### 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) February 2, 2017

## AMGEN INC.

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction of Incorporation)

> One Amgen Center Drive Thousand Oaks, CA (Address of principal executive offices)

001-37702 (Commission File Number) 95-3540776 (IRS Employer Identification No.)

91320-1799 (Zip Code)

Registrant's telephone number, including area code 805-447-1000

N/A

(Former name or former address, if changed since last report)

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 communications 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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02 Results of Operations and Financial Condition.

On February 2, 2017, Amgen Inc. (the Company) issued a press release announcing its unaudited results of operations for the three months and year ended December 31, 2016, and its unaudited financial position as of December 31, 2016. 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 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 amortization of purchased intangible assets including developed product technology rights, licensing rights, R&D technology rights, and marketing-related rights purchased in connection with business acquisitions. The Company incurs charges related to the amortization of these intangibles, and those charges are included in the Company's Condensed Consolidated Financial Statements. Amortization charges for purchased intangible assets are significantly impacted by the timing and magnitude of the Company's acquisitions and product approval as it relates 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 non-cash amortization of intangible assets acquired in business combinations 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 initiative: Restructuring costs are primarily related to facilities charges, including accelerated depreciation, and severance and benefits for employees terminated pursuant to the transformation and process improvement efforts. Restructuring costs 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 also adjusts GAAP financial results for expenses associated with judgments and/or settlements for legal proceedings discussed in our filings. The Company is excluding these expenses 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 expenses 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 restructuring expense, 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 February 2, 2017

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.

By: /s/ David W. Meline

Name: David W. Meline

Title: Executive Vice President and Chief Financial Officer

Date: February 2, 2017

#### EXHIBIT INDEX

#### Exhibit <u>Number</u> Document Description

99.1 Press release dated February 2, 2017



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#### AMGEN REPORTS FOURTH QUARTER AND FULL YEAR 2016 FINANCIAL RESULTS

THOUSAND OAKS, Calif. (Feb. 2, 2017) – Amgen (NASDAQ:AMGN) today announced financial results for the fourth quarter and full year of 2016. Key results include:

- For the fourth quarter, total revenues increased 8 percent versus the fourth quarter of 2015 to \$6.0 billion.
  - Product sales grew 6 percent driven by Enbrel<sup>®</sup> (etanercept), Prolia<sup>®</sup> (denosumab), Repatha<sup>®</sup> (evolocumab) and KYPROLIS<sup>®</sup> (carfilzomib).
- For the full year, total revenues increased 6 percent to \$23.0 billion, with 5 percent product sales growth.
- GAAP earnings per share (EPS) increased 9 percent in the fourth quarter to \$2.59 and 13 percent for the full year to \$10.24, driven by higher revenues and higher operating margins.
  - GAAP operating income increased 22 percent in the fourth quarter to \$2.5 billion and 16 percent for the full year to \$9.8 billion.
- Non-GAAP EPS increased 11 percent in the fourth quarter to \$2.89 and 12 percent for the full year to \$11.65, driven by higher revenues and higher operating margins.
  - Non-GAAP operating income increased 21 percent in the fourth quarter to \$2.9 billion and 14 percent for the full year to \$11.4 billion.
- 2017 total revenues guidance of \$22.3-\$23.1 billion; EPS guidance of \$10.45-\$11.31 on a GAAP basis and \$11.80-\$12.60 on a non-GAAP basis.
- The Company generated \$9.6 billion of free cash flow for the full year versus \$9.1 billion in 2015 driven by higher net income.

"We finished the year with strong operating performance," said Robert A. Bradway, chairman and chief executive officer. "We anticipate several new product development opportunities and launches in 2017, and are excited about the Repatha cardiovascular outcomes data we released today. We have established a firm foundation for longer-term growth."

\$Millions, except EPS and percentages	Q4'16	Q4'15	YOY D	FY '16	FY '15	YOY D
Total Revenues	\$5,965	\$5,536	8%	\$22,991	\$21,662	6%
GAAP Operating Income	\$2,485	\$2,033	22%	\$ 9,794	\$ 8,470	16%
GAAP Net Income	\$1,935	\$1,800	8%	\$ 7,722	\$ 6,939	11%
GAAP EPS	\$ 2.59	\$ 2.37	9%	\$ 10.24	\$ 9.06	13%
Non-GAAP Operating Income	\$2,859	\$2,366	21%	\$11,446	\$10,052	14%
Non-GAAP Net Income	\$2,160	\$1,985	9%	\$ 8,785	\$ 7,954	10%
Non-GAAP EPS	\$ 2.89	\$ 2.61	11%	\$ 11.65	\$ 10.38	12%

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.

