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)
November 2, 2021

Amgen Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37702**	**95-3540776**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
One Amgen Center Drive **Thousand Oaks** **California**		**91320-1799**
(Address of principal executive offices)		(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**
1.250% Senior Notes due 2022	**AMGN22**	**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.

On November 2, 2021, Amgen Inc. (the Company) issued a press release announcing its unaudited results of operations for the three and nine months ended September 30, 2021, and its unaudited financial position as of September 30, 2021. 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 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 also 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. The Company incurs charges related to these items, and those charges are included in the Company's Condensed Consolidated Financial Statements. 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.
- Licensing-related expenses: Licensing-related charges primarily related to an upfront payment made in connection with the entry into a license and collaboration agreement. Charges from such agreements are significantly impacted by the timing and magnitude of these arrangements and potential regulatory related events and milestones as they relate to in-process R&D projects. 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.
- Net charges pursuant to the Company's costs savings initiatives: Costs from cost savings initiatives are primarily related to facilities charges, including 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.
- Other items: The Company adjusts GAAP financial results for certain income and expenses (or gains and losses). These adjustments include certain items from investment transactions, including amortization and impairments from the basis difference that arises from certain equity method investments and certain gains and losses on our investments in equity securities that are recorded to other income and expense. Further, the Company also adjusts GAAP financial results for certain items associated with judgments and/or settlements for legal proceedings discussed in our filings. 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, whereas the tax impact of other adjustments, including expenses related to 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, including, effective January 1, 2021, we began to exclude the gains and losses on our investments in equity securities from our non-GAAP measures that are recorded to other income and expense. This exclusion does not apply to our share of the earnings and losses of our strategic investments in corporations accounted for under the equity method of accounting, such as our investment in BeiGene. The Company began excluding gains and losses from equity investments for the purpose of calculating the non-GAAP financial measures presented because the Company believes the results of such gains and losses are not representative of our normal business operations. We made this change in 2021 because, as we have increased our investments in these companies, we recognized that the resulting variability can impede comparability between periods of our financial performance for our ongoing business operations. For comparability of results to the prior year, non-GAAP net income and non-GAAP EPS amounts for 2020 have also been revised to reflect this update to our non-GAAP policy.

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 November 2, 2021
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: November 2, 2021

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 2021 FINANCIAL RESULTS

THOUSAND OAKS, Calif. (November 2, 2021) - Amgen (NASDAQ:AMGN) today announced financial results for the third quarter of 2021. Key results include:

- Total revenues increased 4% to $6.7 billion in comparison to the third quarter of 2020, driven by higher unit demand, partially offset by lower net selling prices.
  - Product sales increased 4% globally, driven by double-digit volume growth across a number of our products, including Prolia® (denosumab), EVENITY® (romosozumab-aqqg), Repatha® (evolocumab) and MVASI® (bevacizumab-awwb).
- GAAP earnings per share (EPS) decreased 3% to $3.31 driven by a $400 million licensing-related expense from our collaboration with Kyowa Kirin Co., Ltd. (Kyowa Kirin), partially offset by increased revenues.
  - GAAP operating income decreased 3% to $2.4 billion, and GAAP operating margin decreased 2.6 percentage points to 37.6%.
- Non-GAAP EPS increased 11% to $4.67 driven by increased revenues and the impact of fewer weighted average shares outstanding. Total non-GAAP operating expenses increased less than 1%.
  - Non-GAAP operating income increased 8% to $3.5 billion, and non-GAAP operating margin increased 2.5 percentage points to 54.6%.
- The Company generated $2.2 billion of free cash flow in the third quarter versus $3.2 billion in the third quarter of 2020, driven by higher collections in the third quarter of 2020 from customers who had been granted extended payment terms due to COVID-19. This increase was partially offset by the timing of tax payments in the third quarter of 2020.
- 2021 total revenues guidance of $25.8-$26.2 billion; EPS guidance of $9.55-$10.21 on a GAAP basis and $16.50-$17.10 on a non-GAAP basis.

"Our newest product, LUMAKRAS®, a first-in-class lung cancer treatment, is off to a strong start and our robust pipeline of potential new medicines across all stages of development sets us up well to drive growth over the long term," said Robert A. Bradway, chairman and chief executive officer. "We achieved solid growth in the quarter as our medicines reached an increasing number of patients around the world."

$Millions, except EPS, dividends paid per share and percentages	Q3 '21	Q3 '20	YOY Δ
Total Revenues	$ 6,706	$ 6,423	4%
GAAP Operating Income	$ 2,378	$ 2,453	(3%)
GAAP Net Income	$ 1,884	$ 2,021	(7%)
GAAP EPS	$ 3.31	$ 3.43	(3%)
Non-GAAP Operating Income	$ 3,452	$ 3,183	8%
Non-GAAP Net Income	$ 2,664	$ 2,467	8%
Non-GAAP EPS	$ 4.67	$ 4.19	11%
Dividends Paid Per Share	$ 1.76	$ 1.60	10%

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

Product Sales Performance

Total product sales increased 4% for the third quarter of 2021 versus the third quarter of 2020. Unit volumes grew 8% while net selling price declined 7%. In addition, this quarter includes $147 million of favorable changes to estimated sales deductions related to prior periods. In the third quarter last year, the favorable estimated sales deductions were $36 million, resulting in a $111 million year-over-year benefit in this quarter.

