

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 OR 15(d) of
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported)

October 31, 2023

Amgen Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37702
(Commission
File Number)

95-3540776
(IRS Employer
Identification No.)

**One Amgen Center Drive
Thousand Oaks
California**
(Address of principal executive offices)

91320-1799
(Zip Code)

Registrant's telephone number, including area code

(805) 447-1000

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

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.0001 par value	AMGN	The Nasdaq Stock Market LLC
2.000% Senior Notes due 2026	AMGN26	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

Third Quarter 2023 Earnings Press Release and Reconciliation of Non-GAAP Financial Measures

On October 31, 2023, the Company issued a press release announcing its unaudited results of operations for the three and nine months ended September 30, 2023, and its unaudited financial position as of September 30, 2023. The full text of the press release is furnished as Exhibit 99.1 hereto.

In its press release the Company included certain non-U.S. Generally Accepted Accounting Principles (GAAP) financial measures as defined in Regulation G promulgated by the Securities and Exchange Commission. The non-GAAP financial measures included in the press release are non-GAAP earnings per share, non-GAAP operating income, non-GAAP operating margin, non-GAAP tax rate, non-GAAP net income, non-GAAP other (expense) income, net, non-GAAP interest expense, net, non-GAAP operating expenses and sub-components of non-GAAP operating expenses such as non-GAAP cost of sales, non-GAAP research and development (R&D) expenses and non-GAAP selling, general and administrative expenses. Reconciliations for such non-GAAP financial measures to the most directly comparable GAAP financial measures are included in the press release. The Company included Free Cash Flow (FCF), which is computed by subtracting capital expenditures from operating cash flow, each as determined in accordance with GAAP.

The Company believes that this 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 uses non-GAAP financial measures 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.

The following is a summary of the costs and other items excluded from the most directly comparable GAAP financial measures to calculate non-GAAP financial measures:

- Acquisition-related expenses: Acquisition-related charges are primarily associated with intangible assets acquired in connection with business acquisitions. Such charges include amortization of developed-product-technology rights, licensing rights, R&D technology rights, and marketing-related rights, as well as impairments of in-process R&D assets. Charges for purchased intangible assets are significantly impacted by the timing and magnitude of the Company's acquisitions and potential product approvals as they relate to in-process R&D projects acquired. Accordingly, these charges may vary in amount from period to period. The Company excludes these charges for purposes of calculating the non-GAAP financial measures presented to facilitate a more meaningful evaluation of the Company's current operating performance and comparisons to past operating performance. The Company believes that excluding the noncash charges related to those intangible assets acquired in business acquisitions treats those assets as if the Company had developed them internally in the past and, thus, provides a supplemental measure of profitability in which the Company's acquired intellectual property is treated in a comparable manner to its internally-developed-intellectual property.
 - Net charges pursuant to the Company's restructuring and cost savings initiatives: Costs from restructuring and cost savings initiatives are primarily related to facilities charges, including asset impairments and accelerated depreciation, and severance and benefits for employees terminated pursuant to our transformation and process improvement efforts. Costs from such initiatives are inconsistent in amount and are significantly impacted by the timing and nature of these events. Therefore, although the Company may incur these types of expenses in the future, it believes that eliminating these charges for purposes of calculating the non-GAAP financial measures provides a supplemental evaluation of the Company's current operating performance and facilitates comparisons to past operating performance.
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- Other items: The Company adjusts GAAP financial results for certain income and expenses (or gains and losses). These adjustments include (1) certain items from investment transactions, including (i) certain gains and losses on our investments in equity securities and (ii) amortization from the basis difference that arose in prior periods from certain equity method investments, recorded to other income and expense; (2) the impact of nonstrategic divestitures, which includes cumulative foreign currency translation adjustments; (3) certain items associated with judgments and/or settlements for legal proceedings discussed in our filings; and (4) (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 agreement and term loan credit agreement, incurred prior to the closing of our acquisition of Horizon Therapeutics plc. The Company excludes these items for the purpose of calculating the non-GAAP financial measures presented because the Company believes these items are outside the ordinary course of business. The Company believes eliminating these items provides a supplemental evaluation of the Company's current operating performance and facilitates comparisons to past operating performance.
- The tax effect of the adjustments between GAAP and non-GAAP results take 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 and certain gains and losses on our investments in equity securities, 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.

The press release also contains a discussion of the additional purposes for which the Company's management uses these non-GAAP financial measures.

This information and the information contained in the press release shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in Item 2.02 of this Current Report is not incorporated by reference into any filings of the Company made under the Securities Act of 1933, as amended, whether made before or after the date of this Current Report, regardless of any general incorporation language in the filing unless specifically stated so therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 [Press Release dated October 31, 2023](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

AMGEN INC.

Date: October 31, 2023

By: /s/ Peter H. Griffith
Name: Peter H. Griffith
Title: Executive Vice President and Chief Financial Officer



News Release

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AMGEN REPORTS THIRD QUARTER FINANCIAL RESULTS

THOUSAND OAKS, Calif. (October 31, 2023) - Amgen (NASDAQ:AMGN) today announced financial results for the third quarter of 2023¹.

"We are excited about our pipeline progress and our operating performance in the third quarter," said Robert A. Bradway, chairman and chief executive officer. "With the completion of the Horizon acquisition, Amgen has added rare disease medicines that fit well with our broad innovative portfolio."