#### **Product Sales Performance**

- **Total product sales** increased 6 percent for the fourth quarter of 2016 versus the fourth quarter of 2015. The increase was driven primarily by ENBREL, Prolia, Repatha and KYPROLIS. Product sales increased 5 percent for the full year.
- **ENBREL** sales increased 14 percent for the fourth quarter driven by net selling price and favorable changes in inventory levels, offset partially by the impact of competition. Sales increased 11 percent for the full year driven by net selling price, offset partially by the impact of competition.
- **Neulasta**<sup>®</sup> (pegfilgrastim) sales decreased 3 percent for the fourth quarter and 1 percent for the full year driven by lower unit demand.
- **Aranesp**<sup>®</sup> (darbepoetin alfa) sales increased 5 percent for the fourth quarter and 7 percent for the full year driven by higher unit demand due to a shift by some U.S. dialysis customers from EPOGEN<sup>®</sup> (epoetin alfa) to Aranesp, offset partially by unfavorable changes in net selling price.
- Prolia sales increased 22 percent for the fourth quarter and 25 percent for the full year driven by higher unit demand.
- Sensipar/Mimpara<sup>®</sup> (cinacalcet) sales increased 7 percent for the fourth quarter driven by net selling price. Sales increased 12 percent for the full year driven by net selling price and higher unit demand.
- XGEVA® (denosumab) sales increased 6 percent for the fourth quarter and 9 percent for the full year driven by higher unit demand.
- **EPOGEN** sales decreased 8 percent for the fourth quarter and 31 percent for the full year driven by the impact of competition and a shift by some U.S. dialysis customers to Aranesp.
- **KYPROLIS** sales increased 24 percent for the fourth quarter and 35 percent for the full year driven by higher unit demand.
- **NEUPOGEN®** (filgrastim) sales decreased 34 percent for the fourth quarter and 27 percent for the full year driven primarily by the impact of competition in the U.S.
- Nplate<sup>®</sup> (romiplostim) sales increased 9 percent for the fourth quarter and 11 percent for the full year driven by higher unit demand.
- Vectibix<sup>®</sup> (panitumumab) sales increased 6 percent for the fourth quarter and 11 percent for the full year driven by higher unit demand.
- **Repatha** sales growth for the fourth quarter and full year was driven by higher unit demand.
- **BLINCYTO**<sup>®</sup> (blinatumomab) sales increased 32 percent for the fourth quarter and 49 percent for the full year driven by higher unit demand.

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

\$Millions, except percentages	US	Q4'16 ROW	TOTAL	Q4'15 TOTAL	YOY D TOTAL
Enbrel®	\$1,582	\$ 62	\$1,644	\$1,441	14%
Neulasta®	943	3 02 173	1,116	1,156	(3%)
Aranesp®	286	240	526	499	5%
Prolia®	293	170	463	380	22%
Sensipar® / Mimpara®	330	81	411	384	7%
XGEVA®	273	103	376	356	6%
EPOGEN®	316	0	316	342	(8%)
KYPROLIS®	143	40	183	148	24%
NEUPOGEN®	116	57	173	263	(34%)
Nplate®	88	62	150	137	9%
Vectibix®	57	86	143	135	6%
Repatha®	36	22	58	7	*
BLINCYTO®	24	5	29	22	32%
Other**	19	56	75	59	27%
Total product sales	\$4,506	\$1,157	\$5,663	\$5,329	6%

Change in excess of 100%

Other includes MN Pharma, Bergamo, IMLYGIC® and Corlanor® \*\*

\$Millions, except percentages	US	FY '16 ROW	TOTAL	FY '15 TOTAL	YOY D TOTAL
Enbrel®	\$ 5,719	\$ 246	\$ 5,965	\$ 5,364	11%
Neulasta®	3,925	723	4,648	4,715	(1%)
Aranesp®	1,082	1,011	2,093	1,951	7%
Prolia®	1,049	586	1,635	1,312	25%
Sensipar® / Mimpara®	1,240	342	1,582	1,415	12%
XGEVA®	1,115	414	1,529	1,405	9%
EPOGEN®	1,282	0	1,282	1,856	(31%)
NEUPOGEN®	534	231	765	1,049	(27%)
KYPROLIS®	554	138	692	512	35%
Vectibix®	229	382	611	549	11%
Nplate®	350	234	584	525	11%
Repatha®	101	40	141	10	*
BLINCYTO®	85	30	115	77	49%
Other**	60	190	250	204	23%
Total product sales	\$17,325	\$4,567	\$21,892	\$20,944	5%

Change in excess of 100%

Other includes MN Pharma, Bergamo, IMLYGIC® and Corlanor®

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

On a GAAP basis:

