Amgen Reports Third Quarter 2020 Financial Results

October 28, 2020

THOUSAND OAKS, Calif., Oct. 28, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced financial results for the third quarter of 2020.

Key results include:

- Total revenues increased 12% to $6.4 billion in comparison to the third quarter of 2019 driven by higher volume growth, partially offset by lower net selling prices and the effects of the COVID-19 pandemic.
    - Product sales increased 12% globally, driven by 18% volume growth across a number of our newer products, including Otezla® (apremilast), MVASI® (bevacizumab-awwb), KANJINTI® (trastuzumab-anns), and Repatha® (evolocumab), partially offset by declines in select products from the impact of COVID-19, and biosimilar and generic competition.
- GAAP earnings per share (EPS) increased 5% to $3.43 primarily driven by increased revenues and lower weighted-average shares outstanding, partially offset by the amortization of costs associated with our November 2019 acquisition of Otezla.
    - GAAP operating income decreased 1% to $2.5 billion and GAAP operating margin decreased 5.1 percentage points to 40.2%, primarily driven by the amortization of intangible assets from our Otezla acquisition.
- Non-GAAP EPS increased 19% to $4.37 driven by increased revenues.
    - Non-GAAP operating income increased 14% to $3.2 billion and non-GAAP operating margin increased 1.0 percentage point to 52.1%.
- The Company generated $3.2 billion of free cash flow in the third quarter versus $3.2 billion in the third quarter of 2019.
- 2020 total revenues guidance narrowed to $25.1-$25.5 billion; EPS guidance revised to $11.53-$11.93 on a GAAP basis and revised to $15.80-$16.15 on a non-GAAP basis.

"Amgen continues to deliver strong, volume-driven growth in a challenging environment, while also advancing new medicines in our pipeline," said Robert A. Bradway, chairman and chief executive officer.

$Millions, except EPS, dividends paid per share and percentages	Q3 '20	Q3 '19	YOY Δ
Total Revenues	$6,423	$5,737	12%
GAAP Operating Income	$2,453	$2,476	(1%)
GAAP Net Income	$2,021	$1,968	3%
GAAP EPS	$ 3.43	$ 3.27	5%
Non-GAAP Operating Income	$3,183	$2,793	14%
Non-GAAP Net Income	$2,572	$2,201	17%
Non-GAAP EPS	$ 4.37	$ 3.66	19%
Dividends Paid Per Share	$ 1.60	$ 1.45	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.

Product Sales Performance

- **Total product sales** increased 12% versus the third quarter of 2019 driven by 18% volume growth, partially offset by declines in net selling prices.
- **COVID-19 update**: During the third quarter, physician-patient interactions and prescribing volumes continued to increase, but remained modestly below pre-COVID-19 levels on a portfolio basis. While prescription trends were more consistent throughout the third quarter versus the second quarter, we continue to expect quarter-to-quarter variability due to the pandemic.
- **Prolia®** (denosumab) sales increased 11% year-over-year driven by 10% volume growth as patients returned for treatment in the quarter, with rates of osteoporosis diagnoses in the U.S. recovering to ~70% of pre-COVID-19 levels. Our efforts remain focused on assisting patients with continuity of care to improve product access from the initial stages of the pandemic. Prior to the pandemic, the first and third quarters of each year had lower sales than the second and fourth quarters. Given the impact of the pandemic in the second quarter of 2020 and 6-month dosing regimen of Prolia, we expect year-over-year growth rates in the fourth quarter to be lower than pre-COVID-19 growth trends.
- **EVENITY®** (romosozumab-aqqg) generated $59 million of sales in the third quarter of 2020. U.S. sales increased 35% quarter-over-quarter driven by 30% volume growth. Japan sales declined quarter-over-quarter driven by an inventory drawdown by our partner Astellas following large purchases during the first half of 2020, as well as an unfavorable change to estimated sales deductions.
- **Repatha** sales increased 22% year-over-year driven by 60% volume growth, partially offset by lower net selling price and

unfavorable changes to estimated sales deductions. Despite a modest disruption in access in the third quarter, Repatha remains the global segment leader in the proprotein convertase subtilisin/kexin type 9 (PCSK9) class. Repatha's year-over-year net selling price declined as a result of additional contracting to improve Medicare Part D patient access and affordability. At the end of the third quarter, more than 60% of Medicare patients had access to affordable, fixed co-pays of $50 or less.