We continue to see gradual recovery from the impact of the COVID-19 pandemic. As we progressed through the third quarter, we saw improvement in patient visits and diagnoses. Healthcare professional activity also improved during the first half of 2021 and stabilized during the third quarter. Overall, the gap in diagnosis visits over the course of the pandemic has suppressed the number of new patients starting treatment, which we expect will continue to impact our business for the remainder of the year.

General Medicine

- **Prolia** sales increased 15% year-over-year for the third quarter, driven by 13% volume growth. New and repeat patient visits continued to improve as osteoporosis diagnosis rates in the U.S. reached over 90% of pre-COVID levels during the quarter.
- **EVENITY** sales increased 153% year-over-year to a record $149 million for the third quarter, primarily driven by 118% volume growth. U.S. sales grew 74% year-over-year, driven by 65% volume growth as we continued to focus on increasing the number of new patients starting treatment. Outside the U.S., year-over-year volume growth was strong, amplified by inventory drawdowns by our partner Astellas during the third quarter of 2020.
- **Repatha** sales increased 33% year-over-year for the third quarter, primarily driven by 42% volume growth partially offset by lower net selling price. In the U.S., volumes grew 64% year-over-year, and outside the U.S., volumes grew 24% year-over-year. Volume growth in the quarter was partially offset by lower net selling price, primarily as a result of an increase in the number of U.S. Medicare Part D patients receiving Repatha and entering the coverage gap, the so-called "donut hole." The impact of the donut hole is more pronounced in the second half of the year as patients reach their plan deductibles.

- **Aimovig® (erenumab-aooe)** sales decreased 25% year-over-year for the third quarter, driven by lower net selling price.

Inflammation

- **Otezla® (apremilast)** sales increased 13% year-over-year for the third quarter. Volume grew 7% partially offset by lower net selling price. Sales in the quarter benefited from an $18 million favorable adjustment to estimated sales deductions, compared to a $24 million unfavorable adjustment in the third quarter last year, resulting in an 8% year-over-year benefit. In the U.S., Otezla continued to maintain first-line share leadership in psoriasis. Looking forward, we are preparing for the anticipated U.S. approval of the mild-to-moderate psoriasis indication.
- **Enbrel® (etanercept)** sales decreased 3% year-over-year for the third quarter, driven by declines in volume, inventory and net selling price. Sales in the quarter benefited from a $114 million favorable adjustment to estimated sales deductions, compared to a $84 million favorable adjustment in the third quarter last year, resulting in a 2% year-over-year benefit. Year-over-year volume declined by 2%, representing the second consecutive quarter of slowing volume declines. We expect the trend of year-over-year net selling price declines to continue.
- **AMGEVITA™ (adalimumab)** sales increased 39% year-over-year for the third quarter, driven by 73% volume growth partially offset by lower net selling price. AMGEVITA continues to be the most prescribed adalimumab biosimilar in Europe.

Hematology-Oncology

- **LUMAKRAS®/LUMYKRAS™ (sotorasib)** generated $36 million of sales in the quarter and cumulative sales of $45 million through the end of the third quarter. LUMAKRAS has been prescribed by over 500 physicians in both academic and community settings. A majority of the top clinical laboratories have now updated their reports to reflect *KRAS* G12C as an actionable mutation and ~75% of patients with NSCLC are now being tested by their oncologists at diagnosis for the *KRAS* G12C mutation.
- **KYPROLIS® (carfilzomib)** sales increased 13% year-over-year for the third quarter, driven by 10% volume growth supported by physician adoption of KYPROLIS use in combination with DARZALEX® (daratumumab) plus dexamethasone (DKd).
- **XGEVA® (denosumab)** sales increased 7% year-over-year for the third quarter, driven by 9% volume growth partially offset by lower net selling price.
- **Vectibix® (panitumumab)** sales increased 4% year-over-year for the third quarter, driven by 8% volume growth as Vectibix remains the EGFR inhibitor of choice across all lines of therapy.
- **Nplate® (romiplostim)** sales increased 29% year-over-year for the third quarter, primarily driven by 14% volume growth.
- **BLINCYTO® (blinatumomab)** sales increased 40% year-over-year for the third quarter, primarily driven by 30% volume growth as we continue to see broad adoption in the community hospital setting.
- **MVASI** sales increased 19% year-over-year for the third quarter, driven by 54% volume growth partially offset by lower net selling price. In the U.S., MVASI continues to hold leading volume share with 49% of the bevacizumab segment in the quarter. We expect that continued worldwide volume growth from MVASI will be offset by declines in net selling price due to increased competition.