Key results include:

- Total revenues increased 4% to \$6.9 billion in comparison to the third quarter of 2022, resulting from a 5% increase in product sales. Product sales growth was driven by 11% volume growth, partially offset by 3% lower net selling price and 3% unfavorable changes to estimated sales deductions.
 - Volume growth of 11% included double-digit volume growth from BLINCYTO® (blinatumomab), EVENITY® (romosozumab-aqqg), Repatha® (evolocumab) and Nplate® (romiplostim).
 - U.S. volume grew 11% and ex-U.S. volume grew 12%, including 27% volume growth in the Asia Pacific region.
- GAAP earnings per share (EPS) decreased 19% from \$3.98 to \$3.22, driven by a net impairment charge in Q3 2023 of approximately \$650 million following a decision to discontinue development of AMG 340, partially offset by increased revenues.
 - GAAP operating income decreased from \$2.7 billion to \$2.0 billion, and GAAP operating margin decreased 11.7 percentage points to 30.9%.
- Non-GAAP EPS increased 6% from \$4.70 to \$4.96, driven by increased revenues, partially offset by higher operating expenses.
 - Non-GAAP operating income increased from \$3.3 billion to \$3.4 billion, and non-GAAP operating margin decreased 0.5 percentage points to 52.0%.
- The Company generated \$2.5 billion of free cash flow for the third quarter of 2023 versus \$2.8 billion in the third quarter of 2022.

References in this release to "non-GAAP" measures, measures presented "on a non-GAAP basis" and "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. Refer to Non-GAAP Financial Measures below for further discussion.

¹ The accounting impact of this acquisition and the results of operations for Horizon Therapeutics plc will be included in our consolidated financial statements beginning in the fourth quarter of 2023.

Product Sales Performance

Total product sales increased 5% for the third quarter of 2023 versus the third quarter of 2022. Unit volumes grew 11%, partially offset by 3% lower net selling price and 3% unfavorable changes to estimated sales deductions.

General Medicine

- **Repatha[®]** sales increased 31% year-over-year for the third quarter, driven by 44% volume growth, partially offset by lower net selling price. In the U.S., sales grew 29%, driven by 45% volume growth, partially offset by lower net selling price resulting from higher rebates to support and expand access for patients. Outside the U.S., sales grew 34%, driven by 43% volume growth, partially offset by lower net selling price. Repatha remains the global proprotein convertase subtilisin/kexin type 9 (PCSK9) segment leader, with over 2 million patients treated since launch.
- **Prolia[®] (denosumab)** sales increased 14% year-over-year for the third quarter, primarily driven by 7% volume growth and higher net selling price. We are on track to treat over 7 million patients with Prolia in 2023.
- **EVENITY[®]** sales increased 53% year-over-year to a record \$307 million for the third quarter, driven by strong volume growth. U.S. volumes grew 41% year-over-year and volumes outside the U.S. grew 63%.
- **Aimovig[®] (erenumab-aooe)** sales decreased 12% year-over-year for the third quarter, driven by lower net selling price, partially offset by favorable changes to estimated sales deductions.

Inflammation

- **TEZSPIRE[®] (tezepelumab-ekko)** generated \$161 million of sales in the third quarter. Quarter-over-quarter sales increased 21%, driven by 18% volume growth that benefited from the pre-filled, single-use pen, which was approved for self-administration by the U.S. Food and Drug Administration (FDA) in the first quarter. Healthcare providers are increasingly recognizing 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.
- **TAVNEOS[®] (avacopan)** generated \$37 million of sales in the third quarter. Quarter-over-quarter sales increased 23%, driven by volume growth. U.S. volumes grew 18% quarter-over-quarter. In the U.S., approximately 2,300 patients have now been treated with TAVNEOS.
- **Otezla[®] (apremilast)** sales decreased 10% year-over-year for the third quarter, driven by lower net selling price, unfavorable changes to estimated sales deductions and lower inventory levels, partially offset by 1% volume growth. In the U.S., net selling price declined, driven by higher rebates to support and expand access for commercial and Medicare Part D patients. Otezla demand in the quarter continued to be impacted by free drug programs for newly launched competition. For the remainder of 2023, we expect demand to be affected by these free drug programs.

We expect future growth for Otezla to be driven by its established efficacy and safety profile, strong payer 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 who cannot be optimally addressed by a topical and can benefit from a systemic treatment like Otezla.

- **Enbrel® (etanercept)** sales decreased 6% year-over-year for the third quarter, primarily driven by an 8% decline from unfavorable changes to estimated sales deductions, resulting from a \$47 million favorable adjustment in the third quarter of 2022 compared to a \$37 million unfavorable adjustment in this quarter. Year-over-year volume increased 1% in the third quarter, driven by an increase in new patients starting treatment as a result of improved payer coverage. For the remainder of 2023, we expect this improved coverage will lead to growth in new patients and declining net selling price.
- **AMJEVITA®/AMGEVITA™ (adalimumab)** sales increased 30% year-over-year for the third quarter, driven by 53% volume growth, partially offset by lower net selling price. Ex-U.S. sales increased 10% year-over-year, driven by 22% volume growth, partially offset by lower net selling price. U.S. sales increased 21% quarter-over-quarter, driven by 41% volume growth, partially offset by lower inventory levels.