- Total Operating Expenses decreased 1 percent in the fourth quarter and were flat for the full year, with all expense categories reflecting savings from our transformation and process improvement efforts. Cost of Sales margin improved by 1.3 percentage points in the fourth quarter and 1.2 percentage points for the full year driven primarily by manufacturing efficiencies. Research & Development (R&D) expenses were flat for the fourth quarter. For the full year, R&D expenses decreased 6 percent driven primarily by lower spending required to support certain later-stage clinical programs and transformation and process improvement efforts, offset partially by external business development activities. Selling, General & Administrative (SG&A) expenses decreased 7 percent in the fourth quarter due to the Oct. 31, 2016, expiration of ENBREL residual royalty payments. For the full year, SG&A expenses increased 4 percent driven primarily by investments in new product launches, offset partially by the expiration of ENBREL residual royalty payments. Other expenses increased in the fourth quarter and for the full year as the prior year periods included gains from the sale of assets related to our site closures.
- **Operating Margin** improved by 5.8 percentage points in the fourth quarter to 43.9 percent, and 4.3 percentage points for the full year to 44.7 percent.
- **Tax Rate** for the fourth quarter increased 9.3 percentage points driven primarily by changes in the geographic mix of earnings and the discrete impact of the enactment of the federal R&D credit in the fourth quarter of 2015. The full year tax rate increased 2.7 percentage points driven by changes in the geographic mix of earnings, offset partially by the benefit of adopting Accounting Standards Update 2016-09, *Improvements to Employee Share-Based Payment Accounting* (ASU 2016-09).

On a non-GAAP basis:

- Total Operating Expenses decreased 2 percent in the fourth quarter and 1 percent for the full year, with all expense categories reflecting savings from our transformation and process improvement efforts. Cost of Sales margin improved by 1.0 percentage points in the fourth quarter and 1.2 percentage points for the full year driven primarily by manufacturing efficiencies. **R&D** expenses were flat in the fourth quarter. For the full year, R&D expenses decreased 4 percent driven primarily by lower spending required to support certain later-stage clinical programs and transformation and process improvement efforts, offset partially by external business development activities. SG&A expenses decreased 4 percent in the fourth quarter due to the Oct. 31, 2016, expiration of ENBREL residual royalty payments. For the full year, SG&A expenses increased 5 percent driven primarily by investments in new product launches, offset partially by the expiration of ENBREL residual royalty payments.
- **Operating Margin** improved by 6.1 percentage points in the fourth quarter to 50.5 percent, and 4.3 percentage points for the year to 52.3 percent.
- **Tax Rate** for the fourth quarter increased 7.1 percentage points driven primarily by changes in the geographic mix of earnings and the discrete impact of the enactment of the federal R&D credit in the fourth quarter of 2015. The full year tax rate increased 2.0 percentage points driven by changes in the geographic mix of earnings, offset partially by the benefit of adopting ASU 2016-09.

\$Millions, except percentages						
+,F-FB		GAAP			Non-GAAP	
	Q4'16	Q4'15	YOYD	Q4'16	Q4'15	YOYD
Cost of Sales	\$1,067	\$ 1,071	(0%)	\$ 753	\$ 764	(1%)
% of product sales	18.8%	20.1%	(1.3) pts.	13.3%	14.3%	(1) pts.
Research & Development	\$1,078	\$ 1,093	(1%)	\$1,056	\$1,057	0%
% of product sales	19.0%	20.5%	(1.5) pts.	18.6%	19.8%	(1.2) pts.
Selling, General & Administrative	\$1,323	\$ 1,416	(7%)	\$1,297	\$1,349	(4%)
% of product sales	23.4%	26.6%	(3.2) pts.	22.9%	25.3%	(2.4) pts.
Other	\$ 12	(\$ 77)	*	\$ 0	\$ 0	0%
TOTAL Operating Expenses	\$3,480	\$ 3,503	(1%)	\$3,106	\$3,170	(2%)
Operating Margin						
operating income as a % of product sales	43.9%	38.1%	5.8 pts.	50.5%	44.4%	6.1 pts.
Tax Rate	15.2%	5.9%	9.3 pts.	18.7%	11.6%	7.1 pts.