- **KANJINTI® (trastuzumab-anns)** sales decreased 31% year-over-year for the third quarter, driven by lower net selling price, partially offset by 18% volume growth. In the U.S., KANJINTI continues to hold leading volume share with 41% of the trastuzumab segment in the quarter. We expect net selling price to continue to decline as a result of increased competition.

Established Products

- Total sales of our established products, which include **Neulasta® (pegfilgrastim), NEUPOGEN® (filgrastim)**, **EPOGEN® (epoetin alfa)**, **Aranesp® (darbepotein alfa)**, **Parsabiv® (etelcalcetide),** and **Sensipar®/Mimpara™ (cinacalcet)**, decreased 21% year-over-year for the third quarter, primarily driven by volume declines and lower net selling price. Going forward, we expect increased competition to result in additional net price and volume erosion across this portfolio of products.

Product Sales Detail by Product and Geographic Region

$Millions, except percentages	Q3 '21			Q3 '20	YOY Δ
	US	ROW	TOTAL	TOTAL	TOTAL
Prolia®	$ 530	$ 273	$ 803	$ 701	15%
EVENITY®	94	55	149	59	*
Repatha®	139	133	272	205	33%
Aimovig®	77	2	79	105	(25%)
Otezla®	495	114	609	538	13%
Enbrel®	1,263	26	1,289	1,325	(3%)
AMGEVITA™	—	111	111	80	39%
LUMAKRAS®/LUMYKRAS™	33	3	36	—	*
KYPROLIS®	198	95	293	260	13%
XGEVA®	372	145	517	481	7%
Vectibix®	84	116	200	193	4%
Nplate®	156	117	273	212	29%
BLINCYTO®	74	51	125	89	40%
MVASI®	187	87	274	231	19%
KANJINTI®	92	24	116	167	(31%)
Neulasta®	360	55	415	555	(25%)
NEUPOGEN®	32	20	52	65	(20%)
EPOGEN®	138	—	138	149	(7%)
Aranesp®	149	247	396	384	3%
Parsabiv®	24	37	61	183	(67%)
Sensipar®/Mimpara™	—	19	19	39	(51%)
Other products**	61	32	93	83	12%
Total product sales	$ 4,558	$ 1,762	$ 6,320	$ 6,104	4%

* Change in excess of 100%

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

Operating Expense, Operating Margin and Tax Rate Analysis

On a GAAP basis:

- **Total Operating Expenses** increased 9% primarily driven by a licensing-related expense from our recent collaboration with Kyowa Kirin. **Cost of Sales** margin decreased 0.1 percentage points primarily due to lower amortization expense from acquisition-related assets, offset by product mix. **Research & Development (R&D)** expenses increased 34% primarily due to a licensing-related expense from our collaboration with Kyowa Kirin, partially offset by lower late-stage program support. **Selling, General & Administrative (SG&A)** expenses decreased 3%.
- **Operating Margin** as a percentage of product sales decreased 2.6 percentage points to 37.6%.
- **Tax Rate** increased 4.2 percentage points primarily driven by the non-deductible acquired IPR&D expense arising from the acquisition of Five Prime Therapeutics.

On a non-GAAP basis:

- **Total Operating Expenses** increased less than 1%. **Cost of Sales** margin increased 1.5 percentage points primarily due to product mix, including COVID-19 antibody shipments to Lilly that began last quarter. **R&D** expenses decreased 4% primarily due to lower late-stage program support. **SG&A** expenses decreased 5%.
- **Operating Margin** as a percentage of product sales increased 2.5 percentage points to 54.6%.
- **Tax Rate** increased 0.5 percentage points primarily driven by a prior year favorable item partially offset by a change in earnings mix.

$Millions, except percentages	GAAP			Non-GAAP		
	Q3 '21	**Q3 '20**	**YOY Δ**	**Q3 '21**	**Q3 '20**	**YOY Δ**
Cost of Sales	$ 1,609	$ 1,561	3%	$ 997	$ 874	14%
% of product sales	25.5 %	25.6 %	(0.1) pts.	15.8 %	14.3 %	1.5 pts.
Research & Development	$ 1,422	$ 1,062	34%	$ 997	$ 1,037	(4%)
% of product sales	22.5 %	17.4 %	5.1 pts.	15.8 %	17.0 %	(1.2) pts.
Selling, General & Administrative	$ 1,305	$ 1,346	(3%)	$ 1,260	$ 1,329	(5%)
% of product sales	20.6 %	22.1 %	(1.5) pts.	19.9 %	21.8 %	(1.9) pts.
Other	$ (8)	$ 1	*	$ —	$ —	—%
Total Operating Expenses	**$ 4,328**	**$ 3,970**	**9%**	**$ 3,254**	**$ 3,240**	**—%**
Operating Margin						
operating income as % of product sales	37.6 %	40.2 %	(2.6) pts.	54.6 %	52.1 %	2.5 pts.
Tax Rate	**12.6 %**	**8.4 %**	**4.2 pts.**	**13.6 %**	**13.1 %**	**0.5 pts.**

pts: percentage points
* Change in excess of 100%

Cash Flow and Balance Sheet

- The Company generated $2.2 billion of free cash flow in the third quarter of 2021 versus $3.2 billion in the third quarter of 2020, driven by higher collections in the third quarter of 2020 from customers who had been granted extended payment terms due to COVID-19. This increase was partially offset by the timing of tax payments in the third quarter of 2020.