Hematology-Oncology

- **BLINCYTO®** sales increased 55% year-over-year to a record \$220 million for the third quarter, driven by 56% volume growth, supported by broad prescribing for patients with B-cell precursor acute lymphoblastic leukemia.
- **Vectibix® (panitumumab)** sales increased 2% year-over-year for the third quarter to a record \$252 million, driven by higher net selling price and 4% volume growth, partially offset by unfavorable foreign exchange impact.
- **KYPROLIS® (carfilzomib)** sales increased 10% year-over-year for the third quarter, primarily driven by 8% volume growth.
- **LUMAKRAS®/LUMYKRAS™ (sotorasib)** generated \$52 million of sales for the third quarter. Year-over-year sales decreased 31% for the third quarter, primarily driven by unfavorable changes to estimated sales deductions related to ongoing reimbursement negotiations in France.
- **XGEVA® (denosumab)** sales increased 5% year-over-year for the third quarter, driven by higher net selling price.
- **Nplate®** sales increased 45% year-over-year for the third quarter, driven by 43% volume growth resulting from a \$142 million order from the U.S. government.
- **MVASI® (bevacizumab-awwb)** sales increased 2% year-over-year for the third quarter, driven by 17% volume growth and favorable changes to estimated sales deductions, partially offset by lower net selling price. The published third quarter Average Selling Price (ASP) for MVASI in the U.S. declined 19% year-over-year and 1% quarter-over-quarter.

Going forward, we expect continued net selling price erosion driven by increased competition.

- **KANJINTI® (trastuzumab-anns)** sales decreased 72% year-over-year for the third quarter, driven by lower net selling price, unfavorable changes to estimated sales deductions and volume declines.

Established Products

- Total sales of our established products, which include **EPOGEN® (epoetin alfa)**, **Aranesp® (darbepoetin alfa)**, **Parsabiv® (etelcalcetide)** and **Neulasta® (pegfilgrastim)**, decreased 30% year-over-year for the third quarter, driven by lower net selling price and volume declines. 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	Q3 '23			Q3 '22	YOY Δ
	US	ROW	TOTAL	TOTAL	TOTAL
Repatha®	\$ 183	\$ 223	\$ 406	\$ 309	31%
Prolia®	673	313	986	862	14%
EVENITY®	214	93	307	201	53%
Aimovig®	88	6	94	107	(12%)
TEZSPIRE®	161	—	161	55	*
TAVNEOS®	32	5	37	—	NM
Otezla®	462	105	567	627	(10%)
Enbrel®	1,026	9	1,035	1,106	(6%)
AMJEVITA®/AMGEVITA™	23	129	152	117	30%
BLINCYTO®	147	73	220	142	55%
Vectibix®	116	136	252	247	2%
KYPROLIS®	231	118	349	318	10%
LUMAKRAS®/LUMYKRAS™	48	4	52	75	(31%)
XGEVA®	374	145	519	495	5%
Nplate®	322	97	419	288	45%
MVASI®	140	73	213	209	2%
KANJINTI®	7	13	20	72	(72%)
EPOGEN®	50	—	50	136	(63%)
Aranesp®	107	216	323	358	(10%)
Parsabiv®	59	36	95	100	(5%)
Neulasta®	92	32	124	247	(50%)
Other products**	136	31	167	166	1%
Total product sales	\$ 4,691	\$ 1,857	\$ 6,548	\$ 6,237	5%

*Change in excess of 100%

**Consists of AVSOLA®, RIABNI®, Corlanor®, NEUPOGEN®, IMLYGIC®, Sensipar®/Mimpara™ and BEKEMV™, as well as sales in prior periods of our divested Bergamo and GENSENTA subsidiaries.

NM = not meaningful

Operating Expense, Operating Margin and Tax Rate Analysis

On a GAAP basis:

- **Total Operating Expenses** increased 22%. **Cost of Sales** margin increased 2.1 percentage points, primarily driven by higher profit share, higher amortization expense from acquisition-related assets and changes in product mix. **Research & Development (R&D)** expenses decreased 3%, as lower spend in research and early pipeline was partially offset by higher spend in later-stage clinical programs and marketed products. **Selling, General & Administrative (SG&A)** expenses increased 5%, primarily driven by higher general and administrative expenses, including higher acquisition-related expenses. **Other** operating expenses consisted of a net impairment charge for AMG 340.
- **Operating Margin** as a percentage of product sales decreased 11.7 percentage points to 30.9%.
- **Tax Rate** increased 0.7 percentage points, primarily driven by the 2022 Puerto Rico tax law change that replaced the excise tax with an income tax beginning in 2023, partially offset by net favorable items and earnings mix, including the tax benefit from the net impairment charge for AMG 340.

On a non-GAAP basis:

- **Total Operating Expenses** increased 4%. **Cost of Sales** margin increased 1.3 percentage points, primarily driven by higher profit share and changes in product mix. **R&D** expenses decreased 2%, as lower spend in research and early pipeline was partially offset by higher spend in later-stage clinical programs and marketed products. **SG&A** expenses increased 1%.
- **Operating Margin** as a percentage of product sales decreased 0.5 percentage points in the third quarter to 52.0%.
- **Tax Rate** increased 3.2 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 earnings mix.

\$Millions, except percentages	GAAP			Non-GAAP		
	Q3 '23	Q3 '22	YOY Δ	Q3 '23	Q3 '22	YOY Δ
Cost of Sales	\$ 1,806	\$ 1,588	14%	\$ 1,137	\$ 1,003	13%
% of product sales	27.6 %	25.5 %	2.1 pts.	17.4 %	16.1 %	1.3 pts.
Research & Development	\$ 1,079	\$ 1,112	(3%)	\$ 1,070	\$ 1,096	(2%)
% of product sales	16.5 %	17.8 %	(1.3) pts.	16.3 %	17.6 %	(1.3) pts.
Selling, General & Administrative	\$ 1,353	\$ 1,287	5%	\$ 1,293	\$ 1,276	1%
% of product sales	20.7 %	20.6 %	0.1 pts.	19.7 %	20.5 %	(0.8) pts.
Other	\$ 644	\$ 5	*	\$ —	\$ —	NM
Total Operating Expenses	\$ 4,882	\$ 3,992	22%	\$ 3,500	\$ 3,375	4%
Operating Margin						
operating income as % of product sales	30.9 %	42.6 %	(11.7) pts.	52.0 %	52.5 %	(0.5) pts.
Tax Rate	11.1 %	10.4 %	0.7 pts.	16.1 %	12.9 %	3.2 pts.