- **Aimovig®** (erenumab-aooe) sales increased 59% year-over-year driven by 36% volume growth and the effect of unfavorable changes to estimated sales deductions in the prior year. Net selling price declined minimally year-over-year. Aimovig remains the segment leader within the preventive calcitonin gene-related peptide (CGRP) class with 46% share of total prescriptions (TRx) and 38% share of new-to-brand prescriptions (NBRx) in the quarter. With five-year efficacy and safety data, Aimovig is well positioned for the preventive segment which impacts more than 4 million individuals in the U.S.
- **Parsabiv®** (etelcalcetide) sales increased 17% year-over-year driven by 24% volume growth, partially offset by lower net selling price. The final rule from the Centers for Medicare & Medicaid Services (CMS) to include calcimimetics in the end stage renal disease (ESRD) bundled payment system is expected in November 2020, with implementation projected for January 2021. In anticipation of this change, we believe U.S. sales were negatively impacted late in the third quarter and we expect this trend to continue in the fourth quarter.
- **Otezla** generated $538 million of sales in the third quarter of 2020. U.S. Otezla TRx volume growth remained strong with an 11% year-over-year increase, and NBRx volumes continued to recover from the impacts of COVID-19. Net selling price was flat year-over-year in the U.S. Third quarter year-over-year Otezla sales* were negatively impacted by lower inventory levels and unfavorable changes to estimated sales deductions. Otezla continues to lead in biologic-naïve patient share in moderate-to-severe psoriasis.
- **Enbrel®** (etanercept) sales decreased 3% year-over-year driven by lower volumes, partially offset by favorable changes to estimated sales deductions. Enbrel continued to lose share in the third quarter, and that dynamic was compounded with lower growth of the rheumatology segment due to COVID-19. Net selling price was flat year-over-year.
- **AMGEVITA ™** (adalimumab) increased 31% year-over-year driven by 49% volume growth, partially offset by lower net selling price. AMGEVITA continues to be the most prescribed adalimumab biosimilar in Europe.
- **KYPROLIS®** (carfilzomib) sales decreased 2% year-over-year driven by volume declines, as fewer new patients began treatment due to COVID-19. Early indications point to a strong launch of the new once-weekly KYPROLIS and DARZALEX® (daratumumab) combination regimen that was approved by the U.S. Food and Drug Administration (FDA) in August.
- **XGEVA®** (denosumab) sales increased 1% year-over-year. Sales increased 11% quarter-over-quarter, reflecting a recovery in the number of patients returning to treatment.
- **Vectibix®** (panitumumab) sales declined 2% year-over-year driven by volume declines.
- **Nplate®** (romiplostim) sales increased 9% year-over-year driven by volume growth.
- **BLINCYTO®** (blinatumomab) sales increased 5% year-over-year driven by volume growth as we continued to see broader adoption in the community hospital setting.
- **MVASI** generated $231 million of sales in the third quarter of 2020, with 44% exit share of the bevacizumab segment in the U.S. Sales increased 34% quarter-over-quarter driven by 36% volume growth, partially offset by a decline in net selling price. Going forward, we expect the launch of additional competing biosimilars in the U.S.
- **KANJINTI** generated $167 million of sales in the third quarter of 2020, with 34% exit share of the trastuzumab segment in the U.S. Sales increased 36% quarter-over-quarter driven by 11% volume growth and favorable changes to estimated sales deductions. Moving forward, we expect volume growth will be offset by a decline in net selling price due to increased competition.
- **Neulasta®** (pegfilgrastim) sales decreased 22% year-over-year driven by declines in volumes and net selling price due to increased biosimilar competition, partially offset by favorable changes to estimated sales deductions. Within the long-acting granulocyte colony-stimulating factor (G-CSF) segment, Neulasta Onpro® continues to be the preferred choice for physicians and patients, with volume share of 55% in the quarter. CMS's most recently published average selling price for Neulasta in the U.S. declined 19% year-over-year and declined 6% quarter-over-quarter. Going forward, we expect the pricing and volume trends to continue.
- **NEUPOGEN®** (filgrastim) sales increased 20% year-over-year driven by favorable changes to estimated sales deductions, partially offset by 19% volume decline due to competition.
- **EPOGEN®** (epoetin alfa) sales decreased 31% year-over-year driven by volume declines as well as lower net selling price resulting from our existing contractual commitment with DaVita.
- **Aranesp®** (darbepoetin alfa) sales decreased 15% year-over-year driven by lower net selling price and volume declines due to competition.
- **Sensipar/Mimpara®** (cinacalcet) sales decreased 64% year-over-year driven by declines in volume and net selling price due to generic competition.