- The Company's third quarter 2021 dividend of $1.76 per share was declared on July 30, 2021, and was paid on September 8, 2021, to all stockholders of record as of August 17, 2021, representing a 10% increase from 2020.
- During the third quarter, the Company repurchased 4.6 million shares of common stock at a total cost of $1.1 billion. At the end of the third quarter, the Company had $2.9 billion authorization remaining under its stock repurchase program. In October 2021, the Board of Directors increased the amount authorized under our stock repurchase program by an additional $4.5 billion.
- Cash and investments totaled $12.9 billion and debt outstanding totaled $37.6 billion as of September 30, 2021.

$Billions, except shares	Q3 '21	Q3 '20	YOY Δ
Operating Cash Flow	$ 2.4	$ 3.4	$ (1.0)
Capital Expenditures	$ 0.2	$ 0.1	$ 0.1
Free Cash Flow	$ 2.2	$ 3.2	$ (1.1)
Dividends Paid	$ 1.0	$ 0.9	$ 0.1
Share Repurchases	$ 1.1	$ 0.8	$ 0.3
Average Diluted Shares (millions)	570	589	(19)

Note: Numbers may not add due to rounding

$Billions	9/30/21	12/31/20	YTD Δ
Cash and Investments	$ 12.9	$ 10.6	$ 2.3
Debt Outstanding	$ 37.6	$ 33.0	$ 4.6

Note: Numbers may not add due to rounding

2021 Guidance

For the full year 2021, the Company now expects:

- **Total revenues** in the range of $25.8 billion to $26.2 billion.
- On a **GAAP basis, EPS** in the range of $9.55 to $10.21 and a **tax rate** in the range of 12.5% to 14.0%.
- On a **non-GAAP basis, EPS** in the range of $16.50 to $17.10 and a **tax rate** in the range of 13.0% to 14.0%.
- **Capital expenditures** to be approximately $900 million.
- **Share repurchases** at the upper end of $3.0 billion to $5.0 billion range.

Third Quarter Product and Pipeline Update

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

LUMAKRAS/LUMYKRAS

- In September, marketing authorizations were granted for LUMYKRAS in Great Britain and LUMAKRAS in Canada for the treatment of second-line patients with *KRAS* G12C-mutated, advanced non-small cell lung cancer (NSCLC). Regulatory reviews continue in Europe, Japan and other jurisdictions.
- In September, data from LUMAKRAS in combination with Vectibix in patients with advanced *KRAS* G12C-mutated colorectal cancer (CRC) were presented at the European Society for Medical Oncology Congress. A Phase 3 study of LUMAKRAS in combination with Vectibix in third-line colorectal cancer is expected to initiate in Q4 2021.
- In September, data from the Phase 1/2 CodeBreaK 100 monotherapy study in advanced *KRAS* G12C-mutated NSCLC, including biomarker analyses and post hoc analyses of efficacy and safety in patients with stable brain metastases, were presented at the World Conference on Lung Cancer. Enrollment continues in a cohort of patients with active brain metastases in the CodeBreaK 101 study.
- In October, data from cohorts exploring LUMAKRAS in combination with trematinib, a mitogen-activated protein kinase kinase inhibitor, and LUMAKRAS in combination with afatinib, an oral epidermal growth factor receptor inhibitor, were presented at the AACR-NCI-EORTC 2021 Virtual International Conference on Molecular Targets and Cancer Therapeutics.
- A Phase 2 study has initiated in first-line patients with *KRAS* G12C-mutated NSCLC whose tumors express serine/threonine kinase 11 (STK11) mutations and/or less than 1% programmed death-ligand 1.
- Top-line results from the event-driven, confirmatory Phase 3 study comparing LUMAKRAS to docetaxel in patients with *KRAS* G12C-mutated advanced NSCLC are expected in H1 2022.
- Top-line results from the Phase 2 monotherapy study in patients with *KRAS* G12C-mutated solid tumors other than NSCLC and CRC are expected in H1 2022.
- Initial data from cohorts exploring LUMAKRAS in combination with the anti-programmed cell death 1 (PD-1) antibody pembrolizumab and LUMAKRAS in combination with the Src homology-2 domain-containing protein tyrosine phosphatase-2 (SHP2) inhibitor RMC-4630 from Revolution Medicines are expected to be presented in H1 2022.

BLINCYTO

- A Phase 3 study of BLINCYTO alternating with low-intensity chemotherapy versus standard of care for older adults with newly diagnosed Philadelphia-negative B-cell precursor acute lymphoblastic leukemia has initiated.