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

Cash Flow and Balance Sheet

- The Company generated \$2.5 billion of free cash flow in the third quarter of 2023 versus \$2.8 billion in the third quarter of 2022.
- The Company's third quarter 2023 dividend of \$2.13 per share was declared on August 1, 2023, and was paid on September 8, 2023, to all stockholders of record as of August 18, 2023, representing a 10% increase from 2022.
- Cash and investments totaled \$34.7 billion and debt outstanding totaled \$60.5 billion as of September 30, 2023.

\$Billions, except shares	Q3 '23	Q3 '22	YOY Δ
Operating Cash Flow	\$ 2.8	\$ 3.0	\$ (0.2)
Capital Expenditures	\$ 0.2	\$ 0.2	\$ 0.1
Free Cash Flow	\$ 2.5	\$ 2.8	\$ (0.3)
Dividends Paid	\$ 1.1	\$ 1.0	\$ 0.1
Share Repurchases	\$ —	\$ —	\$ 0.0
Average Diluted Shares (millions)	538	538	0

Note: Numbers may not add due to rounding

\$Billions	9/30/23	12/31/22	YTD Δ
Cash and Investments	\$ 34.7	\$ 9.3	\$ 25.4
Debt Outstanding	\$ 60.5	\$ 38.9	\$ 21.5

Note: Numbers may not add due to rounding

2023 Guidance

For the full year 2023, the Company now expects:

- **Total revenues** in the range of \$28.0 billion to \$28.4 billion.
- On a **GAAP basis, EPS** in the range of \$11.23 to \$12.73, and a **tax rate** in the range of 14.0% to 15.5%.
- On a **non-GAAP basis, EPS** in the range of \$18.20 to \$18.80, and a **tax rate** in the range of 16.5% to 17.0%.
- **Capital expenditures** to be approximately \$950 million.
- **Share repurchases** not to exceed \$500 million.

Third Quarter Product and Pipeline Update

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

Oncology

Tarlatamab (AMG 757)

- In October, data were presented from the global Phase 2 DeLLphi-301 study and simultaneously published in the *New England Journal of Medicine*, evaluating tarlatamab, a first-in-class investigational delta-like ligand 3 (DLL3) targeting BiTE[®] (bispecific T-cell engager) molecule, in patients with advanced-stage small cell lung cancer (SCLC) who had failed two or more prior lines of treatment. With a median follow-up of 10.6 months, an intention-to-treat analysis that included 100 patients at the selected 10 mg dose for tarlatamab demonstrated an objective response rate (ORR; primary endpoint) of 40% (97.5% confidence interval: 29-52). There were no new safety signals observed compared to the Phase 1 study.
- Data from the DeLLphi-301 study are being submitted to the U.S. Food and Drug Administration (FDA) which recently granted Breakthrough Therapy Designation to tarlatamab for the treatment of adult patients with extensive-stage SCLC with disease progression on or after platinum-based chemotherapy.
- DeLLphi-304, a Phase 3 study comparing tarlatamab with standard of care chemotherapy in second-line SCLC, is enrolling patients.
- Two additional Phase 3 studies of tarlatamab in earlier lines of SCLC are planned.
- 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 protein 1 (PD1) 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, has completed enrollment.

BLINCYTO

- In September, based upon the E1910 study, the FDA granted Breakthrough Therapy Designation to BLINCYTO for the treatment of adult and pediatric patients with CD19-positive, Philadelphia chromosome-negative (Ph-), B-cell precursor acute lymphoblastic leukemia (B-ALL) during the consolidation phase of multiphase therapy. Global regulatory

authority submissions are planned in late 2023 to early 2024 for the Phase 3 E1910 study conducted by the National Cancer Institute, the Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network (ECOG ACRIN) Cancer Research Group.

- In October, National Comprehensive Cancer Network[®] Clinical Practice Guidelines in Oncology¹ (NCCN Guidelines[®]) for Pediatric Acute Lymphoblastic Leukemia were updated to broaden the recommendation for BLINCYTO as consolidation to include both early and late first relapse patients with bone marrow relapse with or without extramedullary involvement and adding the COG1331 regimen to the list of recommended treatment regimens.
- Golden Gate, a Phase 3 study of BLINCYTO alternating with low-intensity chemotherapy in older adults with newly diagnosed Ph- B-ALL, continues to enroll patients.
- A Phase 1/2 study of subcutaneous BLINCYTO in adults with relapsed or refractory Ph- B-ALL continues to enroll patients.

Xaluritamig (AMG 509)

- In October, initial data from a Phase 1b study were presented and simultaneously published in *Cancer Discovery* on xaluritamig, a first-in-class bispecific molecule targeting six-transmembrane epithelial antigen of prostate 1 (STEAP1) demonstrating encouraging anti-tumor activity in heavily pretreated patients with metastatic castrate-resistant prostate cancer (mCRPC). Efficacy was greater at higher doses (doses ≥ 0.75 mg target dose) where PSA50 was 59% (n=44) and RECIST objective response rate was 41% (n=37). The safety profile was clinically manageable, with CRS that was generally low grade and primarily in cycle 1.
- A Phase 1b monotherapy and combination dose-escalation and expansion study of xaluritamig in mCRPC continues to enroll patients.
- Two additional Phase 1 studies of xaluritamig to evaluate preliminary efficacy and safety in patients with early prostate cancer are planned.

