



News Release

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AMGEN REPORTS FIRST QUARTER FINANCIAL RESULTS

THOUSAND OAKS, Calif. (April 27, 2023) - Amgen (NASDAQ:AMGN) today announced financial results for the first quarter of 2023.

"We delivered 14% volume growth driven by the breadth of our portfolio and strong demand for our products globally," said Robert A. Bradway, chairman and chief executive officer. "We look forward to closing the acquisition of Horizon Therapeutics and joining forces to reach more patients around the world with their innovative medicines."

Key results include:

- Total revenues decreased 2% to \$6.1 billion in comparison to the first quarter of 2022, resulting from lower Other Revenue from our COVID-19 manufacturing collaboration, partially offset by a 2% increase in product sales. Product sales growth was driven by 14% volume growth, partially offset by 5% lower net selling price, 3% unfavorable changes to estimated sales deductions, 2% lower inventory levels and 2% negative impact from foreign exchange. Excluding the 2% negative impact of foreign exchange on product sales, total revenues were largely unchanged from Q1 2022.
 - Volume growth of 14% included double-digit volume growth from EVENITY[®] (romosozumab-aqqg), BLINCYTO[®] (blinatumomab), Nplate[®] (romiplostim), LUMAKRAS[®]/LUMYKRAS[™] (sotorasib), AMJEVITA[®]/AMGEVITA[™] (adalimumab), Repatha[®] (evolocumab), KYPROLIS[®] (carfilzomib) and Vectibix[®] (panitumumab).
 - Ex-U.S. volume grew 22%, including 47% volume growth in the Asia Pacific region.
- GAAP earnings per share (EPS) increased 97% from \$2.68 to \$5.28, driven by other income due to a mark-to-market gain on our investment in BeiGene, Ltd. and lower weighted-average shares outstanding in Q1 2023.
 - GAAP operating income decreased from \$2.5 billion to \$1.9 billion, and GAAP operating margin decreased 10.7 percentage points to 32.9%.
- Non-GAAP EPS decreased 6% from \$4.25 to \$3.98, driven by decreased revenues and higher operating expenses, primarily related to research & development, in Q1 2023.
 - Non-GAAP operating income decreased from \$3.1 billion to \$2.8 billion, and non-GAAP operating margin decreased 6.5 percentage points to 48.3%.
- The Company generated \$0.7 billion of free cash flow for the first quarter of 2023 versus \$2.0 billion in the first quarter of 2022, driven by the timing of payments for sales incentives, rebates and discounts, lower operating income, and higher capital expenditures from the build-out of our new North Carolina and Ohio facilities.

References in this release to “non-GAAP” measures, measures presented “on a non-GAAP basis,” “free cash flow” (computed by subtracting capital expenditures from operating cash flow) and “total revenues and product sales adjusted for foreign exchange impact” (computed by converting our current period local currency product sales using the prior period foreign exchange rates and comparing that to our current period product sales) refer to non-GAAP financial measures. Adjustments to the most directly comparable GAAP financial measures and other items are presented on the attached reconciliations. Refer to Non-GAAP Financial Measures below for further discussion.

Product Sales Performance

Total product sales increased 2% for the first quarter of 2023 versus the first quarter of 2022. Unit volumes grew 14%, partially offset by 5% lower net selling price, 3% unfavorable changes to estimated sales deductions, 2% lower inventory levels and 2% negative impact from foreign exchange.

General Medicine

- **Repatha[®]** sales increased 18% year-over-year to a record \$388 million for the first quarter. Volume growth of 33% for the quarter was partially offset by lower net selling price. In the U.S., sales grew 19%, driven by 32% volume growth, partially offset by lower net selling price and inventory levels. Outside the U.S., sales grew 16%, driven by 34% volume growth, partially offset by lower net selling price and unfavorable foreign exchange impact. Repatha remains the global proprotein convertase subtilisin/kexin type 9 (PCSK9) segment leader, with over 1.7 million patients treated since launch.
- **Prolia[®] (denosumab)** sales increased 9% year-over-year for the first quarter, driven by 8% volume growth.
- **EVENTITY[®]** sales increased 49% year-over-year to a record \$254 million for the first quarter, primarily driven by strong volume growth across our markets. U.S. volumes grew 43% year-over-year and volumes outside the U.S. grew 77%.
- **Aimovig[®] (erenumab-aooe)** sales decreased 32% year-over-year for the first quarter, driven by unfavorable changes to estimated sales deductions and lower net selling price. For 2023, we expect continued year-over-year net selling price declines in order to maintain broad formulary access for patients in response to competitive dynamics.

Inflammation

- **TEZSPIRE[®] (tezepelumab-ekko)** generated \$96 million of sales in the first quarter, driven by strong adoption in the U.S. by both allergists and pulmonologists. Quarter-over-quarter sales increased 22%, driven by volume growth. Healthcare providers appreciate TEZSPIRE's unique, differentiated profile and its broad potential to treat the 2.5 million patients worldwide with severe asthma who are uncontrolled, without any phenotypic or biomarker limitation. During the first quarter, the U.S. Food and Drug Administration (FDA) approved TEZSPIRE for self-administration in a pre-filled, single-use pen, which improves accessibility and provides more flexibility in treatment options for patients in the U.S.
- **TAVNEOS[®] (avacopan)** generated \$23 million of sales in the first quarter. Quarter-over-quarter sales increased 10%, driven by higher net selling price and inventory levels, partially offset by lower ex-U.S. volume driven by the timing of shipments to our ex-U.S. partner in the fourth quarter of 2022. U.S volume grew 27% quarter-over-quarter, driven by an increase in new patients starting treatment.