Bemarituzumab

- The Phase 3 program has initiated for bemarituzumab, a fibroblast growth factor receptor 2b antibody, in first-line advanced gastric and gastroesophageal junction adenocarcinoma. The program will explore bemarituzumab in combination with either backbone chemotherapy or chemotherapy plus a checkpoint inhibitor.
- A Phase 1b signal-seeking study of bemarituzumab alone and in combination with chemotherapy for the treatment of advanced, refractory, squamous NSCLC is expected to initiate by Q1 2022. Planning is underway for signal-seeking studies in other solid tumors.

Acapatamab (AMG 160)

- Data continue to mature in a dose-expansion cohort of acapatamab, a half-life extended (HLE) BiTE® molecule targeting prostate-specific membrane antigen (PSMA) for the treatment of patients with metastatic castrate-resistant prostate cancer (mCRPC). Enrollment of acapatamab is ongoing in cohorts with reduced levels of monitoring during cycle one to explore outpatient administration.
- An acapatamab dose-escalation study is enrolling patients with NSCLC tumors expressing PSMA.
- A master protocol evaluating combinations of acapatamab with AMG 404, an anti-PD-1 antibody, or the novel hormone therapies enzalutamide or abiraterone, continues to enroll patients with earlier-line mCRPC.

AMG 340 (formerly TNB-585)

- A Phase 1 dose-escalation study of AMG 340, a UniAb® bispecific T-cell engager targeting PSMA, is enrolling patients with mCRPC.

Tarlatamab (AMG 757)

- Initiation of a potentially pivotal Phase 2 study for tarlatamab, an HLE BiTE® molecule targeting delta-like ligand 3 (DLL3), in patients with relapsed or refractory small cell lung cancer (SCLC) is planned for Q4 2021.
- A Phase 1b dose-expansion cohort of tarlatamab in patients with SCLC is ongoing.
- A Phase 1b study of tarlatamab continues to enroll patients with neuroendocrine prostate cancer.
- A Phase 1b study of tarlatamab in combination with AMG 404 has initiated for patients with SCLC.

Tezepelumab

- Tezepelumab, a thymic stromal lymphopoietin (TSLP) antibody, is under Priority Review by the U.S. Food and Drug Administration (FDA) for severe asthma with a Prescription Drug User Fee Act (PDUFA) target date in Q1 2022. Regulatory reviews are also underway in the EU, Japan, and other jurisdictions.
- A Phase 3 study continues to enroll patients with chronic rhinosinusitis with nasal polyps.
- A Phase 2b study continues to enroll patients with chronic spontaneous urticaria.
- A Phase 2 study continues to enroll patients with chronic obstructive pulmonary disease.
- Tezepelumab was granted Orphan Drug Designation by the FDA for the treatment of eosinophilic esophagitis.

Otezla

- The FDA review of Otezla for the treatment of adults with mild-to-moderate plaque psoriasis continues to progress, with a PDUFA target action date of December 19, 2021.
- In August, China’s National Medical Products Administration approved Otezla for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- Phase 3 initiation for the treatment of Japanese patients with palmoplantar pustulosis is expected to begin in H1 2022.

AMG 451 / KHK4083

- In October, positive results from the Phase 2b study of AMG 451, an anti-OX40 monoclonal antibody for the treatment of atopic dermatitis, were presented at the European Academy of

Dermatology and Venereology 30th Virtual Congress. Phase 3 development is expected to begin in H1 2022.

- Biomarker analyses from the Phase 2 atopic dermatitis study will be presented at the Inflammatory Skin Disease Summit on November 4, 2021.

Rozibafusp alfa (AMG 570)

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

Efavaleukin alfa (AMG 592)

- A Phase 2b study of efavaleukin alfa, an interleukin-2 mutein Fc fusion protein, continues to enroll patients with SLE.
- Data from a Phase 1b study in patients with SLE will be presented at the American College of Rheumatology Convergence 2021 on November 9, 2021.
- A Phase 2 study of efavaleukin alfa in patients with ulcerative colitis has initiated.

AMG 714 / PRV-015

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

Repatha

- In September, the FDA approved Repatha as an adjunct to diet and other low-density lipoprotein cholesterol (LDL-C)-lowering therapies for the treatment of pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) to reduce LDL-C. The FDA also expanded the homozygous familial hypercholesterolemia (HoFH) indication to patients aged 10 years and older.
- In October, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency adopted a positive opinion recommending an update to the Marketing Authorization for Repatha for the treatment of pediatric patients aged 10 years and older with HeFH, and the expansion of treatment for pediatric HoFH patients aged 10 years and older.
- A Phase 3 cardiovascular outcomes study (VESALIUS-CV) continues to enroll patients at high cardiovascular risk without prior myocardial infarction or stroke.

Olpasiran (AMG 890)

- Results from a Phase 2 study of olpasiran, a lipoprotein(a) (Lp(a)) small interfering RNA molecule, in patients with elevated Lp(a) are expected in H1 2022 with publication expected in H2 2022.