**Third quarter 2019 Sales information derived from Celgene Corporation's reporting for that period.*

Product Sales Detail by Product and Geographic Region

$Millions, except percentages	Q3 '20			Q3 '19	YOY Δ
	US	ROW	TOTAL	TOTAL	TOTAL
Prolia®	$ 478	$ 223	$ 701	$ 630	11%
EVENITY®	54	5	59	59	—
Repatha®	92	113	205	168	22%
Aimovig®	105	—	105	66	59%
Parsabiv®	156	27	183	157	17%
Otezla®	439	99	538	—	NM
Enbrel®	1,289	36	1,325	1,366	(3%)
AMGEVITA ™	—	80	80	61	31%
KYPROLIS®	173	87	260	266	(2%)
XGEVA®	363	118	481	476	1%
Vectibix®	90	103	193	196	(2%)
Nplate®	118	94	212	195	9%
BLINCYTO®	54	35	89	85	5%
MVASI®	185	46	231	43	*
KANJINTI®	149	18	167	69	*
Neulasta®	484	71	555	711	(22%)
NEUPOGEN®	44	21	65	54	20%
EPOGEN®	149	—	149	215	(31%)
Aranesp®	158	226	384	452	(15%)
Sensipar®/Mimpara®	7	32	39	109	(64%)
Other**	31	52	83	85	(2%)
Total product sales	$ 4,618	$ 1,486	$ 6,104	$ 5,463	12%

NM = not meaningful
* Change in excess of 100%
** Other includes GENSENTA, IMLYGIC®, Corlanor®, Bergamo and AVSOLA®

Operating Expense, Operating Margin and Tax Rate Analysis

On a GAAP basis:

- **Total Operating Expenses** increased 22%. **Cost of Sales** margin increased 6.6 percentage points driven by amortization expense related to the Otezla acquisition. **Research & Development (R&D)** expenses increased 6% driven by higher spend in support of our late-stage development programs, primarily sotorasib, our biosimilar programs and Otezla, partially offset by recoveries from our collaboration with BeiGene. **Selling, General & Administrative (SG&A)** expenses increased 10% primarily due to Otezla commercial related expenses.
- **Operating Margin** decreased 5.1 percentage points to 40.2% primarily driven by the amortization of intangible assets from our Otezla acquisition.
- **Tax Rate** decreased 5.2 percentage points primarily driven by favorable items in the quarter, including effective settlement of certain federal income tax matters and adjustments to prior year tax liabilities, partially offset by changes in jurisdictional mix of earnings.

On a non-GAAP basis:

- **Total Operating Expenses** increased 10%. **Cost of Sales** margin increased 0.4 percentage points primarily driven by an increase in royalties, partially offset by favorable product mix. **R&D** expenses increased 6% driven by higher spend in support of our late-stage development programs, primarily sotorasib, our biosimilar programs and Otezla, partially offset by recoveries from our collaboration with BeiGene. **SG&A** expenses increased 10% primarily due to Otezla commercial related expenses.
- **Operating Margin** increased 1.0 percentage point to 52.1%.
- **Tax Rate** decreased 1.7 percentage points primarily driven by favorable items in the quarter, including adjustments to prior year tax liabilities, partially offset by changes in jurisdictional mix of earnings.