- **Otezla® (apremilast)** sales decreased 13% year-over-year for the first quarter, driven by lower inventory levels and net selling price, partially offset by 5% volume growth. Otezla followed the historical pattern of lower first quarter 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 worked through deductibles. U.S. sales in the first quarter were also impacted by lower specialty pharmacy inventory levels compared to previous years, and price declines resulting from patient mix and additional rebates to improve the quality of coverage. In the U.S., Otezla new patient demand was impacted by free drug programs for newly launched topical and systemic competitors. We expect new patient demand to continue to be impacted by free drug programs from newly launched competition throughout 2023.

We continue to see strong growth potential for Otezla given its established efficacy and safety profile, strong payor coverage with limited prior authorization requirements and ease of administration. Otezla remains the only approved oral systemic therapy with a broad indication and is well-positioned to help the 1.5 million U.S. patients with mild-to-moderate psoriasis that cannot be optimally addressed by a topical and can benefit from a systemic treatment like Otezla.

- **Enbrel® (etanercept)** sales decreased 33% year-over-year for the first quarter, driven by decline in net selling price, lower inventory levels in the distribution channel compared to previous years and a 9% unfavorable impact of changes to estimated sales deductions related to prior periods. Consistent with Otezla, sales in the first quarter were also impacted by typical patterns of benefit plan changes and higher co-pay expenses. Year-over-year volume was flat in the first quarter, with U.S. volume growing 1%, supported by improved payor coverage. For the remainder of 2023, we expect low single-digit volume growth, reduced year-over-year decline in net selling price and a gradual recovery in inventory levels.
- **AMJEVITA®/AMGEVITA™** sales increased 52% year-over-year to a record \$164 million for the first quarter, driven by higher inventory levels and 35% volume growth, partially offset by unfavorable foreign exchange impact. AMJEVITA launched in the U.S. early in the first quarter, and a majority of U.S. sales in the quarter were related to inventory build.

Hematology-Oncology

- **BLINCYTO®** sales increased 41% year-over-year to a record \$194 million for the first quarter, driven by 49% volume growth supported by strong adoption across academic and community centers.
- **Vectibix®** sales increased 16% year-over-year for the first quarter, driven by 15% volume growth supported by positive data from the Phase 3 PARADIGM trial demonstrating the superiority of Vectibix over bevacizumab in combination with chemotherapy.
- **KYPROLIS®** sales increased 25% year-over-year to a record \$358 million for the first quarter, driven by 18% volume growth, higher net selling price and strong global execution.
- **LUMAKRAS®/LUMYKRAS™** generated \$74 million of sales for the first quarter. Year-over-year sales increased 19% for the first quarter, driven by 40% volume growth, partially offset by lower net selling price. Outside the U.S., LUMYKRAS has been approved in 50 countries around the world. We are actively launching in over 30 markets and pursuing reimbursement in the remaining countries.

- **XGEVA® (denosumab)** sales increased 7% year-over-year for the first quarter, driven by higher net selling price and 4% volume growth.
- **Nplate®** sales increased 36% year-over-year for the first quarter, driven by 41% volume growth. Nplate sales in the first quarter included \$82 million related to an order from the U.S. government.
- **MVASI® (bevacizumab-awwb)** sales decreased 17% year-over-year for the first quarter, driven by lower net selling price, partially offset by 15% volume growth. The published first quarter Average Selling Price (ASP) for MVASI in the U.S. declined 27% year-over-year and increased 5% quarter-over-quarter. Going forward, we expect continued net selling price erosion driven by increased competition.
- **KANJINTI® (trastuzumab-anns)** sales decreased 51% year-over-year for the first quarter, driven by lower net selling price and volume. The published first quarter ASP for KANJINTI in the U.S. declined 36% year-over-year and increased 3% quarter-over-quarter. Going forward, we expect continued net selling price erosion and declining volume driven by increased competition.

Established Products

- Total sales of our established products, which include **EPOGEN® (epoetin alfa)**, **Aranesp® (darbepoetin alfa)**, **Parsabiv® (etelcalcetide)**, and **Neulasta® (pegfilgrastim)**, decreased 17% year-over-year for the first quarter, driven by lower net selling price, unfavorable changes to estimated sales deductions, and lower volume. The published first quarter ASP for Neulasta in the U.S. declined 26% year-over-year and increased 3% quarter-over-quarter. In the aggregate, we expect the year-over-year net selling price and volume erosion for this portfolio of products to continue.