\* Change in excess of 100%

pts: percentage points

\$Millions, except percentages

\$Millions, except percentages		GAAP			Non-GAAP	
	FY '16	FY '15	YOYD	FY '16	FY '15	YOYD
Cost of Sales	\$ 4,162	\$ 4,227	(2%)	\$ 2,913	\$ 3,033	(4%)
% of product sales	19.0%	20.2%	(1.2) pts.	13.3%	14.5%	(1.2) pts.
Research & Development	\$ 3,840	\$ 4,070	(6%)	\$ 3,755	\$ 3,917	(4%)
% of product sales	17.5%	19.4%	(1.9) pts.	17.2%	18.7%	(1.5) pts.
Selling, General & Administrative	\$ 5,062	\$ 4,846	4%	\$ 4,877	\$ 4,660	5%
% of product sales	23.1%	23.1%	0 pts.	22.3%	22.2%	0.1 pts.
Other	\$ 133	\$ 49	*	\$ 0	\$ 0	0%
TOTAL Operating Expenses	\$13,197	\$13,192	0%	\$11,545	\$11,610	(1%)
Operating Margin						
operating income as a % of product sales	44.7%	40.4%	4.3 pts.	52.3%	48.0%	4.3 pts.
Tax Rate	15.7%	13.0%	2.7 pts.	18.8%	16.8%	2 pts.

\* Change in excess of 100%

pts: percentage points

#### **Cash Flow and Balance Sheet**

- The Company generated \$2.9 billion of free cash flow in the fourth quarter of 2016 versus \$1.9 billion in the fourth quarter of 2015 due primarily to the timing of tax and other payments, as well as higher net income. The Company generated \$9.6 billion of free cash flow in 2016 versus \$9.1 billion in 2015 due to higher net income.
- The Company's first quarter 2017 dividend of \$1.15 per share declared on Dec. 20, 2016, will be paid on March 8, 2017, to all stockholders of record as of Feb. 15, 2017. This represents a 15 percent increase from that paid in each of the previous four quarters.
- During the fourth quarter, the Company repurchased 6.7 million shares of common stock at a total cost of \$1.0 billion. For the full year, the Company repurchased 19.7 million shares of common stock at a total cost of \$3.0 billion. At the end of 2016, the Company had \$4.1 billion remaining under its stock repurchase authorization.

\$Billions, except shares	Q4'16	Q4'15	YOYD	FY '16	FY '15	YOYD
Operating Cash Flow	\$ 3.1	\$ 2.1	\$ 1.0	\$10.4	\$ 9.7	\$ 0.6
Capital Expenditures	0.2	0.2	0.0	0.7	0.6	0.1
Free Cash Flow	2.9	1.9	1.0	9.6	9.1	0.5
Dividends Paid	0.7	0.6	0.2	3.0	2.4	0.6
Share Repurchase	1.0	0.2	0.8	3.0	1.9	1.1
Avg. Diluted Shares (millions)	748	761	(13)	754	766	(12)
Cash and Investments	38.1	31.4	6.7	38.1	31.4	6.7
Debt Outstanding	34.6	31.4	3.2	34.6	31.4	3.2
Stockholders' Equity	29.9	28.1	1.8	29.9	28.1	1.8

Note: Numbers may not add due to rounding

#### 2017 Guidance

For the full year 2017, the Company expects:

- Total revenues in the range of \$22.3 billion to \$23.1 billion.
- On a **GAAP basis, EPS** in the range of \$10.45 to \$11.31 and a **tax rate** in the range of 16 percent to 18 percent.
- On a non-GAAP basis, EPS in the range of \$11.80 to \$12.60 and a tax rate in the range of 18.5 percent to 19.5 percent.
- Capital expenditures to be approximately \$700 million.
- Share repurchases of approximately \$2.5 billion to \$3.5 billion.

#### Fourth Quarter Product and Pipeline Update

Key development milestones:

Clinical Program	Indication	Projected Milestone
Repatha	Hyperlipidemia	Phase 3 CV outcomes data presentation Q1 2017*
KYPROLIS	Relapsed or refractory multiple myeloma	Phase 3 study initiation with DARZALEX®
XGEVA	Prevention of SREs in multiple myeloma	Global regulatory submissions
BLINCYTO	Diffuse large B-cell lymphoma	Phase 2/3 study initiations
EVENITY™ (romosozumab)†	Postmenopausal osteoporosis	U.S. regulatory review Active controlled Phase 3 fracture data Q2 2017*
Erenumab (AMG 334)	Migraine prophylaxis	Global regulatory submissions
Parsabiv™ (etelcalcetide)†	Secondary hyperparathyroidism	U.S. regulatory review
ABP 215 (biosimilar bevacizumab)	Oncology	Global regulatory reviews
ABP 501 (biosimilar adalimumab)	Inflammatory diseases	Ex-U.S. regulatory reviews
ABP 980 (biosimilar trastuzumab)	Breast cancer	Global regulatory submissions

\* Event driven study; *†*Trade name provisionally approved by FDA; CV = cardiovascular; SRE = skeletal-related event

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

#### Repatha

- In December, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion for an extension to the marketing authorization of a new 420 mg single-dose delivery option.
- Data from a Phase 3 study evaluating the effects of Repatha on cardiovascular outcomes that met its primary composite endpoint and key secondary composite endpoint will be presented at the American College of Cardiology 66th Annual Scientific Session on March 17.