$Millions, except percentages	GAAP			Non-GAAP		
	Q3 '20	Q3 '19	YOY Δ	Q3 '20	Q3 '19	YOY Δ
Cost of Sales	$ 1,561	$ 1,036	51%	$ 874	$ 760	15%
% of product sales	25.6%	19.0%	6.6 pts	14.3%	13.9%	0.4 pts
Research & Development	$ 1,062	$ 1,001	6%	$ 1,037	$ 977	6%
% of product sales	17.4%	18.3%	(0.9) pts	17.0%	17.9%	(0.9) pts
Selling, General & Administrative	$ 1,346	$ 1,223	10%	$ 1,329	$ 1,207	10%
% of product sales	22.1%	22.4%	(0.3) pts	21.8%	22.1%	(0.3) pts

Other	$ 1	$ 1	—	$ —	$ —	— %
Total Operating Expenses	**$ 3,970**	**$ 3,261**	**22%**	**$ 3,240**	**$ 2,944**	**10%**
Operating Margin						
operating income as % of product sales	40.2%	45.3%	(5.1) pts	52.1%	51.1%	1.0 pts
Tax Rate	**8.4%**	**13.6%**	**(5.2) pts**	**13.5%**	**15.2%**	**(1.7) pts**

pts: percentage points

Cash Flow and Balance Sheet

- The Company generated $3.2 billion of free cash flow in the third quarter of 2020 versus $3.2 billion in the third quarter of 2019.
- The Company's third quarter 2020 dividend of $1.60 per share was declared on July 23, 2020, and was paid on September 8, 2020 to all stockholders of record as of August 17, 2020, representing a 10% increase from 2019.
- During the third quarter, the Company repurchased 3.0 million shares of common stock at a total cost of $752 million. At the end of the third quarter, the Company had $4.2 billion remaining under its stock repurchase authorization.
- Cash and investments totaled $12.4 billion and debt outstanding totaled $34.3 billion at the end of Q3 2020.

$Billions, except shares	Q3 '20	Q3 '19	YOY Δ
Operating Cash Flow	$ 3.4	$ 3.4	$ 0.0
Capital Expenditures	0.1	0.2	0.0
Free Cash Flow	3.2	3.2	0.0
Dividends Paid	0.9	0.9	0.1
Share Repurchases	0.8	1.2	(0.4)
Average Diluted Shares (millions)	589	602	(13)
	9/30/20	**12/31/19**	**YTD Δ**
Cash and Investments	$ 12.4	$ 8.9	$ 3.5
Debt Outstanding	34.3	29.9	4.4

Note: Numbers may not add due to rounding

2020 Guidance

For the full year 2020, the Company now expects:

- **Total revenues** in the range of $25.1 billion to $25.5 billion.
  - Previously, the Company expected total revenues in the range of $25.0 billion to $25.6 billion.
- On a **GAAP basis, EPS** in the range of $11.53 to $11.93 and a **tax rate** in the range of 9.5% to 10.5%.
  - Previously, the Company expected GAAP EPS in the range of $10.73 to $11.43 and a tax rate in the range of 10.5% to 11.5%.
- On a **non-GAAP basis, EPS** in the range of $15.80 to $16.15 and a **tax rate** in the range of 13.0% to 14.0%.
  - Previously, the Company expected non-GAAP EPS in the range of $15.10 to $15.75 and a tax rate in the range of 13.5% to 14.5%.
- **Capital expenditures** to be approximately $600 million.
- **Quarterly dividend** maintained at $1.60 per share.
- **Share repurchases** at the lower end of our previous guidance of $3 billion to $5 billion.