Product Sales Detail by Product and Geographic Region

\$Millions, except percentages	Q1 '23			Q1 '22	YOY Δ
	US	ROW	TOTAL	TOTAL	TOTAL
Repatha®	197	191	388	329	18%
Prolia®	623	304	927	852	9%
EVENITY®	164	90	254	170	49%
Aimovig®	64	5	69	101	(32%)
TEZSPIRE®	96	—	96	7	*
TAVNEOS®	23	—	23	—	NM
Otezla®	294	98	392	451	(13%)
Enbrel®	564	15	579	862	(33%)
AMJEVITA®/AMGEVITA™	51	113	164	108	52%
BLINCYTO®	126	68	194	138	41%
Vectibix®	111	122	233	201	16%
KYPROLIS®	234	124	358	287	25%
LUMAKRAS®/LUMYKRAS™	48	26	74	62	19%
XGEVA®	384	152	536	502	7%
Nplate®	246	116	362	266	36%
MVASI®	121	81	202	244	(17%)
KANJINTI®	33	14	47	96	(51%)
EPOGEN®	60	—	60	120	(50%)
Aranesp®	115	240	355	358	(1%)
Parsabiv®	58	33	91	86	6%
Neulasta®	211	38	249	348	(28%)
Other products**	152	41	193	143	35%
Total product sales	<u>\$ 3,975</u>	<u>\$ 1,871</u>	<u>\$ 5,846</u>	<u>\$ 5,731</u>	<u>2%</u>

*Change in excess of 100%

** Other products include Corlanor®, AVSOLA®, NEUPOGEN®, RIABNI®, IMLYGIC® and Sensipar®/Mimpara™, as well as sales by Bergamo and GENSENTA subsidiaries.

NM = not meaningful

Operating Expense, Operating Margin and Tax Rate Analysis

On a GAAP basis:

- **Total Operating Expenses** increased 12%. **Cost of Sales** margin increased 2.2 percentage points, primarily driven by amortization of intangible assets from acquisitions, asset-related impairments, changes in product mix, and higher profit share. **Research & Development (R&D)** expenses increased 10%, primarily due to higher investments in late-stage programs, research and the early pipeline, and marketed product support. **Selling, General & Administrative (SG&A)** expenses increased 2%.
- **Operating Margin** as a percentage of product sales decreased 10.7 percentage points to 32.9%.
- **Tax Rate** increased 5.6 percentage points, primarily driven by the 2022 Puerto Rico tax law change that replaced the excise tax with an income tax beginning in 2023 and an increase in the interest expense on tax reserves.

On a non-GAAP basis:

- **Total Operating Expenses** increased 6%. **Cost of Sales** margin increased 0.8 percentage points, primarily driven by changes in product mix and higher profit share. **R&D** expenses increased 12%, due to higher investments in late-stage programs, research and the early pipeline, and marketed product support. **SG&A** expenses increased 1%.
- **Operating Margin** as a percentage of product sales decreased 6.5 percentage points in the first quarter to 48.3%.
- **Tax Rate** increased 3.7 percentage points, primarily due to the 2022 Puerto Rico tax law change that replaced the excise tax with an income tax beginning in 2023 and an increase in the interest expense on tax reserves.

\$Millions, except percentages	GAAP			Non-GAAP		
	Q1 '23	Q1 '22	YOY Δ	Q1 '23	Q1 '22	YOY Δ
Cost of Sales	\$ 1,720	\$ 1,561	10%	\$ 1,016	\$ 951	7%
% of product sales	29.4 %	27.2 %	2.2 pts.	17.4 %	16.6 %	0.8 pts.
Research & Development	\$ 1,058	\$ 959	10%	\$ 1,044	\$ 934	12%
% of product sales	18.1 %	16.7 %	1.4 pts.	17.9 %	16.3 %	1.6 pts.
Selling, General & Administrative	\$ 1,258	\$ 1,228	2%	\$ 1,224	\$ 1,213	1%
% of product sales	21.5 %	21.4 %	0.1 pts.	20.9 %	21.2 %	(0.3) pts.
Other	\$ 148	\$ (10)	*	\$ —	\$ —	NM
Total Operating Expenses	\$ 4,184	\$ 3,738	12%	\$ 3,284	\$ 3,098	6%
Operating Margin						
operating income as % of product sales ..	32.9 %	43.6 %	(10.7) pts.	48.3 %	54.8 %	(6.5) pts.
Tax Rate	17.5 %	11.9 %	5.6 pts.	17.8 %	14.1 %	3.7 pts.

pts: percentage points
* change in excess of 100%
NM = not meaningful

Cash Flow and Balance Sheet

- The Company generated \$0.7 billion of free cash flow in the first quarter of 2023 versus \$2.0 billion in the first quarter of 2022, driven by the timing of payments for sales incentives, rebates and discounts, lower operating income, and higher capital expenditures from the build-out of our new North Carolina and Ohio facilities.
- The Company's first quarter 2023 dividend of \$2.13 per share was declared on December 12, 2022, and was paid on March 8, 2023, to all stockholders of record as of February 15, 2023, representing a 10% increase from 2022.
- During the first quarter, there were no repurchases of common stock.
- Cash and investments totaled \$31.6 billion and debt outstanding totaled \$61.6 billion as of March 31, 2023.

