Amgen Outlines Strategy, Growth Objectives And Capital Allocation Plans

October 28, 2014

Plans to Payout Approximately 60 Percent of Adjusted Net Income on Average to Shareholders Through 2018
Guides to Improved Adjusted Operating Margin of 52-54 Percent by 2018
Reinitiating Share Repurchases With Plans for Approximately $2 Billion Through 2015
Plans to Increase Dividend 30 Percent Beginning 1Q 2015
Expects to Deliver Double-Digit Adjusted Earnings Per Share (EPS) Growth on Average Through 2018
$1.5 Billion in Annual Savings Planned by 2018
Preparing to Launch Four High-Potential Innovative Medicines in 2015
Expands Biosimilars Portfolio to Nine Programs, Total Portfolio Represents a $3 Billion Plus Opportunity
Launching Next-Generation Biomanufacturing Technologies in 2017
Provides Preliminary 2015 Guidance of Revenues of $20.8-$21.3 Billion and Adjusted EPS of $9.05-$9.40

NEW YORK, Oct. 28, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today outlined the Company's strategy, growth objectives and capital allocation plans, and provided financial guidance for 2015.

Robert A. Bradway, chairman and chief executive officer at Amgen, opened the meeting by affirming that the Company's strategy will continue to focus on discovery and development of innovative medicines to address serious illnesses, development of branded biosimilars, next-generation biomanufacturing of high quality biologics, developing improved biologic drug delivery systems, global expansion, and capital allocation and return to shareholders and long-term value opportunities. Bradway highlighted that while delivering on Amgen's strategy for growth, the Company is transforming to enhance its capabilities to deliver long-term industry-leading innovation and industry-leading financial returns.

"With four potential product launches in 2015 and a strong pipeline of innovative and biosimilar molecules, we are well positioned to deliver breakthrough medicines for patients and drive long-term growth," said Bradway.

Amgen initiated a company-wide re-engineering process in 2013 to ensure clear reallocation of resources to invest in our continuing innovation and the launch of our new pipeline medicines. The Company's transformation includes a significant restructuring, with an approximate 23 percent decrease in facilities footprint and an approximate 20 percent reduction in staff by the end of 2015. As a result, the Company expects to generate up to $1.5 billion in annual savings and a 15 point adjusted operating margin increase by 2018.

Bradway affirmed Amgen is on track to produce commercial products from its new Singapore next-generation biomanufacturing facility beginning in 2017. Next-generation biomanufacturing will enable dramatically increased bulk production capabilities versus conventional alternatives at one-quarter of the capital costs, one-third of the operating expense, and twice the speed. The Company estimates these new capabilities will result in an estimated cost reduction of 60 percent or more per gram of protein.

"This is an exciting new era for Amgen. We are on the cusp of an important new product cycle with our rich pipeline of innovative and biosimilar medicines that address important societal needs," said Bradway. "Our significantly expanded global presence and new biomanufacturing technologies give us confidence that Amgen is uniquely positioned to capitalize on the latest wave of opportunity for innovative biologic therapies."

Strategic Approach to R&D
Sean E. Harper, M.D., executive vice president of Research and Development at Amgen discussed Amgen's strategic approach to R&D, progress on operational efficiency, and highlights of the Company's ongoing clinical programs.

The Company's R&D approach will follow a refined set of guiding principles:

- Focus on innovative medicines for unmet needs in patients with serious illnesses;
- Emphasis on target validation in humans;
- Modality independence with focus on biologics;
- Focus on return on investment and operational efficiency;
- Harness external innovation; and
- Demonstrate the value of Amgen's medicines.

In addition, Amgen has refocused and differentiated its Discovery Research efforts. Amgen's Discovery Research efforts are focused within inflammation and oncology, metabolism and bone, cardiovascular and neuroscience. The Company has consolidated small, medium and large molecule technologies into one integrated platform; focused efforts on immuno-oncology; and leveraged its industry-leading position in human population genetics to identify or validate targets in humans wherever possible.