Biosimilars

- A Phase 3 study of ABP 938, an investigational biosimilar to EYLEA® (aflibercept) continues to enroll patients, with data expected in 2022.
- Phase 3 studies of ABP 654, an investigational biosimilar to STELARA® (ustekinumab), and ABP 959, an investigational biosimilar to SOLIRIS® (eculizumab), are ongoing, with data expected in 2022.
- Phase 3 studies to support an interchangeability designation in the U.S. for ABP 654 and AMJEVITA™ (adalimumab-atto) are enrolling patients.

Amgenpipeline.com

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

Tezepelumab is being developed in collaboration with AstraZeneca

AMG 451 (also known as KHK4083) is being developed in collaboration with Kyowa Kirin

AMG 714 (also known as PRV-015) is being developed in collaboration with Provention Bio

DARZALEX® and STELARA® are a registered trademarks of Janssen Pharmaceutica NV

EYLEA® is a registered trademark of Regeneron Pharmaceuticals, Inc.

SOLIRIS® is a registered trademark of Alexion Pharmaceuticals, Inc.

Non-GAAP Financial Measures

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

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

Beginning January 1, 2021, we began to exclude the gains and losses on our investments in equity securities from our non-GAAP measures that are recorded to Other income (expense). This exclusion will not apply to our share of the earnings and losses of our strategic investments in corporations accounted for under the equity method of accounting, such as our investment in BeiGene. The Company will be excluding gains and losses from equity investments for the purpose of calculating the non-GAAP financial measures presented because the Company believes the results of such gains and losses are not representative of our normal business operations. We are making this change beginning in 2021 because, as we have increased our investments in these companies, we recognized that the resulting variability can impede comparability between periods of our financial performance for our ongoing business operations. For comparability of results to the prior year, non-GAAP net income and non-GAAP EPS amounts for 2020 have been revised to reflect the update to our non-GAAP policy that excludes gains and losses on certain equity investments.

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

About Amgen

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

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

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

Forward-Looking Statements

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

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical

devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product sales	$ 6,320	$ 6,104	$ 18,026	$ 17,906
Other revenues	386	319	1,107	884
Total revenues	6,706	6,423	19,133	18,790
Operating expenses:				
Cost of sales	1,609	1,561	4,736	4,562
Research and development	1,422	1,062	3,471	2,978
Acquired in-process research and development	—	—	1,505	—
Selling, general and administrative	1,305	1,346	3,943	3,957
Other	(8)	1	143	162
Total operating expenses	4,328	3,970	13,798	11,659
Operating income	2,378	2,453	5,335	7,131
Other income (expense):				
Interest expense, net	(296)	(302)	(862)	(944)
Other income, net	73	55	97	69
Income before income taxes	2,155	2,206	4,570	6,256
Provision for income taxes	271	185	576	607
Net income	$ 1,884	$ 2,021	$ 3,994	$ 5,649
Earnings per share:				
Basic	$ 3.32	$ 3.45	$ 6.98	$ 9.61
Diluted	$ 3.31	$ 3.43	$ 6.93	$ 9.54
Weighted-average shares used in calculation of earnings per share:				
Basic	567	585	572	588
Diluted	570	589	576	592

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 12,921	$ 10,647
Trade receivables, net	4,765	4,525
Inventories	4,152	3,893
Other current assets	2,542	2,079
Total current assets	24,380	21,144
Property, plant and equipment, net	4,982	4,889
Intangible assets, net	14,659	16,587
Goodwill	14,665	14,689
Other noncurrent assets	6,307	5,639
Total assets	$ 64,993	$ 62,948
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 10,554	$ 11,562
Current portion of long-term debt	4,288	91
Total current liabilities	14,842	11,653
Long-term debt	33,291	32,895
Long-term tax liabilities	6,483	6,968
Other noncurrent liabilities	2,160	2,023
Total stockholders’ equity	8,217	9,409
Total liabilities and stockholders’ equity	$ 64,993	$ 62,948
Shares outstanding	565	578