\$Billions, except shares	Q1 '23	Q1 '22	YOY Δ
Operating Cash Flow	\$ 1.1	\$ 2.2	\$ (1.1)
Capital Expenditures	\$ 0.3	\$ 0.2	\$ 0.2
Free Cash Flow	\$ 0.7	\$ 2.0	\$ (1.3)
Dividends Paid	\$ 1.1	\$ 1.1	\$ 0.1
Share Repurchases	\$ —	\$ 6.3	\$ (6.3)
Average Diluted Shares (millions)	538	551	(13)

Note: Numbers may not add due to rounding

\$Billions	3/31/23	12/31/22	YTD Δ
Cash and Investments	\$ 31.6	\$ 9.3	\$ 22.3
Debt Outstanding	\$ 61.6	\$ 38.9	\$ 22.7

Note: Numbers may not add due to rounding

2023 Guidance (Excludes any contribution from the announced acquisition of Horizon Therapeutics plc)

The Company expects the announced acquisition of Horizon Therapeutics plc (Horizon) to close in the first half of 2023. For the full year 2023, excluding any contribution from the announced acquisition of Horizon, the Company now expects:

- **Total revenues** in the range of \$26.2 billion to \$27.3 billion.
- On a **GAAP basis, EPS** in the range of \$15.38 to \$16.59, and a **tax rate** in the range of 17.0% to 18.5%.
- On a **non-GAAP basis, EPS** in the range of \$17.60 to \$18.70, and a **tax rate** in the range of 18.0% to 19.0%.
- **Capital expenditures** to be approximately \$925 million.
- **Share repurchases** not to exceed \$500 million.

First Quarter Product and Pipeline Update

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

General Medicine

Olpasiran (AMG 890)

- A Phase 3 cardiovascular outcomes study of olpasiran, a small interfering RNA molecule that reduces Lp(a) synthesis in the liver, in participants with atherosclerotic cardiovascular disease (ASCVD) and elevated Lipoprotein(a) (Lp(a)), continues to enroll.
- In March, a new analysis from the OCEAN(a) Phase 2 Dose study was presented at the American College of Cardiology's 72nd Annual Scientific Session, together with World Heart Federation's World Congress of Cardiology. This analysis demonstrated that olpasiran treatment resulted in a placebo-adjusted percentage reduction in Lp(a) of > 95% when dosed 75 mg or higher every 12 weeks irrespective of baseline Lp(a) level in individuals with ASCVD and Lp(a) > 150 nmol/L.
- In February, the Company announced the initiation of the African American Heart Study, in collaboration with the Association of Black Cardiologists and the Morehouse School of Medicine. This study will measure the association between Lp(a) and ASCVD in 5,000 African American individuals to better understand the association between Lp(a) levels and incident ASCVD in persons of African American descent.

AMG 133

- A Phase 2 study of AMG 133, a multispecific molecule that inhibits the gastric inhibitory polypeptide receptor (GIPR) and activates the glucagon like peptide 1 (GLP 1) receptor, in overweight or obese adults, with or without type 2 diabetes mellitus, continues to enroll.

AMG 786

- A small-molecule obesity program continues to enroll patients in a Phase 1 study. This molecule has a different target than AMG 133 and is not an incretin-based therapy.

Repatha

- In March, analyses from the Repatha FOURIER and FOURIER open-label extension studies were presented at the American College of Cardiology's 72nd Annual Scientific Session, together with World Heart Federation's World Congress of Cardiology, demonstrating that earlier initiation with Repatha was associated with a reduced number of major cardiovascular events, including cardiovascular death, myocardial infarction, stroke, unstable angina, or coronary revascularization.
- EVOLVE-MI, a Phase 4 study of Repatha administered very early to reduce the risk of cardiovascular events in patients hospitalized with acute myocardial infarction, continues to enroll patients.

Prolia

- In May, the Company will present results of the largest head-to-head, real-world study in postmenopausal osteoporosis, comparing fracture risk reduction of Prolia with bisphosphonates at the European Society for Clinical and Economic Aspects of Osteoporosis meeting.

Aimovig

- A randomized, double-blind, placebo-controlled Phase 4 trial investigating the efficacy and safety of Aimovig in patients with chronic migraine and medication overuse headache (MOH) met its primary endpoint (absence of MOH at month 6) in the 140 mg dose group. This group also experienced statistically significant improvements on the secondary endpoints of change from baseline in acute headache medication days and sustained MOH remission. Other secondary endpoints were consistent in favoring the Aimovig-treated groups; however, they did not achieve statistical significance with the testing methodology applied. There were no new safety signals observed in the study, and the overall safety profile was consistent with what has been described.

Inflammation

TEZSPIRE

- In February, the FDA approved TEZSPIRE for self-administration in a prefilled, single-use pen for patients aged 12 years and older with severe asthma.
- In severe asthma, the PASSAGE Phase 4 real-world effectiveness study, the WAYFINDER Phase 3b study and the SUNRISE Phase 3 study continue to enroll patients.
- A Phase 3 study of TEZSPIRE in chronic rhinosinusitis with nasal polyps continues to enroll patients.
- A Phase 3 study of TEZSPIRE in eosinophilic esophagitis has begun enrolling patients.
- A Phase 2b study of TEZSPIRE in chronic spontaneous urticaria is complete, with top-line data anticipated in mid-2023.
- A Phase 2 study of TEZSPIRE in chronic obstructive pulmonary disease is fully enrolled. Data read out is anticipated in H1 2024.

