether the amounts are deductible in the respective tax jurisdictions and the applicable tax rate(s) in those jurisdictions. Due to these factors, the effective tax rate for the adjustments to our GAAP income before income taxes, for the three months ended March 31, 2021, was 20.7%, compared to 20.9% for the corresponding period of the prior year.

(d) The adjustments related to certain acquisition items and prior period items excluded from GAAP earnings.

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

	Three months ended March 31,	
	2021	2020
Net cash provided by operating activities	$ 2,104	$ 2,134
Net cash used in investing activities	(319)	(230)
Net cash used in financing activities	(1,939)	(254)
(Decrease) increase in cash and cash equivalents	(154)	1,650
Cash and cash equivalents at beginning of period	6,266	6,037
Cash and cash equivalents at end of period	$ 6,112	$ 7,687

	Three months ended March 31,	
	2021	2020
Net cash provided by operating activities	$ 2,104	$ 2,134
Capital expenditures	(166)	(142)
Free cash flow	$ 1,938	$ 1,992

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

GAAP diluted EPS guidance	$ 9.11	—	$ 10.71
Known adjustments to arrive at non-GAAP*:			
Acquisition-related expenses (a)	3.90	—	3.98
Acquired IPR&D (b)	2.50	—	3.02
Certain charges pursuant to our cost savings initiatives	0.07		
Net (gains)/losses from equity investments	(0.20)		
Legal proceedings	0.02		
Non-GAAP diluted EPS guidance	$ 16.00	—	$ 17.00

* The known adjustments are presented net of their related tax impact, which amount to approximately $0.98 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.

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

GAAP tax rate guidance	14.0 %	—	15.5 %
Tax rate of known adjustments discussed above	(1.0%)	—	(0.5%)
Non-GAAP tax rate guidance	13.5 %	—	14.5 %

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)	$2,506	$2,484	$2,467	$2,022	$9,479
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