#### **Omecamtiv mecarbil**

• Enrollment of the Phase 3 cardiovascular outcomes study in chronic heart failure patients commenced in Q1 2017.

#### **KYPROLIS**

- The primary endpoint in a Phase 3 study of once weekly KYPROLIS administration in relapsed and refractory multiple myeloma patients (ARROW) has been modified from overall response rate to progression free survival, an event driven endpoint, with results expected in 2019.
- In November, a collaboration was established with Janssen Biotech, Inc. (Janssen) to evaluate the combination of KYPROLIS and Janssen's DARZALEX® (daratumumab) in multiple clinical studies in patients with multiple myeloma.
- A Phase 3 registrational study evaluating KYPROLIS in combination with DARZALEX and dexamethasone compared to KYPROLIS and dexamethasone alone in patients with multiple myeloma who have had one, two or three prior lines of therapy is anticipated to begin enrollment in Q2 2017.

#### XGEVA

Regulatory submissions for the prevention of skeletal-related events in multiple myeloma patients are expected in 2017.

#### BLINCYTO

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- Regulatory submissions for Philadelphia chromosome-positive relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL) are expected in 2017. BLINCYTO is currently approved for the treatment of adult and pediatric patients with Philadelphia chromosome-negative R/R B-cell precursor ALL.
- Phase 2/3 studies in patients with diffuse large B-cell lymphoma will enroll patients in 2017.

#### EVENITY<sup>™</sup> (romosozumab)

- In December, an application for marketing approval for the treatment of osteoporosis for men and women at high risk for fracture was submitted to the Pharmaceuticals and Medical Devices Agency in Japan. This follows the postmenopausal osteoporosis U.S. filing in 2016 with a U.S. Food and Drug Administration (FDA) Prescription Drug User Fee Act (PDUFA) target action date of July 19, 2017.
- Primary results from an event driven active controlled Phase 3 fracture study (ARCH) in postmenopausal women with osteoporosis are expected in Q2 2017.

#### Erenumab

- In November, a second Phase 3 study met its primary endpoint, demonstrating statistically significant reductions from baseline in monthly migraine days in patients with episodic migraine treated with either 70 mg or 140 mg erenumab compared with placebo.
- Regulatory submissions for the prevention of episodic and chronic migraine are expected in Q2 2017.

#### **CNP520**

• In December, FDA granted fast track designation to CNP520, a small molecule beta-site amyloid precursor protein-cleaving enzyme-1 (BACE) inhibitor for the potential treatment of Alzheimer's disease.

#### Parsabiv

- FDA has set a Feb. 9, 2017, PDUFA target action date for the review of Parsabiv for the treatment of secondary hyperparathyroidism (sHPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.
- In November, the EMA granted marketing authorization for the treatment of sHPT in adult patients with CKD on hemodialysis.

#### ENBREL

• In November, FDA approved the supplemental Biologics License Application (BLA) for the expanded use to treat pediatric patients (ages 4-17) with chronic moderate-to-severe plaque psoriasis.

#### ABP 215 (biosimilar bevacizumab)

- In January 2017, a BLA was accepted by FDA with a Sept. 14, 2017, Biosimilar User Fee target action date.
- In December, a Marketing Authorization Application was submitted to the EMA.

#### ABP 501 (biosimilar adalimumab)

• In January 2017, the CHMP adopted a positive opinion for the Marketing Authorization of ABP 501, recommending approval for all available indications. ABP 501 has been recommended for approval for the treatment of certain

inflammatory diseases in adults, including moderate-to-severe rheumatoid arthritis, psoriatic arthritis, severe ankylosing spondylitis (AS), severe axial spondyloarthritis without radiographic evidence of AS, moderate-to-severe chronic plaque psoriasis, moderate-to-severe hidradenitis suppurativa, non-infectious intermediate, posterior and panuveitis, moderate-to-severe Crohn's disease and moderate-to-severe ulcerative colitis. The CHMP opinion also recommends approval for the treatment of certain pediatric inflammatory diseases, including moderate-to-severe Crohn's disease (ages six and older), severe chronic plaque psoriasis (ages four and older), enthesitis-related arthritis (ages six and older) and polyarticular juvenile idiopathic arthritis (ages two and older).