Harper discussed how the Company has deployed deCODE to enhance R&D productivity, citing examples of programs validated and accelerated or invalidated and terminated. He also reviewed how the BiTE® antibody construct platform is now clinically validated and also attractive for combination approaches.

Harper described the continuous improvement culture that is contributing to the total enterprise annual savings of up to $1.5 billion by 2018:

- Disciplined project prioritization to maintain focus;
- Partnering strategy to complement core competencies;

- Refocused Discovery Research investment;
- Reduced geographic complexity and cost;
- Reduced cycle times for biologics and genetically validated targets; and
- Leaner clinical trial programs.

"Amgen's world-class modality platform and our ability to associate genetic variation with risk of disease make us uniquely positioned to advance breakthrough medicines to address serious illness," said Harper. "Our exceptional genetic validation capabilities have strengthened our pipeline, allowing us to 'pick the winners' and focus our investment decisions."

Harper said Amgen's late-stage pipeline is advancing with four programs currently under regulatory review, Phase 3 data expected from three additional programs by the end of this year, Phase 3 rilotumumab data expected in 2015, and Phase 3 romosozumab data expected in 2016. Highlights include:

- **Evolocumab:** Under regulatory review in the U.S. and Europe for dyslipidemia. Results from a Phase 3 vascular imaging study in 950 patients are expected in 2016. Our long-term Phase 3 outcomes trial has been expanded by 5,000 patients to 27,500, and results are expected no later than 2017 (event-driven).
- **Ivabradine:** Under Priority Review by the U.S. Food and Drug Administration (FDA) for chronic heart failure.
- **Omecamtiv mecarbil**: Results from the Phase 2b oral formulation study in chronic heart failure patients are expected in 2015.
- **Romosozumab:** Results from a Phase 3 placebo-controlled study in 6,000 women with postmenopausal osteoporosis are expected in the first half of 2016. Results from a second event-driven Phase 3 study evaluating romosozumab versus alendronate in 4,000 women are expected in 2017.
- **Brodalumab:** Data from two placebo-controlled studies of brodalumab versus ustekinumab are expected by year-end. Phase 3 psoriatic arthritis data are expected in 2016.
- **AMG 334:** Results from a Phase 2b episodic migraine study are expected by year-end, followed by results from a Phase 2 chronic migraine study in 2016.
- **Talimogene laherparepvec:** Under regulatory review in the U.S. and Europe for the treatment of regionally or distantly metastatic melanoma. Data from a Phase 2 combination study with ipilimumab are expected in 2016, followed by results from a Phase 2 combination study with pembrolizumab in 2017.
- **Blinatumomab:** Under Priority Review by the FDA for relapsed/refractory B-precursor acute lymphocytic leukemia (ALL); under regulatory review in Europe. Results from a Phase 2 study in adult patients with minimal residual disease positive ALL are expected in 2014 and from a Phase 3 study in adult patients with relapsed, refractory ALL in 2016.
- **Trebananib**: Overall survival results from the TRINOVA-1 Phase 3 trial in women with recurrent ovarian cancer are expected by year-end. Progression-free survival data are expected from the TRINOVA-2 first-line ovarian cancer study in 2015.
- **Rilotumomab:** Data from an event-driven Phase 3 trial evaluating rilotumomab for the treatment of gastric cancer are expected in 2015.
- **AMG 416**: Results from a Phase 3 trial evaluating AMG 416 versus Sensipar® (cinacalcet) for the treatment of secondary hyperparathyroidism are expected in 2015.

Harper also discussed AMG 157, a human monoclonal antibody that inhibits the action of Thymic Stromal Lymphopoietin (TSLP), as an example of Amgen's innovative approach in inflammation.

Onyx Update

Pablo J. Cagnoni, M.D., president of Amgen's subsidiary, Onyx Pharmaceuticals, Inc., described the substantial growth opportunity for Kyprolis® (carfilzomib) in relapsed multiple myeloma based on the unprecedented progression-free survival observed in the ASPIRE study, as well as potential opportunity for weekly dosing administration. Results from the ENDEAVOR Phase 3 head-to-head study versus bortezomib in relapsed patients are expected in 2016, followed by results from the head-to-head CLARION trial in newly diagnosed patients in 2017. A Phase 3 trial evaluating weekly dosing administration is being planned.