Rocatinlimab (AMG 451 / KHK4083)

- The ROCKET Phase 3 program, composed of seven studies evaluating rocatinlimab, an anti-OX40 monoclonal antibody, is enrolling adult and adolescent patients with moderate to severe atopic dermatitis.

Rozibafusp alfa (AMG 570)

- A Phase 2b study of rozibafusp alfa, an antibody-peptide conjugate that simultaneously blocks inducible T-cell costimulatory ligand (ICOSL) and B-cell activating factor (BAFF) activity, in systemic lupus erythematosus (SLE), was stopped for futility.

Efavaleukin alfa (AMG 592)

- A Phase 2b study of efavaleukin alfa, an interleukin-2 (IL-2) mutein Fc fusion protein, in SLE was stopped for futility.
- A Phase 2b study of efavaleukin alfa in ulcerative colitis continues to enroll patients.

Ordesekimab (AMG 714 / PRV-015)

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

Oncology

BLINCYTO

- Global regulatory authority submissions are planned in H2 2023 for E1910, a Phase 3 trial conducted by the National Cancer Institute, the Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network (ECOG ACRIN) Cancer Research Group that demonstrated superior overall survival with BLINCYTO treatment added to consolidation chemotherapy over standard of care consolidation chemotherapy in newly diagnosed adult patients with Philadelphia chromosome negative B-cell acute lymphoblastic leukemia (ALL) who were measurable residual disease (MRD) negative following induction and intensification chemotherapy.
- Golden Gate, a Phase 3 study of BLINCYTO alternating with low-intensity chemotherapy in older adults with newly diagnosed Philadelphia chromosome negative B-cell ALL, continues to enroll patients.
- A Phase 1/2 study of subcutaneous BLINCYTO in adults with relapsed or refractory Philadelphia chromosome negative B-cell ALL continues to enroll patients.

Tarlatamab (AMG 757)

- DeLLphi-304, a Phase 3 study comparing tarlatamab, a half-life extended BiTE molecule targeting delta-like ligand 3, with standard of care chemotherapy in second-line small-cell lung cancer (SCLC), will be initiated this month.
- DeLLphi-301, a potentially registrational Phase 2 study of tarlatamab being studied in heavily pretreated patients with SCLC, continues to enroll patients. Data readout is anticipated in H2 2023.
- DeLLphi-300, a Phase 1 study of tarlatamab in relapsed/refractory SCLC, continues to enroll patients.
- DeLLphi-302, a Phase 1b study of tarlatamab in combination with AMG 404, an anti-programmed cell death-1 monoclonal antibody, in second-line or later SCLC, is ongoing.
- DeLLphi-303, a Phase 1b study of tarlatamab in combination with standard-of-care in first-line SCLC, continues to enroll patients.
- DeLLpro-300, a Phase 1b study of tarlatamab, in de novo or treatment-emergent neuroendocrine prostate cancer, continues to enroll patients.

Bemarituzumab

- FORTITUDE-101, a Phase 3 study of bemarituzumab, a fibroblast growth factor receptor 2b (FGFR2b) targeting monoclonal antibody, plus chemotherapy in first-line gastric cancer, continues to enroll patients.
- FORTITUDE-102, a Phase 1b/3 study of bemarituzumab plus chemotherapy and nivolumab in first-line gastric cancer, continues to enroll patients in the Phase 3 portion of the study.
- FORTITUDE-103, a Phase 1b study of bemarituzumab plus oral chemotherapy regimens with or without nivolumab in first-line gastric cancer, continues to enroll patients.
- FORTITUDE-201, a Phase 1b study of bemarituzumab monotherapy and in combination with standard-of-care therapy, in squamous non-small cell lung cancer (NSCLC) with FGFR2b overexpression, continues to enroll patients.
- FORTITUDE-301, a Phase 1b/2 basket study of bemarituzumab monotherapy in solid tumors with FGFR2b overexpression, continues to enroll patients in the Phase 2 portion of the study.

LUMAKRAS/LUMYKRAS

- The Company continues to investigate novel combinations and is advancing a comprehensive global clinical development program in NSCLC, colorectal cancer (CRC), and other solid tumors to further explore the potential of LUMAKRAS.
- A Phase 3 study of LUMAKRAS in combination with Vectibix in third-line CRC is fully enrolled. Data readout is anticipated in H2 2023.
- Combination study data of LUMAKRAS in combination with standard of care chemotherapy in NSCLC and LUMAKRAS in combination with Vectibix and standard of care chemotherapy in CRC will be presented at the American Society of Clinical Oncology annual meeting.
- In March, the Company completed submission of the LUMAKRAS CodeBreak 200 Phase 3 confirmatory data, along with data from the Phase 2 dose comparison substudy, to the FDA and to the European Medicines Agency (EMA).
- In February, results from a Phase 3 multicenter, randomized, open label, active-controlled, study of LUMAKRAS versus docetaxel for the treatment of previously treated locally advanced and unresectable or metastatic NSCLC subjects with mutated KRAS G12C (CodeBreak 200) were published in *The Lancet*.

Xaluritamig (formerly AMG 509)

- A Phase 1 dose-escalation/expansion study of xaluritamig, a bispecific molecule targeting six-transmembrane epithelial antigen of prostate 1 (STEAP1) in metastatic castrate-resistant prostate cancer (mCRPC), continues to enroll patients. Initial data readout is anticipated in H2 2023.