#### Erenumab and CNP520 are developed in collaboration with Novartis AG

Omecamtiv mecarbil is developed in collaboration with Cytokinetics and in an alliance with Servier for certain territories. EVENITY<sup>™</sup> is developed in collaboration with UCB globally, as well as our joint venture partner Astellas in Japan DARZALEX<sup>®</sup> is a registered trademark of Janssen Biotech, Inc.

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

In this news release, management has presented its operating results for the fourth quarters and full years of 2016 and 2015, in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and on a non-GAAP basis. In addition, management has presented its full year 2017 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 fourth quarters and full years of 2016 and 2015. 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.

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 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 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 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 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 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. 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 cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. 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.

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

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

	Decen	Three months ended December 31,		ended ber 31,
Revenues:	2016	2015	2016	2015
Product sales	\$ 5,663	\$ 5,329	\$21,892	\$20,944
Other revenues	302	207	1,099	¢20,544 718
Total revenues	5,965	5,536	22,991	21,662
Operating expenses:				
Cost of sales	1,067	1,071	4,162	4,227
Research and development	1,078	1,093	3,840	4,070
Selling, general and administrative	1,323	1,416	5,062	4,846
Other	12	(77)	133	49
Total operating expenses	3,480	3,503	13,197	13,192
Operating income	2,485	2,033	9,794	8,470
Interest expense, net	328	284	1,260	1,095
Interest and other income, net	126	164	629	603
Income before income taxes	2,283	1,913	9,163	7,978
Provision for income taxes	348	113	1,441	1,039
Net income	\$ 1,935	\$ 1,800	\$ 7,722	\$ 6,939
Earnings per share:				
Basic	\$ 2.61	\$ 2.39	\$ 10.32	\$ 9.15
Diluted	\$ 2.59	\$ 2.37	\$ 10.24	\$ 9.06
Weighted average shares used in calculation of earnings per share:				
Basic	742	754	748	758
Diluted	748	761	754	766

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

	Dec	December 31, 2016		December 31, 2015	
Assets					
Current assets:					
Cash, cash equivalents and marketable securities	\$	38,085	\$	31,382	
Trade receivables, net		3,165		2,995	
Inventories		2,745		2,435	
Other current assets		2,015		1,703	
Total current assets		46,010		38,515	
Property, plant and equipment, net		4,961		4,907	
Intangible assets, net		10,279		11,641	
Goodwill		14,751		14,787	
Other assets		1,625		1,599	
Total assets	\$	77,626	\$	71,449	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable and accrued liabilities	\$	6,801	\$	6,417	
Current portion of long-term debt		4,403		2,247	
Total current liabilities		11,204		8,664	
Long-term debt		30,193		29,182	
Long-term deferred tax liability		2,436		2,239	
Long-term tax liability		2,419		1,973	
Other noncurrent liabilities		1,499		1,308	
Stockholders' equity		29,875		28,083	
Total liabilities and stockholders' equity	\$	77,626	\$	71,449	
Shares outstanding		738		754	

#### Amgen Inc.

GAAP to Non-GAAP Reconciliations (In millions) (Unaudited)