Cagnoni also described U.S. launch plans for blinatumomab in adult relapsed/refractory ALL.

Commercial Update

During the meeting, Anthony C. Hooper, executive vice president of Global Commercial Operations at Amgen, described the potential doubling of the product portfolio over the next three years and outlined several growth opportunities, including leveraging strong specialty market experience; driving continued momentum in the current portfolio of growth phase products; successfully launching several new innovative products and biosimilars; and continuing to move into new geographic growth markets. Approximately $2 billion in sales in new and emerging markets in Asia, Turkey and the Middle East, Latin America, and Russia and Eastern Europe are anticipated by 2018.

Hooper provided an update on Amgen's commercial strategy in its five specialty areas. Highlights include:

- **Inflammation:** Enbrel® (etanercept) is expected to reach $5 billion in sales ahead of Amgen's biosimilar adalimumab launch and realize a step up in profitability starting in November 2016 with expiry of the Pfizer royalty.
- **Nephrology:** Sensipar has the potential to reach approximately $1.5 billion in sales before patent expiry in 2018.
- **Bone Health:** Prolia® (denosumab) U.S. share has quadrupled over the past two years and is annualizing at $1 billion in sales in 2014[1]. Romosozumab potentially provides a monthly bone-building alternative for patients with osteoporosis.

- **Oncology:** The Company announced that the Neulasta® (pegfilgrastim) on-body delivery system is under FDA review. The commercial opportunity and launch strategy for talimogene laherparepvec was discussed.
- **Cardiovascular:** The commercial opportunity and launch strategy for ivabradine and evolocumab was discussed.

Hooper also discussed how Amgen is transforming its commercial model and contributing to the total enterprise annual savings of up to $1.5 billion by 2018:

- Focusing on therapeutic areas that leverage the Company's expertise and infrastructure;
- Enhancing capabilities to derive deeper customer insights and prepare for value and access challenges;
- Increasing field flexibility to adapt to the changing customer and healthcare provider system landscape;
- Testing innovative models for engaging patients, providers and payers; and
- Deploying innovative technology to enable customer partnerships.

Biosimilars
Scott Foraker, vice president and general manager, Biosimilars, at Amgen, discussed how biosimilars are a good strategic fit for the Company and represent a compelling growth opportunity with the potential to deliver more than $3 billion in annual revenues. In addition to the biosimilar adalimumab, trastuzumab, bevacizumab, infliximab, rituximab and cetuximab programs, Amgen has initiated three additional biosimilar programs. Foraker noted that Amgen's biosimilar infliximab and rituximab have advanced to the "clinical ready" phase. Amgen's first biosimilar is expected to launch in 2017, followed by four others through 2019.

Foraker described how Amgen's decades of proven biologics R&D experience, strong biologics manufacturing heritage, track record for high quality and reliable supply, and branded commercial capabilities provide a significant competitive advantage.

Multiple Approaches to Creating Shareholder Value
David Meline, executive vice president and chief financial officer at Amgen, reviewed the Company's financial strategy and multiple approaches to create shareholder value:

- Deliver long-term growth and shareholder returns through new global innovative product launches, biosimilars and international expansion;
- Execute a focused operating model to increase efficiency, agility, and speed to market while increasing operating margins; and
- Provide attractive returns to shareholders through share repurchases and dividend growth, while maintaining continuous access to capital markets and investing in the business.

Meline highlighted strong commercial execution, continued pipeline progress, international expansion, transformation efforts and capital allocation strategy.

Meline described how the Company is executing a focused operating model designed to generate growth, drive innovation, align resources to the highest priorities and support pipeline development, improve key cross-functional processes and create capabilities to drive change and continuous improvement. The operating model is contributing to adjusted operating margin improvement to 52-54 percent by 2018.