AMG 340

- A Phase 1 dose-escalation study of AMG 340, a lower T-cell affinity BiTE molecule targeting prostate-specific membrane antigen (PSMA), in mCRPC, continues to enroll patients.

AMG 193

- A Phase 1/1b/2 study of AMG 193, a small-molecule methylthioadenosine (MTA)-cooperative protein arginine methyltransferase 5 (PRMT5) inhibitor, continues to enroll patients with advanced methylthioadenosine phosphorylase (MTAP)-null solid tumors.

Biosimilars

- In April 2023, the European Commission (EC) granted marketing authorization for BEKEMV[®] (eculizumab, formerly ABP 959), a biosimilar to SOLIRIS[®] (eculizumab). BEKEMV is the first biosimilar to SOLIRIS approved by the EC. BEKEMV is approved only for the treatment of adults and children with paroxysmal nocturnal hemoglobinuria (PNH), a rare, life-threatening bone marrow disorder. In February, the Company submitted the U.S. Biologics License Application to the FDA for this molecule.
- A Phase 3 switching study to support an interchangeability designation in the U.S. for AMJEVITA, using an investigational high-concentration formulation of AMJEVITA (ABP 501, 100 mg/mL) evaluating multiple switches between Humira[®] (adalimumab) and AMJEVITA compared with continued use of Humira, met its primary endpoint of similarity for the primary pharmacokinetics (PK) endpoints, based on a prespecified PK similarity range.
- A Phase 3 switching study to support an interchangeability designation in the U.S. for ABP 654, an investigational biosimilar to STELARA[®] (ustekinumab), is ongoing. Data readout is anticipated in H1 2023.
- The final analysis from a Phase 3 study evaluating the efficacy and safety of ABP 938, an investigational biosimilar to EYLEA[®] (aflibercept) compared with EYLEA in patients with neovascular age-related macular degeneration, is expected in H1 2023.

TEZSPIRE is being developed in collaboration with AstraZeneca.

Rocatinlimab, formerly AMG 451 / KHK4083 is being developed in collaboration with Kyowa Kirin.

Ordesekimab formerly AMG 714 and also known as PRV-015 is being developed in collaboration with Provention Bio.

AMG 509 is being developed in collaboration with Xencor.

Humira is a registered trademark of AbbVie, Inc.

STELARA is a registered trademark 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 2023 and 2022, in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and on a non-GAAP basis. In addition, management has presented its full year 2023 EPS and tax 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, divestitures, restructuring and certain other items from the related GAAP financial measures. Beginning January 1, 2022, following industry guidance from the U.S. Securities and Exchange Commission, the Company no longer excludes adjustments for upfront license fees, development milestones and in-process research and development (IPR&D) expenses of pre-approval programs related to licensing, collaboration and asset acquisition transactions from its non-GAAP financial measures. GAAP financial measures are included in the news release. Management has presented Free Cash Flow (FCF), which is a non-GAAP financial measure, for the first quarter of 2023 and 2022. FCF is computed by subtracting capital expenditures from operating cash flow, each as determined in accordance with GAAP. Management has also presented Total Revenues and Product Sales Adjusted for Foreign Exchange Impact, which is a non-GAAP financial measure, for the first quarter of 2023. Total Revenues and Product Sales Adjusted for Foreign Exchange Impact is computed by converting our current period local currency product sales using the prior period foreign exchange rates and comparing that to our current period product sales.

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. The Company believes Total Revenues and Product Sales Adjusted for Foreign Exchange Impact provides supplementary information on the Company's product sales performance by excluding changes in foreign exchange rates between comparative periods.

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.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2022, Amgen was named one of the "World's Best Employers" by Forbes and one of "America's 100 Most Sustainable Companies" by Barron's.

For more information, visit [Amgen.com](https://www.amgen.com) and follow us on Twitter, LinkedIn, Instagram, TikTok and YouTube.

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., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla[®] (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Teneobio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the proposed acquisition of Horizon Therapeutics plc, 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, 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 of our information technology systems 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. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. 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,	
	2023	2022
Revenues:		
Product sales	\$ 5,846	\$ 5,731
Other revenues	259	507
Total revenues	<u>6,105</u>	<u>6,238</u>
Operating expenses:		
Cost of sales	1,720	1,561
Research and development	1,058	959
Selling, general and administrative	1,258	1,228
Other	148	(10)
Total operating expenses	<u>4,184</u>	<u>3,738</u>
Operating income	1,921	2,500
Other income (expense):		
Interest expense, net	(543)	(295)
Other income (expense), net	<u>2,064</u>	<u>(530)</u>
Income before income taxes	3,442	1,675
Provision for income taxes	<u>601</u>	<u>199</u>
Net income	<u>\$ 2,841</u>	<u>\$ 1,476</u>
Earnings per share:		
Basic	\$ 5.32	\$ 2.69
Diluted	\$ 5.28	\$ 2.68
Weighted-average shares used in calculation of earnings per share:		
Basic	534	548
Diluted	538	551