Third Quarter Product and Pipeline Update

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

Sotorasib

- The Company discussed the previously announced Phase 1 data and positive topline results from the Phase 2 monotherapy study of sotorasib in patients with advanced non-small cell lung cancer (NSCLC).
- Data from the Phase 2 monotherapy study in advanced colorectal cancer patients are expected in H1 2021.
- A Phase 3 study comparing sotorasib to docetaxel is enrolling patients with advanced NSCLC.
- 7 Phase 1b combination cohorts are now enrolling patients.

Bispecific Programs

- The Company expects initial data from Phase 1 dose escalation studies of the following half-life extended (HLE) BiTE® constructs in Q4 2020:
  - AMG 701 targeting BCMA (B-cell maturation antigen) for relapsed or refractory multiple myeloma
  - AMG 757 targeting DLL3 (delta-like ligand 3) for relapsed or refractory small cell lung cancer, to be presented at

the Society for Immunotherapy of Cancer Annual Meeting, November 9-14, 2020

- Phase 1 development of the HLE BiTE® construct, AMG 562, targeting CD19 for non-Hodgkin's lymphoma has been stopped due to portfolio prioritization.

BLINCYTO

- The Company discussed encouraging results recently published in the New England Journal of Medicine from an independent clinical study of an investigational regimen of dasatinib induction therapy followed by blinatumomab consolidation therapy in adults with Philadelphia chromosome positive acute lymphoblastic leukemia.

Tezepelumab

- Data are expected in Q4 from the pivotal Phase 3 NAVIGATOR study evaluating tezepelumab in adults and adolescents with severe, uncontrolled asthma.
- Data are expected in Q4 from the Phase 3 SOURCE study evaluating tezepelumab for the reduction of oral corticosteroid use in adults with oral corticosteroid dependent asthma.

Efavaleukin alfa (AMG 592)

- In October, the Company announced that the planned Phase 2 study of efavaleukin alfa in patients with Systemic Lupus Erythematosus was selected for participation in the FDA's Complex Innovative Trial Designs (CID) Pilot Program. The CID Pilot Program aims to facilitate and advance the use of novel clinical trial designs that support the development and regulatory review of new therapeutics. The FDA considers several eligibility factors when selecting qualifying programs, including the level of innovation of the trial design, and the therapeutic need.

ABP 654 (biosimilar ustekinumab)

- The Company has advanced ABP 654, a biosimilar candidate to STELARA® (ustekinumab), into Phase 3 development.

KYPROLIS

- In August, the FDA approved the expansion of the KYPROLIS U.S. prescribing information to include its use in combination with DARZALEX® plus dexamethasone in two dosing regimens—once weekly and twice weekly—for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three previous lines of therapy.

MCL-1 Inhibitor Program

- Phase 1 studies of MCL-1 inhibitors AMG 176 and AMG 397 are reinitiating enrollment of patients with hematologic malignancies.

Nplate

- The FDA has granted priority review for Nplate for the treatment of Hematopoietic Syndrome of Acute Radiation Syndrome, with a Prescription Drug User Fee Act target action date of January 28, 2021. Research was conducted in collaboration with and support from both the National Institute of Allergy and Infectious Diseases and the Biomedical Advanced Research and Development Authority.

ABP 798 (biosimilar rituximab)

- The FDA Biosimilar User Fee Act target action date for the Biologics License Application for ABP 798, a biosimilar candidate to RITUXAN® (rituximab), is December 19, 2020.

Omecamtiv mecarbil

- The Company discussed the topline results from the Phase 3 GALACTIC-HF trial of omecamtiv mecarbil in patients with heart failure with reduced ejection fraction.

Olpasiran (AMG 890)

- The FDA granted Fast Track designation for olpasiran, a lipoprotein(a) small interfering RNA currently in Phase 2 development for the treatment of atherosclerotic cardiovascular disease.

Otezla

- Otezla is being investigated as a potential immunomodulatory treatment in patients hospitalized with SARS-CoV-2 infections in multiple COVID-19 platform trials.