AMG 193

- Initial results from a Phase 1/1b study of AMG 193, a first-in-class small molecule methylthioadenosine (MTA)-cooperative protein arginine methyltransferase 5 (PRMT5) inhibitor, demonstrate promising monotherapy activity across six methylthioadenosine phosphorylase (MTAP)-null tumor types. Dose-limiting adverse events and treatment discontinuations were typically due to gastrointestinal events and were manageable and reversible.
- This Phase 1/1b/2 study of AMG 193 continues to enroll patients with advanced MTAP-null solid tumors.
- A Phase 1/2 study of AMG 193 in combination with IDE397, an investigational methionine adenosyltransferase 2A (MAT2A) inhibitor, is enrolling patients.

LUMAKRAS/LUMYKRAS

- In October, data were presented and simultaneously published in the *New England Journal of Medicine* from the global Phase 3 CodeBreak 300 trial evaluating two doses of LUMAKRAS (960 mg or 240 mg) in combination with Vectibix. Both doses demonstrated a statistically significant superiority in PFS over the investigator's choice of standard therapy in patients with chemorefractory KRAS G12C-mutated metastatic colorectal cancer (CRC). No new safety signals were observed. Discussions continue with regulatory agencies on a potential approval pathway for this indication.
- In September, LUMAKRAS was included in the colon cancer and the rectal cancer NCCN Guidelines^{®1} (category 2A) and is recommended for treatment of previously treated metastatic colorectal or rectal cancer with KRAS G12C-mutated tumors in combination with cetuximab or panitumumab.
- The Company is planning to initiate a Phase 3 study of LUMAKRAS in combination with Vectibix and FOLFIRI in first-line KRAS G12C-mutated CRC.
- In September, data were presented from an arm of the CodeBreak 101 clinical trial, a Phase 1b study evaluating LUMAKRAS with carboplatin and pemetrexed in adult patients with KRAS G12C-mutated advanced NSCLC. LUMAKRAS treatment resulted in encouraging objective response rates and disease control rates in first-line and second-line patients.
- A global, randomized Phase 3 study of LUMAKRAS plus chemotherapy vs. pembrolizumab plus chemotherapy in first-line KRAS G12C-mutated and programmed cell death protein ligand-1 (PD-L1) negative advanced NSCLC was initiated.
- Regulatory review by the FDA and the European Medicines Agency (EMA) of the CodeBreak 200 Phase 3 trial of previously treated patients with KRAS G12C-mutated advanced NSCLC along with data from the Phase 2 dose comparison substudy is ongoing.
- In November, data² comparing sotorasib 960 mg versus 240 mg in adults with pretreated KRAS G12C-mutated advanced NSCLC will be presented at a European Society for Medical Oncology (ESMO) Virtual Plenary session.

Bemarituzumab

- FORTITUDE-101, a Phase 3 study of bemarituzumab, a first-in-class 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-301, a Phase 1b/2 basket study of bemarituzumab monotherapy in solid tumors with FGFR2b overexpression, is ongoing.
- FORTITUDE-201, a Phase 1b study of bemarituzumab monotherapy and in combination with standard of care therapy, in squamous NSCLC with FGFR2b overexpression, will be discontinued.

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 will be discontinued.

General Medicine

Maridebart cafraglutide (AMG 133)

- A Phase 2 study of maridebart cafraglutide, 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 has completed enrollment with topline data anticipated in late 2024.

AMG 786

- A Phase 1 study of AMG 786, a small molecule obesity program, is ongoing with initial data readout anticipated in H1 2024. This molecule has a different target than AMG 133 and is not an incretin-based therapy.

Olpasiran (AMG 890)

- A Phase 3 cardiovascular outcomes study of olpasiran, a potentially best-in-class small interfering ribonucleic acid (siRNA) molecule that reduces lipoprotein(a) (Lp(a)) synthesis in the liver, in participants with atherosclerotic cardiovascular disease and elevated Lp(a) continues to enroll patients.
- In August, data were presented from the final analysis of the Phase 2 OCEAN(a)-DOSE study. The results from the off-treatment extension period (at least 24 weeks since the last dose) show that patients previously dosed every 12 weeks for up to 36 weeks with ≥ 75 mg of olpasiran sustained a ~ 40 -50% placebo-adjusted percent reduction in Lp(a) nearly a year after the last dose. No new safety concerns were identified during the off-treatment extension period.

Repatha

- New data from the FOURIER Open Label Extension (OLE) study reinforcing the safety and efficacy of Repatha, including results from the evaluation of long-term neurocognitive safety in atherosclerotic cardiovascular disease patients treated with Repatha, will be presented at the American Heart Association Scientific Sessions in November.
- EVOLVE-MI, a Phase 4 study of Repatha administered shortly after an acute myocardial infarction and designed to reduce the risk of cardiovascular events in hospitalized acute coronary syndrome patients, continues to enroll patients.
- A Phase 3 cardiovascular outcomes study (VESALIUS-CV) in patients at high cardiovascular risk without prior myocardial infarction or stroke is ongoing.

Inflammation

TEZSPIRE

- In severe asthma, the WAYFINDER Phase 3b study is fully enrolled. The PASSAGE Phase 4 real-world effectiveness study and the SUNRISE Phase 3 study continue to enroll patients.
- A Phase 3 study of TEZSPIRE in chronic rhinosinusitis with nasal polyps is fully enrolled.
- A Phase 3 study of TEZSPIRE in eosinophilic esophagitis continues to enroll patients.