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

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 31,561	\$ 9,305
Trade receivables, net	5,736	5,563
Inventories	5,011	4,930
Other current assets	2,395	2,388
Total current assets	44,703	22,186
Property, plant and equipment, net	5,460	5,427
Intangible assets, net	15,393	16,080
Goodwill	15,531	15,529
Other noncurrent assets	7,633	5,899
Total assets	<u>\$ 88,720</u>	<u>\$ 65,121</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 13,381	\$ 14,096
Current portion of long-term debt	834	1,591
Total current liabilities	14,215	15,687
Long-term debt	60,761	37,354
Long-term tax liabilities	5,864	5,757
Other noncurrent liabilities	2,532	2,662
Total stockholders' equity	5,348	3,661
Total liabilities and stockholders' equity	<u>\$ 88,720</u>	<u>\$ 65,121</u>
Shares outstanding	534	534

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

	Three months ended March 31,	
	2023	2022
GAAP cost of sales	\$ 1,720	\$ 1,561
Adjustments to cost of sales:		
Acquisition-related expenses (a)	(669)	(610)
Certain net charges pursuant to our restructuring and cost savings initiatives	(35)	—
Total adjustments to cost of sales	(704)	(610)
Non-GAAP cost of sales	<u>\$ 1,016</u>	<u>\$ 951</u>
GAAP cost of sales as a percentage of product sales	29.4 %	27.2 %
Acquisition-related expenses (a)	(11.4)	(10.6)
Certain net charges pursuant to our restructuring and cost savings initiatives	(0.6)	0.0
Non-GAAP cost of sales as a percentage of product sales	<u>17.4 %</u>	<u>16.6 %</u>
GAAP research and development expenses	\$ 1,058	\$ 959
Adjustments to research and development expenses:		
Acquisition-related expenses (a)	(14)	(25)
Non-GAAP research and development expenses	<u>\$ 1,044</u>	<u>\$ 934</u>
GAAP research and development expenses as a percentage of product sales	18.1 %	16.7 %
Acquisition-related expenses (a)	(0.2)	(0.4)
Non-GAAP research and development expenses as a percentage of product sales	<u>17.9 %</u>	<u>16.3 %</u>
GAAP selling, general and administrative expenses	\$ 1,258	\$ 1,228
Adjustments to selling, general and administrative expenses:		
Acquisition-related expenses (a)	(34)	(15)
Non-GAAP selling, general and administrative expenses	<u>\$ 1,224</u>	<u>\$ 1,213</u>
GAAP selling, general and administrative expenses as a percentage of product sales	21.5 %	21.4 %
Acquisition-related expenses (a)	(0.6)	(0.2)
Non-GAAP selling, general and administrative expenses as a percentage of product sales	<u>20.9 %</u>	<u>21.2 %</u>
GAAP operating expenses	\$ 4,184	\$ 3,738
Adjustments to operating expenses:		
Adjustments to cost of sales	(704)	(610)
Adjustments to research and development expenses	(14)	(25)
Adjustments to selling, general and administrative expenses	(34)	(15)
Certain net charges pursuant to our restructuring and cost savings initiatives (b)	(141)	(2)
Certain other expenses (c)	(7)	12
Total adjustments to operating expenses	(900)	(640)
Non-GAAP operating expenses	<u>\$ 3,284</u>	<u>\$ 3,098</u>

	Three months ended March 31,	
	2023	2022
GAAP operating income	\$ 1,921	\$ 2,500
Adjustments to operating expenses	900	640
Non-GAAP operating income	<u>\$ 2,821</u>	<u>\$ 3,140</u>
GAAP operating income as a percentage of product sales	32.9 %	43.6 %
Adjustments to cost of sales	12.0	10.6
Adjustments to research and development expenses	0.2	0.4
Adjustments to selling, general and administrative expenses	0.6	0.2
Certain net charges pursuant to our restructuring and cost savings initiatives (b)	2.5	0.1
Certain other expenses (c)	0.1	(0.1)
Non-GAAP operating income as a percentage of product sales	<u>48.3 %</u>	<u>54.8 %</u>
GAAP interest expense, net	\$ (543)	\$ (295)
Adjustments to interest expense, net:		
Interest expense on acquisition-related debt (d)	123	—
Non-GAAP interest expense, net	<u>\$ (420)</u>	<u>\$ (295)</u>
GAAP other income (expense), net	\$ 2,064	\$ (530)
Adjustments to other income (expense), net:		
Interest income and other expenses on acquisition-related debt (d)	(6)	—
Equity method investment basis difference amortization	—	47
Net (gains)/losses from equity investments (e)	(1,853)	365
Total adjustments to other income (expense), net	<u>(1,859)</u>	<u>412</u>
Non-GAAP other income (expense), net	<u>\$ 205</u>	<u>\$ (118)</u>
GAAP income before income taxes	\$ 3,442	\$ 1,675
Adjustments to income before income taxes:		
Adjustments to operating expenses	900	640
Adjustments to interest expense, net	123	—
Adjustments to other income (expense), net	(1,859)	412
Total adjustments to income before income taxes	<u>(836)</u>	<u>1,052</u>
Non-GAAP income before income taxes	<u>\$ 2,606</u>	<u>\$ 2,727</u>
GAAP provision for income taxes	\$ 601	\$ 199
Adjustments to provision for income taxes:		
Income tax effect of the above adjustments (f)	(117)	189
Other income tax adjustments (g)	(19)	(4)
Total adjustments to provision for income taxes	<u>(136)</u>	<u>185</u>
Non-GAAP provision for income taxes	<u>\$ 465</u>	<u>\$ 384</u>
GAAP tax as a percentage of income before taxes	17.5 %	11.9 %
Adjustments to provision for income taxes:		
Income tax effect of the above adjustments (f)	1.0	2.3
Other income tax adjustments (g)	(0.7)	(0.1)
Total adjustments to provision for income taxes	<u>0.3</u>	<u>2.2</u>
Non-GAAP tax as a percentage of income before taxes	<u>17.8 %</u>	<u>14.1 %</u>
GAAP net income	\$ 2,841	\$ 1,476
Adjustments to net income:		
Adjustments to income before income taxes, net of the income tax effect	(719)	863
Other income tax adjustments (g)	19	4
Total adjustments to net income	<u>(700)</u>	<u>867</u>
Non-GAAP net income	<u>\$ 2,141</u>	<u>\$ 2,343</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 March 31, 2023		Three months ended March 31, 2022	
	GAAP	Non-GAAP	GAAP	Non-GAAP
Net income	\$ 2,841	\$ 2,141	\$ 1,476	\$ 2,343
Weighted-average shares for diluted EPS	538	538	551	551
Diluted EPS	<u>\$ 5.28</u>	<u>\$ 3.98</u>	<u>\$ 2.68</u>	<u>\$ 4.25</u>