	Three months ended December 31,		December 31, Dece		December 31,December 31		
GAAP cost of sales	2016 \$1.067	2015 \$1,071	2016 \$ 4,162	2015 \$ 4,227			
Adjustments to cost of sales:	\$1,067	\$1,0/1	\$ 4,162	\$ 4,227			
Acquisition-related expenses (a)	(314)	(297)	(1,248)	(1,142)			
Certain net charges pursuant to our restructuring initiative	(514)	(10)	(1,240)	(1,142)			
Total adjustments to cost of sales	(314)		(1,249)	(1,194)			
		(307)					
Non-GAAP cost of sales	<u>\$ 753</u>	\$ 764	\$ 2,913	\$ 3,033			
GAAP cost of sales as a percentage of product sales	18.8%	20.1%	19.0%	20.29			
Acquisition-related expenses (a)	-5.5	-5.6	-5.7	-5.5			
Certain net charges pursuant to our restructuring initiative	0.0	-0.2	0.0	-0.2			
Non-GAAP cost of sales as a percentage of product sales	13.3%	14.3%	13.3%	14.59			
GAAP research and development expenses	\$1,078	\$1,093	\$ 3,840	\$ 4,070			
Adjustments to research and development expenses:							
Acquisition-related expenses (a)	(20)	(20)	(78)	(89)			
Certain net charges pursuant to our restructuring initiative	(2)	(16)	(7)	(64)			
Total adjustments to research and development expenses	(22)	(36)	(85)	(153)			
Non-GAAP research and development expenses	\$1,056	\$1,057	\$ 3,755	\$ 3,917			
GAAP research and development expenses as a percentage of product sales	19.0%	20.5%	17.5%	19.49			
Acquisition-related expenses (a)	-0.4	-0.4	-0.3	-0.4			
Certain net charges pursuant to our restructuring initiative	0.0	-0.3	0.0	-0.3			
Non-GAAP research and development expenses as a percentage of product sales	18.6%	19.8%	17.2%	18.79			
GAAP selling, general and administrative expenses	\$1,323	\$1,416	\$ 5,062	\$ 4,846			
Adjustments to selling, general and administrative expenses:	ψ1,020	ψ1,410	\$ 3,002	φ -,0+0			
Acquisition-related expenses (b)	(26)	(46)	(180)	(130)			
Certain net charges pursuant to our restructuring initiative	(=0)	(21)	(100)	(56)			
Total adjustments to selling, general and administrative expenses	(26)	(67)	(185)	(186)			
Non-GAAP selling, general and administrative expenses	\$1,297	\$1,349	\$ 4,877	\$ 4,660			
	\$1,237	\$1,345	\$ 4,077				
GAAP selling, general and administrative expenses as a percentage of product sales	23.4%	26.6%	23.1%	23.1%			
Acquisition-related expenses (b)	-0.5	-0.9	-0.8	-0.6			
Certain net charges pursuant to our restructuring initiative	0.0	-0.4	0.0	-0.3			
Non-GAAP selling, general and administrative expenses as a percentage of product sales	22.9%	25.3%	22.3%	22.29			
GAAP operating expenses	\$3,480	\$3,503	\$13,197	\$13,192			
Adjustments to operating expenses:							
Adjustments to cost of sales	(314)	(307)	(1,249)	(1,194)			
Adjustments to research and development expenses	(22)	(36)	(85)	(153)			
Adjustments to selling, general and administrative expenses	(26)	(67)	(185)	(186)			
Certain net charges pursuant to our restructuring initiative <b>(c)</b>	(9)	99	(24)	58			
Expense related to various legal proceedings		(18)	(105)	(91)			
Acquisition-related adjustments (d)	(3)	(4)	(4)	(16)			
Total adjustments to operating expenses	(374)	(333)	(1,652)	(1,582)			
Non-GAAP operating expenses	\$3,106	\$3,170	\$11,545	\$11,610			
GAAP operating income	\$2,485	\$2,033	\$ 9,794	\$ 8,470			
Adjustments to operating expenses	374	333	1,652	1,582			
Non-GAAP operating income	\$2,859	\$2,366	\$11,446	\$10,052			
ton of an operating meane	φ2,000	φ2,000	Ψ±1, <del>11</del> 0	φ10,002			
GAAP operating income as a percentage of product sales	43.9%	38.1%	44.7%	40.49			
Adjustments to cost of sales	5.5	5.8	5.7	5.7			
Adjustments to research and development expenses	0.4	0.7	0.3	0.7			
Adjustments to selling, general and administrative expenses	0.5	1.3	0.8	0.9			
Certain net charges pursuant to our restructuring initiative (c)	0.2	-1.9	0.2	-0.3			
Expense related to various legal proceedings	0.0	0.3	0.6	0.4			
Acquisition-related adjustments (d)	0.0	0.1	0.0	0.0			
Non-GAAP operating income as a percentage of product sales	50.5%	44.4%	52.3%	47.89			
	\$2,283	\$1,913	\$ 9,163	\$ 7,978			
GAAP income before income taxes				1,582			
GAAP income before income taxes Adjustments to operating expenses	374	333	1,652	1,502			
	374 \$2,657	333 \$2,246	\$10,815	\$ 9,560			
Adjustments to operating expenses							

Income tax effect of the above adjustments to operating expenses (e)	113	92	525	496
Other income tax adjustments <b>(f)</b>	36	56	64	71
Total adjustments to provision for income taxes	149	148	589	567
Non-GAAP provision for income taxes	\$ 497	\$ 261	\$ 2,030	\$ 1,606
GAAP tax rate as a percentage of income before taxes	15.2%	5.9%	15.7%	13.0%
Adjustments to provision for income taxes:				
Income tax effect of the above adjustments to operating expenses (e)	2.1	3.2	2.5	3.0
Other income tax adjustments <b>(f)</b>	1.4	2.5	0.6	0.8
Total adjustments to provision for income taxes	3.5	5.7	3.1	3.8
Non-GAAP tax rate as a percentage of income before taxes	18.7%	11.6%	18.8%	16.8%
GAAP net income	\$1,935	\$1,800	\$ 7,722	\$ 6,939
Adjustments to net income:				
Adjustments to income before income taxes, net of the income tax effect	261	241	1,127	1,086
Other income tax adjustments <b>(f)</b>	(36)	(56)	(64)	(71)
Total adjustments to net income	225	185	1,063	1,015
Non-GAAP net income	\$2,160	\$1,985	\$ 8,785	\$ 7,954