Aimovig

- In September, a marketing authorization application was filed with the Japan Pharmaceuticals and Medical Devices Agency for Aimovig for the prevention of migraine.
- In October, results from the five-year, open-label treatment period of a Phase 2 study in episodic migraine prevention showed Aimovig helped patients achieve sustained reductions in monthly migraine days and in use of acute migraine-specific medication. The safety profile was consistent with what was observed in the double-blind treatment phase of the study, with no increases in adverse event rates over five years of exposure.

COVID-19 Therapeutics

- In September, the Company announced a global antibody manufacturing collaboration to significantly increase the supply capacity available for Eli Lilly's potential COVID-19 therapies.

DARZALEX and STELARA are registered trademarks of Janssen Pharmaceutica NV

Omecamtiv mecarbil is being developed under a collaboration between Amgen and Cytokinetics, with funding and strategic support from Servier

Tezepelumab is being developed in collaboration with AstraZeneca

RITUXAN is a registered trademark of Biogen Inc.

Non-GAAP Financial Measures

In this news release, management has presented its operating results for the third quarters of 2020 and 2019, in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and on a non-GAAP basis. In addition, management has presented its full year 2020 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 2020 and 2019. 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 any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company, including BeiGene, Ltd. or any collaboration or potential collaboration in pursuit of therapeutic antibodies against COVID-19 (including statements regarding such collaboration's, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 or antibodies against targets other than the SARS-CoV-2 receptor binding domain, and/or to produce any such antibodies to potentially prevent or treat COVID-19), or the Otezla acquisition (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in

manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. 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,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Product sales	$ 6,104	$ 5,463	$ 17,906	$ 16,323
Other revenues	319	274	884	842
Total revenues	6,423	5,737	18,790	17,165
Operating expenses:				
Cost of sales	1,561	1,036	4,562	3,103
Research and development	1,062	1,001	2,978	2,804
Selling, general and administrative	1,346	1,223	3,957	3,637
Other	1	1	162	(5)
Total operating expenses	3,970	3,261	11,659	9,539
Operating income	2,453	2,476	7,131	7,626
Interest expense, net	302	313	944	988
Interest and other income, net	55	114	69	517
Income before income taxes	2,206	2,277	6,256	7,155
Provision for income taxes	185	309	607	1,016
Net income	$ 2,021	$ 1,968	$ 5,649	$ 6,139
Earnings per share:				
Basic	$ 3.45	$ 3.29	$ 9.61	$ 10.08
Diluted	$ 3.43	$ 3.27	$ 9.54	$ 10.01

Weighted-average shares used in calculation of earnings per share:				
Basic	585	599	588	609
Diluted	589	602	592	613

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

	September 30, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 12,360	$ 8,911
Trade receivables, net	4,094	4,057
Inventories	3,942	3,584
Other current assets	2,265	1,888
Total current assets	22,661	18,440
Property, plant and equipment, net	4,816	4,928
Intangible assets, net	17,254	19,413
Goodwill	14,674	14,703
Other assets	5,232	2,223
Total assets	$ 64,637	$ 59,707
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 9,862	$ 9,882
Current portion of long-term debt	91	2,953
Total current liabilities	9,953	12,835
Long-term debt	34,196	26,950
Long-term deferred tax liabilities	210	606
Long-term tax liabilities	7,560	8,037
Other noncurrent liabilities	1,759	1,606
Total stockholders' equity	10,959	9,673
Total liabilities and stockholders' equity	$ 64,637	$ 59,707
Shares outstanding	584	591

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
GAAP cost of sales	$ 1,561	$ 1,036	$ 4,562	$ 3,103
Adjustments to cost of sales:				
Acquisition-related expenses (a)	(687)	(276)	(2,159)	(828)
Non-GAAP cost of sales	$ 874	$ 760	$ 2,403	$ 2,275
GAAP cost of sales as a percentage of product sales	25.6%	19.0%	25.5%	19.0%
Acquisition-related expenses (a)	-11.3	-5.1	-12.1	-5.1
Non-GAAP cost of sales as a percentage of product sales	14.3%	13.9%	13.4%	13.9%
GAAP research and development expenses	$ 1,062	$ 1,001	$ 2,978	$ 2,804
Adjustments to research and development expenses:				
Acquisition-related expenses (a)	(24)	(24)	(77)	(62)
Certain net charges pursuant to our restructuring initiatives	(1)	—	(1)	—
Total adjustments to research and development expenses	(25)	(24)	(78)	(62)
Non-GAAP research and development expenses	$ 1,037	$ 977	$ 2,900	$ 2,742
GAAP research and development expenses as a percentage of product sales	17.4%	18.3%	16.6%	17.2%