- (a) The adjustments related primarily to noncash amortization of intangible assets from business acquisitions.
- (b) For the three months ended March 31, 2023, the adjustments related primarily to severance expenses associated with our restructuring plan initiated in early 2023.
- (c) For the three months ended March 31, 2023, the adjustments related to the change in fair values of contingent consideration liabilities. For the three months ended March 31, 2022, the adjustments related primarily to an in-process research and development asset adjustment.
- (d) For the three months ended March 31, 2023, the adjustments included (i) interest expense and income on senior notes issued in March 2023 and (ii) debt issuance costs and other fees related to our bridge credit and term loan credit agreements, incurred prior to the closing of our proposed acquisition of Horizon Therapeutics plc.
- (e) For the three months ended March 31, 2023, the adjustments related primarily to our BeiGene, Ltd. equity fair value adjustment.
- (f) 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 expenses related to restructuring and 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, 2023, was 14.0% compared to 18.0% for the corresponding period of the prior year.
- (g) 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)

	Three months ended March 31,	
	2023	2022
Net cash provided by operating activities	\$ 1,064	\$ 2,164
Net cash provided by (used in) investing activities	1,358	(111)
Net cash provided by (used in) financing activities	21,509	(3,514)
Increase (decrease) in cash and cash equivalents	23,931	(1,461)
Cash and cash equivalents at beginning of period	7,629	7,989
Cash and cash equivalents at end of period	<u>\$ 31,560</u>	<u>\$ 6,528</u>

	Three months ended March 31,	
	2023	2022
Net cash provided by operating activities	\$ 1,064	\$ 2,164
Capital expenditures	(344)	(190)
Free cash flow	<u>\$ 720</u>	<u>\$ 1,974</u>

Amgen Inc.

**Reconciliation of Total Revenues and Product Sales Adjusted for Foreign Exchange (FX) Impact
(Dollars in millions)
(Unaudited)**

	Three months ended March 31,		Change	FX impact \$ (a)	Three months ended March 31, 2023 excluding FX	FX impact % (a)	Change excluding FX
	2023	2022					
Product Sales	\$ 5,846	\$ 5,731	2%	\$ (103)	\$ 5,949	(2%)	4%
Total Revenues	\$ 6,105	\$ 6,238	(2%)	\$ (103)	\$ 6,208	(2%)	—%

- (a) Foreign exchange impact was calculated by converting our current period local currency Product sales using the prior period foreign exchange rates and comparing that to our current period Product sales.

Amgen Inc.
Reconciliation of GAAP EPS Guidance to Non-GAAP
EPS Guidance for the Year Ending December 31, 2023
(Unaudited)

GAAP diluted EPS guidance	\$ 15.38	—	\$ 16.59
Known adjustments to arrive at non-GAAP*:			
Acquisition-related expenses (a)	4.31	—	4.36
Net charges related to restructuring and cost savings initiatives	0.47	—	0.53
Net (gains)/losses from equity investments		(2.70)	
Other		0.03	
Non-GAAP diluted EPS guidance	<u>\$ 17.60</u>	<u>—</u>	<u>\$ 18.70</u>

* The known adjustments are presented net of their related tax impact, which amount to approximately \$0.48 - \$0.50 per share.

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

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, including any impact of the proposed Horizon acquisition, divestitures, asset impairments, litigation, changes in fair value of our contingent consideration obligations 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, 2023
(Unaudited)

GAAP tax rate guidance	17.0 %	—	18.5 %
Tax rate of known adjustments discussed above	0.5%	—	1.0%
Non-GAAP tax rate guidance	<u>18.0 %</u>	<u>—</u>	<u>19.0 %</u>