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020*	2021	2020*
GAAP cost of sales	$ 1,609	$ 1,561	$ 4,736	$ 4,562
Adjustments to cost of sales:				
Acquisition-related expenses (a)	(606)	(687)	(1,827)	(2,159)
Other	(6)	—	(11)	—
Total adjustments to cost of sales	(612)	(687)	(1,838)	(2,159)
Non-GAAP cost of sales	$ 997	$ 874	$ 2,898	$ 2,403
GAAP cost of sales as a percentage of product sales	25.5 %	25.6 %	26.3 %	25.5 %
Acquisition-related expenses (a)	(9.6)	(11.3)	(10.1)	(12.1)
Other	(0.1)	0.0	(0.1)	0.0
Non-GAAP cost of sales as a percentage of product sales	15.8 %	14.3 %	16.1 %	13.4 %
GAAP research and development expenses	$ 1,422	$ 1,062	$ 3,471	$ 2,978
Adjustments to research and development expenses:				
Licensing- and acquisition-related expenses (b)	(425)	(24)	(494)	(77)
Certain net charges pursuant to our cost savings initiatives	—	(1)	—	(1)
Total adjustments to research and development expenses	(425)	(25)	(494)	(78)
Non-GAAP research and development expenses	$ 997	$ 1,037	$ 2,977	$ 2,900
GAAP research and development expenses as a percentage of product sales	22.5 %	17.4 %	19.3 %	16.6 %
Licensing- and acquisition-related expenses (b)	(6.7)	(0.4)	(2.8)	(0.4)
Certain net charges pursuant to our cost savings initiatives	0.0	0.0	0.0	0.0
Non-GAAP research and development expenses as a percentage of product sales	15.8 %	17.0 %	16.5 %	16.2 %
GAAP acquired IPR&D	$ —	$ —	$ 1,505	$ —
Adjustments to acquired IPR&D:				
Five Prime acquisition IPR&D expense	—	—	(1,505)	—
Non-GAAP acquired IPR&D	$ —	$ —	$ —	$ —
GAAP acquired IPR&D expenses as a percentage of product sales	— %	— %	8.3 %	— %
Five Prime acquisition IPR&D expense	0.0	0.0	(8.3)	0.0
Non-GAAP acquired IPR&D expenses as a percentage of product sales	— %	— %	— %	— %
GAAP selling, general and administrative expenses	$ 1,305	$ 1,346	$ 3,943	$ 3,957
Adjustments to selling, general and administrative expenses:				
Acquisition-related expenses (a)	(16)	(15)	(67)	(74)
Other	(29)	(2)	(45)	(2)
Total adjustments to selling, general and administrative expenses	(45)	(17)	(112)	(76)
Non-GAAP selling, general and administrative expenses	$ 1,260	$ 1,329	$ 3,831	$ 3,881
GAAP selling, general and administrative expenses as a percentage of product sales	20.6 %	22.1 %	21.9 %	22.1 %
Acquisition-related expenses (a)	(0.2)	(0.3)	(0.4)	(0.4)
Other	(0.5)	0.0	(0.2)	0.0
Non-GAAP selling, general and administrative expenses as a percentage of product sales	19.9 %	21.8 %	21.3 %	21.7 %
GAAP operating expenses	$ 4,328	$ 3,970	$ 13,798	$ 11,659
Adjustments to operating expenses:				
Adjustments to cost of sales	(612)	(687)	(1,838)	(2,159)
Adjustments to research and development expenses	(425)	(25)	(494)	(78)
Adjustments to acquired IPR&D	—	—	(1,505)	—
Adjustments to selling, general and administrative expenses	(45)	(17)	(112)	(76)
Certain charges pursuant to our cost savings initiatives	(1)	—	(129)	4
Certain other expenses (c)	9	(1)	(14)	(166)
Total adjustments to operating expenses	(1,074)	(730)	(4,092)	(2,475)
Non-GAAP operating expenses	$ 3,254	$ 3,240	$ 9,706	$ 9,184

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020*	2021	2020*
GAAP operating income	$ 2,378	$ 2,453	$ 5,335	$ 7,131
Adjustments to operating expenses	1,074	730	4,092	2,475
Non-GAAP operating income	$ 3,452	$ 3,183	$ 9,427	$ 9,606
GAAP operating income as a percentage of product sales	37.6 %	40.2 %	29.6 %	39.8 %
Adjustments to cost of sales	9.7	11.3	10.2	12.1
Adjustments to research and development expenses	6.7	0.4	2.8	0.4
Acquired IPR&D	0.0	0.0	8.3	0.0
Adjustments to selling, general and administrative expenses	0.7	0.3	0.6	0.4
Certain charges pursuant to our cost savings initiatives	0.0	0.0	0.7	0.0
Certain other expenses (c)	(0.1)	0.0	0.1	0.9
Non-GAAP operating income as a percentage of product sales	54.6 %	52.1 %	52.3 %	53.6 %
GAAP other income, net	$ 73	$ 55	$ 97	$ 69
Adjustments to other income (expense), net:				
Equity method investment basis difference amortization	44	36	128	72
Net (gains)/losses from equity investments	(191)	(134)	(335)	(139)
Gain from legal judgment proceeds	—	—	—	(72)
Total adjustments to other income (expense), net	(147)	(98)	(207)	(139)
Non-GAAP other income (expense), net	$ (74)	(43)	$ (110)	(70)
GAAP income before income taxes	$ 2,155	$ 2,206	$ 4,570	$ 6,256
Adjustments to income before income taxes:				
Adjustments to operating expenses	1,074	730	4,092	2,475
Adjustments to other income, net	(147)	(98)	(207)	(139)
Total adjustments to income before income taxes	927	632	$ 3,885	$ 2,336
Non-GAAP income before income taxes	$ 3,082	$ 2,838	$ 8,455	$ 8,592
GAAP provision for income taxes	$ 271	$ 185	$ 576	$ 607
Adjustments to provision for income taxes:				
Income tax effect of the above adjustments (d)	118	131	526	465
Other income tax adjustments (e)	29	55	17	63
Total adjustments to provision for income taxes	147	186	543	528
Non-GAAP provision for income taxes	$ 418	$ 371	$ 1,119	$ 1,135
GAAP tax as a percentage of income before taxes	12.6 %	8.4 %	12.6 %	9.7 %
Adjustments to provision for income taxes:				
Income tax effect of the above adjustments (d)	0.1	2.8	0.4	2.8
Other income tax adjustments (e)	0.9	1.9	0.2	0.7
Total adjustments to provision for income taxes	1.0	4.7	0.6	3.5
Non-GAAP tax as a percentage of income before taxes	13.6 %	13.1 %	13.2 %	13.2 %
GAAP net income	$ 1,884	$ 2,021	$ 3,994	$ 5,649
Adjustments to net income:				
Adjustments to income before income taxes, net of the income tax effect	809	501	3,359	1,871
Other income tax adjustments (e)	(29)	(55)	(17)	(63)
Total adjustments to net income	780	446	3,342	1,808
Non-GAAP net income	$ 2,664	2,467	$ 7,336	$ 7,457