Acquisition-related expenses (a)	-0.4	-0.4	-0.4	-0.4
Certain net charges pursuant to our restructuring initiatives	0.0	0.0	0.0	0.0
Non-GAAP research and development expenses as a percentage of product sales	17.0%	17.9%	16.2%	16.8%
GAAP selling, general and administrative expenses	$ 1,346	$ 1,223	$ 3,957	$ 3,637
Adjustments to selling, general and administrative expenses:				
Acquisition-related expenses (a)	(15)	(17)	(74)	(26)
Certain net charges pursuant to our restructuring initiatives	—	1	—	1
Other	(2)	—	(2)	—
Total adjustments to selling, general and administrative expenses	(17)	(16)	(76)	(25)
Non-GAAP selling, general and administrative expenses	$ 1,329	$ 1,207	$ 3,881	$ 3,612
GAAP selling, general and administrative expenses as a percentage of product sales	22.1%	22.4%	22.1%	22.3%
Acquisition-related expenses (a)	-0.3	-0.3	-0.4	-0.2
Certain net charges pursuant to our restructuring initiatives	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Non-GAAP selling, general and administrative expenses as a percentage of product sales	21.8%	22.1%	21.7%	22.1%
GAAP operating expenses	$ 3,970	$ 3,261	$ 11,659	$ 9,539
Adjustments to operating expenses:				
Adjustments to cost of sales	(687)	(276)	(2,159)	(828)
Adjustments to research and development expenses	(25)	(24)	(78)	(62)
Adjustments to selling, general and administrative expenses	(17)	(16)	(76)	(25)
Certain net charges pursuant to our restructuring initiatives	—	—	4	2
Certain other expenses (b)	(1)	(1)	(166)	3
Total adjustments to operating expenses	(730)	(317)	(2,475)	(910)
Non-GAAP operating expenses	$ 3,240	$ 2,944	$ 9,184	$ 8,629
GAAP operating income	$ 2,453	$ 2,476	$ 7,131	$ 7,626
Adjustments to operating expenses	730	317	2,475	910
Non-GAAP operating income	$ 3,183	$ 2,793	$ 9,606	$ 8,536

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
GAAP operating income as a percentage of product sales	40.2%	45.3%	39.8%	46.7%
Adjustments to cost of sales	11.3	5.1	12.1	5.1
Adjustments to research and development expenses	0.4	0.4	0.4	0.4
Adjustments to selling, general and administrative expenses	0.3	0.3	0.4	0.2
Certain net charges pursuant to our restructuring initiatives	0.0	0.0	0.0	0.0
Certain other expenses (b)	0.0	0.0	0.9	-0.1
Non-GAAP operating income as a percentage of product sales	52.1%	51.1%	53.6%	52.3%
GAAP interest and other income, net	$ 55	$ 114	$ 69	$ 517
Adjustments to interest and other income, net (c)	36	—	—	—
Non-GAAP interest and other income, net	$ 91	$ 114	$ 69	$ 517
GAAP income before income taxes	$ 2,206	$ 2,277	$ 6,256	$ 7,155
Adjustments to operating expenses	730	317	2,475	910
Adjustments to interest and other income, net	36	—	—	—
Non-GAAP income before income taxes	$ 2,972	$ 2,594	$ 8,731	$ 8,065
GAAP provision for income taxes	$ 185	$ 309	$ 607	$ 1,016
Adjustments to provision for income taxes:				
Income tax effect of the above adjustments (d)	160	92	495	230
Other income tax adjustments (e)	55	(8)	63	(35)
Total adjustments to provision for income taxes	215	84	558	195
Non-GAAP provision for income taxes	$ 400	$ 393	$ 1,165	$ 1,211
GAAP tax as a percentage of income before taxes	8.4%	13.6%	9.7%	14.2%
Adjustments to provision for income taxes:				
Income tax effect of the above adjustments (d)	3.2	1.9	2.9	1.2
Other income tax adjustments (e)	1.9	-0.3	0.7	-0.4
Total adjustments to provision for income taxes	5.1	1.6	3.6	0.8
Non-GAAP tax as a percentage of income before taxes	13.5%	15.2%	13.3%	15.0%