- A Phase 2 study of TEZSPIRE in chronic obstructive pulmonary disease is fully enrolled. Data readout is anticipated in H1 2024.
- A Phase 2b study of TEZSPIRE in chronic spontaneous urticaria did not meet the primary endpoint comparing tezepelumab with placebo in the overall and anti-IgE-naïve populations at week 16. By the end of the study at week 32 (18 weeks after last dose), a sustained treatment effect was observed in both tezepelumab dose groups in anti-IgE naïve patients. The Company and its partner AstraZeneca are determining next steps for this indication and plan to publish full results in the future.

Rocatinlimab (AMG 451/KHK4083)

- In October, three posters of post-hoc analysis data from the Phase 2b study of rocatinlimab, a first-in-class anti-OX40 monoclonal antibody, in patients with moderate to severe atopic dermatitis were presented. These included patient reported outcomes data demonstrating the benefit of rocatinlimab.
- The ROCKET Phase 3 program, composed of seven studies evaluating rocatinlimab in moderate to severe atopic dermatitis, continues to enroll adult and adolescent patients. To date, over 1,500 patients have been randomized into the ROCKET program.
- A Phase 2 study of rocatinlimab in moderate to severe uncontrolled asthma is planned.

Otezla

- In October, results were presented from the DISCREET Phase 3 study which demonstrated that Otezla treated patients across subgroups experienced greater improvement in genital psoriasis and genital itch at week 16 compared to placebo, with women achieving numerically greater responses.
- A Phase 3 study evaluating the efficacy and safety of Otezla in Japanese patients with palmoplantar pustulosis successfully met the primary and secondary endpoints.

TAVNEOS

- Data will be presented from the ADVOCATE study at the American College of Rheumatology and American Society of Nephrology Scientific sessions in November on the efficacy and safety of TAVNEOS in key sub-groups including patients 65 years old and older and patients with renal involvement.

Efavaleukin alfa (AMG 592)

- A Phase 2b study of efavaleukin alfa, an interleukin 2 (IL 2) mutein Fc fusion protein, 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.

Biosimilars

- The clinical comparative study portion of a randomized, double-blind pivotal study evaluating pharmacokinetic (PK) similarity of ABP 206 compared with OPDIVO® (nivolumab) in resected stage III or stage IV melanoma patients in the adjuvant setting was initiated.

- The FDA accepted the Biologics License Application for ABP 938, an investigational biosimilar to EYLEA® (aflibercept).

¹National Comprehensive Cancer Network® (NCCN®) makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

²Previously provided in the publicly available ODAC briefing book.

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, a Sanofi company. For the purposes of the collaboration, Provention Bio conducts a clinical trial and leads certain development and regulatory activities for the program.

Xaluritamig, formerly AMG 509, is being developed pursuant to a research collaboration with Xencor, Inc.

IDE397 is an investigational MAT2A inhibitor from IDEAYA Biosciences.

OPDIVO is a registered trademark of Bristol-Myers Squibb Company.

EYLEA is a registered trademark of Regeneron Pharmaceuticals, Inc.

Non-GAAP Financial Measures

In this news release, management has presented its operating results for the third 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. Management has presented Free Cash Flow (FCF), which is a non-GAAP financial measure, for the third quarters of 2023 and 2022. 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 normal and recurring business activities by facilitating comparisons of results of normal and recurring business operations among current, past and future periods. The Company believes that FCF provides a further measure of the Company's liquidity.

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 2023, Amgen was named one of "America's Greatest Workplaces" by Newsweek, one of "America's Climate Leaders" by USA Today and one of the "World's Best Companies" by TIME.

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

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 Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), our acquisitions of Teneobio, Inc., ChemoCentryx, Inc., or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition, and any projected impacts from the Horizon acquisition on our acquisition-related expenses going forward), 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 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. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate Horizon, and such acquisition or integration may take longer, be more difficult or cost more than expected. 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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product sales	\$ 6,548	\$ 6,237	\$ 19,077	\$ 18,249
Other revenues	355	415	917	1,235
Total revenues	<u>6,903</u>	<u>6,652</u>	<u>19,994</u>	<u>19,484</u>
Operating expenses:				
Cost of sales	1,806	1,588	5,339	4,659
Research and development	1,079	1,112	3,250	3,110
Selling, general and administrative	1,353	1,287	3,905	3,842
Other	644	5	874	537
Total operating expenses	<u>4,882</u>	<u>3,992</u>	<u>13,368</u>	<u>12,148</u>
Operating income	2,021	2,660	6,626	7,336
Other income (expense):				
Interest expense, net	(759)	(368)	(2,054)	(991)
Other income (expense), net	685	100	2,431	(747)
Income before income taxes	1,947	2,392	7,003	5,598
Provision for income taxes	217	249	1,053	662
Net income	<u>\$ 1,730</u>	<u>\$ 2,143</u>	<u>\$ 5,950</u>	<u>\$ 4,936</u>
Earnings per share:				
Basic	\$ 3.23	\$ 4.01	\$ 11.12	\$ 9.16
Diluted	\$ 3.22	\$ 3.98	\$ 11.06	\$ 9.11
Weighted-average shares used in calculation of earnings per share:				
Basic	535	535	535	539
Diluted	538	538	538	542

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

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 34,741	\$ 9,305
Trade receivables, net	6,145	5,563
Inventories	5,026	4,930
Other current assets	2,565	2,388
Total current assets	<u>48,477</u>	<u>22,186</u>
Property, plant and equipment, net	5,563	5,427
Intangible assets, net	13,150	16,080
Goodwill	15,509	15,529
Other noncurrent assets	7,835	5,899
Total assets	<u>\$ 90,534</u>	<u>\$ 65,121</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 15,526	\$ 14,096
Current portion of long-term debt	1,428	1,591
Total current liabilities	<u>16,954</u>	<u>15,687</u>
Long-term debt	59,040	37,354
Long-term tax liabilities	4,579	5,757
Other noncurrent liabilities	2,305	2,662
Total stockholders' equity	7,656	3,661
Total liabilities and stockholders' equity	<u>\$ 90,534</u>	<u>\$ 65,121</u>
Shares outstanding	535	534