#### 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 EPS.

		Three months ended December 31, 2016		onths ended er 31, 2015
	GAAP	Non-GAAP	GAAP	Non-GAAP
Net income	\$1,935	\$ 2,160	\$1,800	\$ 1,985
Weighted-average shares for diluted EPS	748	748	761	761
Diluted EPS	\$ 2.59	\$ 2.89	\$ 2.37	\$ 2.61
	Decemi GAAP	r ended ber 31, 2016 <u>Non-GAAP</u>	Year ended December 31, 2015 GAAP Non-G	
Net income	\$7,722	\$ 8,785	\$6,939	\$ 7,954
Weighted-average shares for diluted EPS	754	754	766	766
Diluted EPS	\$10.24	\$ 11.65	\$ 9.06	\$ 10.38

(a) The adjustments related primarily to non-cash amortization of intangible assets acquired in business combinations.

(b) For the three months and years ended December 31, 2016 and 2015, the adjustments related primarily to non-cash amortization of intangible assets acquired in business combinations. For the year ended December 31, 2016, the adjustments also included a \$73-million charge resulting from the reacquisition of Prolia<sup>®</sup>, XGEVA<sup>®</sup> and Vectibix<sup>®</sup> license agreements in certain markets from Glaxo Group Limited.

(c) For the three months and year ended December 31, 2016, the adjustments related primarily to asset-related charges from our site closures. For the three months ended December 31, 2015, the adjustments related primarily to a gain recognized on the sale of assets related to our site closures. The adjustments for the year ended December 31, 2015, related primarily to gains recognized on the sale of assets related to our site closures, partially offset by severance expenses.

(d) The adjustments related primarily to the impairment of non-key contract assets acquired as part of a business combination and the change in fair values of contingent consideration.

(e) 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 expense, 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 rates for the adjustments to our GAAP income before income taxes, for the three months and year ended December 31, 2016, were 30.2% and 31.8%, respectively, compared with 27.6% and 31.4% for the corresponding periods of the prior year.

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

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

	Three months ended December 31,		Years ended December 31,	
	2016	2015	2016	2015
Net cash provided by operating activities	\$ 3,100	\$ 2,073 <b>(a)</b>	\$10,354	\$ 9,731 <b>(a)</b>
Net cash used in investing activities	(1,222)	(233)	(8,658)	(5,547)
Net cash used in financing activities	(2,122)	(922)	(2,599)	(3,771)
(Decrease) increase in cash and cash equivalents	(244)	918	(903)	413
Cash and cash equivalents at beginning of period	3,485	3,226	4,144	3,731
Cash and cash equivalents at end of period	\$ 3,241	\$4,144	\$ 3,241	\$ 4,144
	Three months ended December 31, 2016 2015		Years ended <u>December 31,</u> 2016 2015	
Net cash provided by operating activities	\$ 3,100	\$2,073 (a)	\$10,354	\$ 9,731 (a)
Capital expenditures	(227)	(205)	(738)	(594)
Free cash flow	\$ 2,873	\$ 1,868	\$ 9,616	\$ 9,137

(a) Restated to include \$13 million and \$654 million for the three months and year ended December 31, 2015, respectively, which was previously included in Net cash used in financing activities, as a result of the adoption of Accounting Standards Update 2016-09, *Improvements to Employee Share-Based Payment Accounting*.

#### Reconciliation of GAAP EPS Guidance to Non-GAAP EPS Guidance for the Year Ending December 31, 2017 (Unaudited)

GAAP diluted EPS guidance	\$10.45 - \$11.31
Known adjustments to arrive at non-GAAP*:	
Acquisition-related expenses (a)	1.22
Restructuring charges	0.07 - 0.13
Non-GAAP diluted EPS guidance	\$11.80 - \$12.60

\* The known adjustments are presented net of their related tax impact which amount to approximately \$0.61 to \$0.64 per share, in the aggregate.

(a) The adjustments relate primarily to non-cash amortization of intangible assets acquired in prior year business combinations.

#### Reconciliation of GAAP Tax Rate Guidance to Non-GAAP Tax Rate Guidance for the Year Ending December 31, 2017 (Unaudited)

	2017
GAAP tax rate guidance	16.0% - 18.0%
Tax rate effect of known adjustments discussed above	1.5% - 2.5%
Non-GAAP tax rate guidance	18.5% - 19.5%