Meline provided an update on previously announced plans to reduce the Company's global workforce by approximately 2,900 positions by the end of 2015 and reduce its facilities footprint by approximately 23 percent. Next steps of the Company's restructuring efforts were announced, including plans to reduce headcount by an additional 600-1,100 positions in 2015. The additional actions will result in pre-tax accounting charges in the range of $100-$150 million, which are expected to be incurred primarily in 2015. The total restructuring pre-tax GAAP charges of between approximately $935 million and $1,035 million will be incurred in 2014 and 2015, with $376 million already incurred in the third quarter of 2014. The focused operating model and combined restructuring actions will result in a total annual savings of up to $1.5 billion and an approximate 15 point adjusted operating margin improvement by 2018.

Meline said that Amgen will continue to execute on its capital allocation strategy focused on supporting the business with a minimum weighted average cost of capital. Additionally, it is the Company's plan to return, on average, approximately 60 percent of adjusted net income to shareholders through 2018. The Company plans to increase its dividend 30 percent in the first quarter of 2015 and to repurchase approximately $2 billion in Amgen shares through year-end 2015; additionally, the Company's share repurchase authorization has been increased to $4 billion in total. In addition, Meline affirmed Amgen plans to maintain its investment-grade rating and continuous access to the capital markets.

The Company provided preliminary financial guidance for 2015:

- Revenues of $20.8-$21.3 billion;
- Adjusted earnings per share (EPS) of $9.05-$9.40;
- Adjusted tax rate of 18-19 percent, excluding the R&D tax credit; and
- Capital expenditures of approximately $800 million.

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 biologics manufacturing 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 the world's largest independent biotechnology company, 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 Inc. and its subsidiaries (Amgen or us) and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. 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 (SEC) reports filed by Amgen Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Oct. 28, 2014, and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. 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, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us and our partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, 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. 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. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products (including products of our wholly-owned subsidiaries) are affected by the 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 as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while Amgen and its partners routinely obtain patents for their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, 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 integrate the operations of companies we have acquired may not be successful. Cost saving initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plans. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our common stock.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

Amgen Inc
GAAP Operating Income and Margin to Adjusted Operating Income and Margin Reconciliations
(In millions)
(Unaudited)

	2011	2013
GAAP operating income	$ 4,312	$ 5,867
Adjustments to operating income:		
Acquisition-related expenses (a)	342	986
Certain charges pursuant to our efforts to improve cost efficiencies in our operations (b)	162	71
Stock option expense	85	34
Expense related to various legal proceedings	786	14
Total adjustments to operating income	1,375	1,105
Adjusted operating income	$ 5,687	$ 6,972

Product sales	$15,295	$18,192
GAAP operating margin	28.2%	32.3%
Impact of total adjustments to operating income	9.0%	6.0%
Adjusted operating margin	37.2%	38.3%

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

(b) The adjustments related primarily to severance expenses.

Reconciliation of GAAP Income Before Income Taxes to Earnings Before Interest, Tax, Depreciation and Amortization (EBITDA)
(In millions)
(Unaudited)

	2013
GAAP income before income taxes	$ 5,265
Add:	
GAAP depreciation and amortization	1,286
GAAP interest expense, net	1,022
EBITDA	$ 7,573
Total debt	$32,128
Debt to EBITDA ratio	4.2

Amgen Inc
Reconciliation of GAAP Earnings Per Share to Adjusted Earnings Per Share (Unaudited)

	2011	2012	2013
GAAP earnings per share (diluted)	$ 4.04	$ 5.52	$ 6.64
Adjustments to GAAP earnings per share (a):			
Acquisition-related expenses (b)	0.24	0.42	0.91
Cost savings initiatives	0.12	0.31	0.06
Expenses related to various legal proceedings	0.78	0.07	0.02
Non-cash interest expense associated with our convertible notes	0.10	0.11	0.01
Stock option expense	0.06	0.05	-
Other tax adjustments (c)	(0.01)	0.03	(0.04)
Adjusted earnings per share (diluted)	$ 5.33	$ 6.51	$ 7.60

(a) The above adjustments are presented net of their related per-share tax impact of $0.38, $0.42 and $0.49 for 2011, 2012 and 2013, respectively.