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
GAAP cost of sales	\$ 1,806	\$ 1,588	\$ 5,339	\$ 4,659
Adjustments to cost of sales:				
Acquisition-related expenses (a)	(668)	(585)	(2,008)	(1,779)
Certain net charges pursuant to our restructuring and cost savings initiatives	(1)	—	(36)	—
Total adjustments to cost of sales	(669)	(585)	(2,044)	(1,779)
Non-GAAP cost of sales	\$ 1,137	\$ 1,003	\$ 3,295	\$ 2,880
GAAP cost of sales as a percentage of product sales	27.6 %	25.5 %	28.0 %	25.5 %
Acquisition-related expenses (a)	(10.2)	(9.4)	(10.5)	(9.7)
Certain net charges pursuant to our restructuring and cost savings initiatives	0.0	0.0	(0.2)	0.0
Non-GAAP cost of sales as a percentage of product sales	17.4 %	16.1 %	17.3 %	15.8 %
GAAP research and development expenses	\$ 1,079	\$ 1,112	\$ 3,250	\$ 3,110
Adjustments to research and development expenses:				
Acquisition-related expenses (a)	(9)	(16)	(27)	(60)
Certain net charges pursuant to our restructuring and cost savings initiatives	—	—	(17)	—
Total adjustments to research and development expenses	(9)	(16)	(44)	(60)
Non-GAAP research and development expenses	\$ 1,070	\$ 1,096	\$ 3,206	\$ 3,050
GAAP research and development expenses as a percentage of product sales	16.5 %	17.8 %	17.0 %	17.0 %
Acquisition-related expenses (a)	(0.2)	(0.2)	(0.1)	(0.3)
Certain net charges pursuant to our restructuring and cost savings initiatives	0.0	0.0	(0.1)	0.0
Non-GAAP research and development expenses as a percentage of product sales	16.3 %	17.6 %	16.8 %	16.7 %
GAAP selling, general and administrative expenses	\$ 1,353	\$ 1,287	\$ 3,905	\$ 3,842
Adjustments to selling, general and administrative expenses:				
Acquisition-related expenses (a)	(47)	(11)	(138)	(40)
Certain net charges pursuant to our restructuring and cost savings initiatives	(13)	—	(13)	—
Total adjustments to selling, general and administrative expenses	(60)	(11)	(151)	(40)
Non-GAAP selling, general and administrative expenses	\$ 1,293	\$ 1,276	\$ 3,754	\$ 3,802
GAAP selling, general and administrative expenses as a percentage of product sales	20.7 %	20.6 %	20.5 %	21.1 %
Acquisition-related expenses (a)	(0.8)	(0.1)	(0.7)	(0.3)
Certain net charges pursuant to our restructuring and cost savings initiatives	(0.2)	0.0	(0.1)	0.0
Non-GAAP selling, general and administrative expenses as a percentage of product sales	19.7 %	20.5 %	19.7 %	20.8 %
GAAP operating expenses	\$ 4,882	\$ 3,992	\$ 13,368	\$ 12,148
Adjustments to operating expenses:				
Adjustments to cost of sales	(669)	(585)	(2,044)	(1,779)
Adjustments to research and development expenses	(9)	(16)	(44)	(60)
Adjustments to selling, general and administrative expenses	(60)	(11)	(151)	(40)
Certain net charges pursuant to our restructuring and cost savings initiatives (b)	(16)	8	(183)	7
Certain other expenses (c)	(628)	(13)	(691)	(544)
Total adjustments to operating expenses	(1,382)	(617)	(3,113)	(2,416)
Non-GAAP operating expenses	\$ 3,500	\$ 3,375	\$ 10,255	\$ 9,732