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, 2021		Three months ended September 30, 2020*	
	GAAP	Non-GAAP	GAAP	Non-GAAP
Net income	$ 1,884	$ 2,664	$ 2,021	$ 2,467
Weighted-average shares for diluted EPS	570	570	589	589
Diluted EPS	$ 3.31	$ 4.67	$ 3.43	$ 4.19

	Nine months ended September 30, 2021		Nine months ended September 30, 2020*	
	GAAP	Non-GAAP	GAAP	Non-GAAP
Net income	$ 3,994	$ 7,336	$ 5,649	$ 7,457
Weighted-average shares for diluted EPS	576	576	592	592
Diluted EPS	$ 6.93	$ 12.74	$ 9.54	$ 12.60

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

(a) The adjustments related primarily to noncash amortization of intangible assets from business acquisitions.

(b) The adjustments for the three and nine months ended September 30, 2021, related primarily to licensing-related expense from the upfront payment to Kyowa Kirin Co., Ltd. and noncash amortization of intangible assets from business acquisitions. The adjustments for the three and nine months ended September 30, 2020, related primarily to noncash amortization of intangible assets from business acquisitions.

(c) For the three and nine months ended September 30, 2021, the adjustments related primarily to the change in fair values of contingent consideration liabilities. For the nine months ended September 30, 2020, the adjustment related primarily to legal settlement expenses and an impairment charge associated with an in-process research and development asset.

(d) The tax effect of the adjustments between our GAAP and non-GAAP results takes into account the tax treatment and related tax rate(s) that apply to each adjustment in the applicable tax jurisdiction(s). Generally, this results in a tax impact at the U.S. marginal tax rate for certain adjustments, including the majority of amortization of intangible assets, whereas the tax impact of other adjustments, including restructuring initiatives, depends on whether the amounts are deductible in the respective tax jurisdictions and the applicable tax rate(s) in those jurisdictions. Acquired IPR&D expense from the Five Prime acquisition was not tax deductible. Due to these factors, the effective tax rates for the adjustments to our GAAP income before income taxes, for the three and nine months ended September 30, 2021, were 12.7% and 13.5%, compared to 20.7% and 19.9% for the corresponding periods of the prior year.

(e) 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,	
	2021	2020	2021	2020
Net cash provided by operating activities	$ 2,418	$ 3,368	$ 6,453	$ 8,344
Net cash provided by (used in) investing activities	73	(1,628)	963	(4,017)
Net cash provided by (used in) financing activities	2,848	(1,798)	(1,713)	(1,277)
Increase (decrease) in cash and cash equivalents	5,339	(58)	5,703	3,050
Cash and cash equivalents at beginning of period	6,630	9,145	6,266	6,037
Cash and cash equivalents at end of period	$ 11,969	$ 9,087	$ 11,969	$ 9,087

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Net cash provided by operating activities	$ 2,418	$ 3,368	$ 6,453	$ 8,344
Capital expenditures	(242)	(135)	(593)	(435)
Free cash flow	$ 2,176	$ 3,233	$ 5,860	$ 7,909

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

GAAP diluted EPS guidance	$ 9.55	—	$ 10.21
Known adjustments to arrive at non-GAAP*:			
Acquisition-related and licensing expenses (a)	4.46	—	4.52
Acquired IPR&D (b)	2.62		
Certain charges pursuant to our cost savings initiatives	0.21		
Net gains from equity investments	(0.46)		
Legal proceedings	0.06		
Non-GAAP diluted EPS guidance	$ 16.50	—	$ 17.10

* The known adjustments are presented net of their related tax impact, which amount to approximately $1.13 per share.

(a) The adjustments relate primarily to noncash amortization of intangible assets acquired in business acquisitions and licensing-related expense related to an upfront payment to enter into a license and collaboration agreement.
(b) The adjustment relates to in-process research & development (IPR&D) expense as a result of acquiring Five Prime Therapeutics. The acquired IPR&D is not tax deductible.

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

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

GAAP tax rate guidance	12.5 %	—	14.0 %
Tax rate of known adjustments discussed above	0.0 %	—	0.5 %
Non-GAAP tax rate guidance	13.0 %	—	14.0 %

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

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

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