GAAP net income	$ 2,021	$ 1,968	$ 5,649	$ 6,139
Adjustments to net income:				
Adjustments to income before income taxes, net of the income tax effect	606	225	1,980	680
Other income tax adjustments (e)	(55)	8	(63)	35
Total adjustments to net income	551	233	1,917	715
Non-GAAP net income	$ 2,572	$ 2,201	$ 7,566	$ 6,854

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, 2020		Three months ended September 30, 2019	
	GAAP	**Non-GAAP**	**GAAP**	**Non-GAAP**
Net income	$ 2,021	$ 2,572	$ 1,968	$ 2,201
Weighted-average shares for diluted EPS	589	589	602	602
Diluted EPS	$ 3.43	$ 4.37	$ 3.27	$ 3.66

	Nine months ended September 30, 2020		Nine months ended September 30, 2019	
	GAAP	**Non-GAAP**	**GAAP**	**Non-GAAP**
Net income	$ 5,649	$ 7,566	$ 6,139	$ 6,854
Weighted-average shares for diluted EPS	592	592	613	613
Diluted EPS	$ 9.54	$ 12.78	$ 10.01	$ 11.18

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

(b) 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.

(c) For the three months ended September 30, 2020, the adjustment related to the amortization of the basis difference from our BeiGene equity method investment. For the nine months ended September 30, 2020, the adjustment related primarily to a gain from legal judgment proceeds offset by amortization of the basis difference from our BeiGene equity method investment.

(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. 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, 2020, were 20.9% and 20.0%, compared with 29.0% and 25.3% for the corresponding periods of the prior year.

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2020	**2019**	**2020**	**2019**
Net cash provided by operating activities	$ 3,368	$ 3,377	$ 8,344	$ 6,636
Net cash (used in) provided by investing activities	(1,628)	5,372	(4,017)	11,672
Net cash used in financing activities	(1,798)	(2,859)	(1,277)	(13,838)
(Decrease) increase in cash and cash equivalents	(58)	5,890	3,050	4,470
Cash and cash equivalents at beginning of period	9,145	5,525	6,037	6,945

Cash and cash equivalents at end of period	$ 9,087	$ 11,415	$ 9,087	$ 11,415

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Net cash provided by operating activities	$ 3,368	$ 3,377	$ 8,344	$ 6,636
Capital expenditures	(135)	(170)	(435)	(430)
Free cash flow	$ 3,233	$ 3,207	$ 7,909	$ 6,206

Amgen Inc.
Reconciliation of GAAP EPS Guidance to Non-GAAP
EPS Guidance for the Year Ending December 31, 2020
(Unaudited)

GAAP diluted EPS guidance	$11.53	—	$11.93
Known adjustments to arrive at non-GAAP*:			
Acquisition-related expenses (a)	4.24	—	4.29
Net legal proceedings	0.09		
Other tax adjustments (b)	(0.11)		
Non-GAAP diluted EPS guidance	$15.80	—	$16.15

* The known adjustments are presented net of their related tax impact, which amount to approximately $1.17 - $1.18 per share.

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

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

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 and changes in the fair value or our contingent consideration.

Reconciliation of GAAP Tax Rate Guidance to Non-GAAP
Tax Rate Guidance for the Year Ending December 31, 2020
(Unaudited)

GAAP tax rate guidance	9.5 %	—	10.5%
Tax rate of known adjustments discussed above	3.5%		
Non-GAAP diluted EPS guidance	13.0%	—	14.0%

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