(b) To exclude acquisition-related expenses related primarily to non-cash amortization of intangible assets, including developed product technology rights, acquired in business combinations.

(c) The adjustments related to resolving certain non-routine transfer-pricing and acquisition-related issues with tax authorities as well as the impact related to certain prior period items excluded from adjusted earnings, as applicable.

Amgen Inc
Reconciliation of GAAP EPS Guidance to Adjusted
EPS Guidance for the Year Ending December 31, 2014
(Unaudited)

		2014
GAAP diluted EPS guidance		$ 6.51 - $ 6.61
Known adjustments to arrive at Adjusted earnings*:		
Acquisition-related expenses	(a)	1.26
Restructuring and other cost savings initiatives		0.51

Branded prescription drug fee		0.19
Tax adjustments	(b)	(0.02)
Adjusted diluted EPS guidance		$ 8.45 - $ 8.55

***** The known adjustments are presented net of their related tax impact which amount to approximately $0.90 per share in the aggregate.

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

(b) The adjustments related to certain prior period items excluded from adjusted earnings.

Reconciliation of GAAP Tax Rate Guidance to Adjusted Tax Rate Guidance for the Year Ending December 31, 2014 (Unaudited)

	2014
GAAP tax rate guidance	10% - 11%
Tax rate effect of known adjustments discussed above	6%
Adjusted tax rate guidance	16% - 17%

Amgen Inc
Reconciliation of GAAP EPS Guidance to Adjusted EPS Guidance for the Year Ending December 31, 2015 (Unaudited)

		2015
GAAP diluted EPS guidance		$ 7.52 - $ 7.92
Known adjustments to arrive at Adjusted earnings*:		
Acquisition-related expenses	(a)	1.16
Restructuring and other cost savings initiatives		0.32 - 0.37
Adjusted diluted EPS guidance		$ 9.05 - $ 9.40

***** The known adjustments are presented net of their related tax impact which amount to approximately $0.74 to $0.76 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 Adjusted Tax Rate Guidance for the Year Ending December 31, 2015 (Unaudited)

	2015
GAAP tax rate guidance	14% - 16%
Tax rate effect of known adjustments discussed above	3% - 4%
Adjusted tax rate guidance	18% - 19%

Reconciliation of Future GAAP to Adjusted Financial Measures

Management has presented herein certain forward-looking statements about the Company's future financial performance that include non-GAAP (or "as-adjusted") net income, EPS, operating expenses, operating margin and income tax rate for various years through December 31, 2018 and EBITDA (which is a non-GAAP financial measure) for the Year Ending December 31, 2014. These non–GAAP financial measures are derived by excluding certain amounts, expenses or income, from the corresponding financial measures determined in accordance with GAAP. The determination of the amounts that are excluded from these non-GAAP financial measures are a matter of management judgment and depend upon, among other factors, the nature of the underlying expense or income amounts recognized in a given period. We are unable to present a quantitative reconciliation of the aforementioned forward-looking non-GAAP financial measures to their most directly comparable forward-looking GAAP financial measure because management cannot reliably predict all of the necessary components of such GAAP measures. Historically, management has excluded the following items from this non-GAAP financial measure, and such items may also be excluded in future periods and could be significant:

- Expenses related to the acquisition of businesses, including amortization and / or impairment of acquired intangible assets, including in-process research and development, adjustments to contingent consideration, integration costs, severance and retention costs and transaction costs;
- Charges associated with restructuring or cost saving initiatives, including but not limited to asset impairments, accelerated depreciation, severance costs and lease abandonment charges;
- Legal settlements or awards;
- The tax effect of the above items; and
- Non-routine settlements with tax authorities.

[1] Q3 2014 sales times 4

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