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
GAAP operating income	\$ 2,021	\$ 2,660	\$ 6,626	\$ 7,336
Adjustments to operating expenses	1,382	617	3,113	2,416
Non-GAAP operating income	\$ 3,403	\$ 3,277	\$ 9,739	\$ 9,752
GAAP operating income as a percentage of product sales	30.9 %	42.6 %	34.7 %	40.2 %
Adjustments to cost of sales	10.2	9.4	10.7	9.7
Adjustments to research and development expenses	0.2	0.2	0.2	0.3
Adjustments to selling, general and administrative expenses	1.0	0.1	0.8	0.3
Certain net charges pursuant to our restructuring and cost savings initiatives (b)	0.2	0.0	1.0	0.0
Certain other expenses (c)	9.5	0.2	3.7	2.9
Non-GAAP operating income as a percentage of product sales	52.0 %	52.5 %	51.1 %	53.4 %
GAAP interest expense, net	\$ (759)	\$ (368)	\$ (2,054)	\$ (991)
Adjustments to interest expense, net:				
Interest expense on acquisition-related debt (d)	332	—	788	—
Non-GAAP interest expense, net	\$ (427)	\$ (368)	\$ (1,266)	\$ (991)
GAAP other income (expense), net	\$ 685	\$ 100	\$ 2,431	\$ (747)
Adjustments to other income (expense), net				
Interest income and other expenses on acquisition-related debt (d)	(313)	—	(607)	—
Equity method investment basis difference amortization	—	47	—	143
Net (gains)/losses from equity investments (e)	(170)	(150)	(1,305)	401
Total adjustments to other income (expense), net	(483)	(103)	(1,912)	544
Non-GAAP other income (expense), net	\$ 202	\$ (3)	\$ 519	\$ (203)
GAAP income before income taxes	\$ 1,947	\$ 2,392	\$ 7,003	\$ 5,598
Adjustments to income before income taxes:				
Adjustments to operating expenses	1,382	617	3,113	2,416
Adjustments to interest expense, net	332	—	788	—
Adjustments to other income (expense), net	(483)	(103)	(1,912)	544
Total adjustments to income before income taxes	1,231	514	1,989	2,960
Non-GAAP income before income taxes	\$ 3,178	\$ 2,906	\$ 8,992	\$ 8,558
GAAP provision for income taxes	\$ 217	\$ 249	\$ 1,053	\$ 662
Adjustments to provision for income taxes:				
Income tax effect of the above adjustments (f)	271	122	442	527
Other income tax adjustments (g)	23	5	6	1
Total adjustments to provision for income taxes	294	127	448	528
Non-GAAP provision for income taxes	\$ 511	\$ 376	\$ 1,501	\$ 1,190
GAAP tax as a percentage of income before taxes	11.1 %	10.4 %	15.0 %	11.8 %
Adjustments to provision for income taxes:				
Income tax effect of the above adjustments (f)	4.2	2.3	1.6	2.1
Other income tax adjustments (g)	0.8	0.2	0.1	0.0
Total adjustments to provision for income taxes	5.0	2.5	1.7	2.1
Non-GAAP tax as a percentage of income before taxes	16.1 %	12.9 %	16.7 %	13.9 %
GAAP net income	\$ 1,730	\$ 2,143	\$ 5,950	\$ 4,936
Adjustments to net income:				
Adjustments to income before income taxes, net of the income tax effect	960	392	1,547	2,433
Other income tax adjustments (g)	(23)	(5)	(6)	(1)
Total adjustments to net income	937	387	1,541	2,432
Non-GAAP net income	\$ 2,667	\$ 2,530	\$ 7,491	\$ 7,368

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 September 30, 2023		Three months ended September 30, 2022	
	GAAP	Non-GAAP	GAAP	Non-GAAP
Net income	\$ 1,730	\$ 2,667	\$ 2,143	\$ 2,530
Weighted-average shares for diluted EPS	538	538	538	538
Diluted EPS	\$ 3.22	\$ 4.96	\$ 3.98	\$ 4.70
	Nine months ended September 30, 2023		Nine months ended September 30, 2022	
	GAAP	Non-GAAP	GAAP	Non-GAAP
Net income	\$ 5,950	\$ 7,491	\$ 4,936	\$ 7,368
Weighted-average shares for diluted EPS	538	538	542	542
Diluted EPS	\$ 11.06	\$ 13.92	\$ 9.11	\$ 13.59

- (a) The adjustments related primarily to noncash amortization of intangible assets from business acquisitions.
- (b) For the three and nine months ended September 30, 2023, the adjustments related primarily to separation costs associated with our restructuring plan initiated in early 2023.
- (c) For the three and nine months ended September 30, 2023, the adjustments related primarily to a net impairment charge for AMG 340. For the three months ended September 30, 2022, the adjustments related primarily to an impairment charge associated with an in-process research and development asset. For the nine months ended September 30, 2022, the adjustments related primarily to cumulative foreign currency translation adjustments from the divestiture of Gensenta.
- (d) For the three and nine months ended September 30, 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 acquisition of Horizon Therapeutics plc.
- (e) For the nine months ended September 30, 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 and certain gains and losses on our investments in equity securities, 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 and nine months ended September 30, 2023, were 22.0% and 22.2%, respectively, compared to 23.7% and 17.8% for the corresponding periods 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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net cash provided by operating activities	\$ 2,760	\$ 2,978	\$ 7,933	\$ 7,072
Net cash (used in) provided by investing activities	(262)	(267)	885	(2,571)
Net cash (used in) provided by financing activities	(2,005)	1,588	18,294	(2,988)
Increase in cash and cash equivalents	493	4,299	27,112	1,513
Cash and cash equivalents at beginning of period	34,248	5,203	7,629	7,989
Cash and cash equivalents at end of period	\$ 34,741	\$ 9,502	\$ 34,741	\$ 9,502

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net cash provided by operating activities	\$ 2,760	\$ 2,978	\$ 7,933	\$ 7,072
Capital expenditures	(248)	(160)	(863)	(596)
Free cash flow	\$ 2,512	\$ 2,818	\$ 7,070	\$ 6,476

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

GAAP diluted EPS guidance	\$	11.23	—	\$	12.73
Known adjustments to arrive at non-GAAP*:					
Acquisition-related expenses (a)		7.60	—		8.35
Net charges related to restructuring and cost savings initiatives		0.38	—		0.53
Net (gains)/losses from equity investments			(1.90)		
Other			(0.01)		
Non-GAAP diluted EPS guidance	\$	18.20	—	\$	18.80

* The known adjustments are presented net of their related tax impact, which amount to approximately \$1.50 - \$1.69 per share.

(a) The adjustments include noncash amortization of intangible assets and fair value step-up of inventory acquired in business combinations and the net impairment charge for AMG 340, as well as transaction, integration and employee-related costs. Adjustments above include a preliminary range for the projected impact from the October 6, 2023 Horizon Therapeutics plc (Horizon) acquisition to be recognized in the fourth quarter of 2023. The initial accounting for the Horizon acquisition is incomplete, pending identification and measurement of assets acquired and liabilities assumed, and as a result this preliminary projected range of adjustments related to this acquisition is subject to change.

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 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	14.0 %	—	15.5 %
Tax rate of known adjustments discussed above	1.5 %	—	2.5 %
Non-GAAP tax rate guidance	16.5 %	—	17.0 %