



## Amgen Outlines Long-Term Strategy

February 7, 2013

### Amgen Emphasizes Pipeline, International Expansion and Biosimilars as Growth Drivers Pivotal Data from Eight Late-Stage Programs Anticipated Between 2013 and 2016

NEW YORK, Feb. 7, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today outlined the company's long-term strategy during a Business Review meeting with analysts and investors in New York City.

Robert A. Bradway, chairman and chief executive officer at Amgen, opened the meeting by affirming the company's core strategy will continue to focus on innovation, discovery and development of breakthrough molecules to address significant unmet medical needs, and manufacturing of high-quality biologics. Bradway highlighted how certain elements of the company's strategy have evolved:

- **Research and Development (R&D):** A more selective approach to R&D, embracing a "pick the winners" strategy with greater focus on human genetics to identify and validate targets, and a strong commitment to return on capital;
- **Commercial:** Transformation of the commercial model with an emphasis on expanded access and value to payers, increased presence in key new and emerging markets, investment in new growth opportunities, including biosimilars, and greater product differentiation through drug delivery devices; and
- **Manufacturing:** Emphasis on new manufacturing processes and technologies, driving expanded throughput and flexibility and lower capital needs.

"Amgen is in a unique position to capitalize on major advances in drug discovery and biologics manufacturing," said Bradway. "We are making strategic investments to drive long-term growth and deliver for both patients and shareholders."

#### More Strategic Approach to R&D

Sean E. Harper, M.D., executive vice president of Research and Development at Amgen, discussed Amgen's new strategic approach to R&D and provided highlights of the company's ongoing clinical programs.

The company's R&D approach will continue to focus on innovations that address significant unmet needs for patients with serious illnesses, but will follow four strategic priorities:

- Demonstrating the value of our medicines;
- Following a "biology first" approach;
- Identifying and validating targets through human genetics; and
- Driving improvements in operational efficiency.

Amgen will continue to be opportunistic about acquiring external innovation to complement internal capabilities and programs.

"Amgen is uniquely positioned to shape the future of biotechnology," said Harper. "Our new R&D strategy embraces a 'pick the winners' approach, which takes advantage of the knowledge we've gained from decades of experience and our industry-leading position in human genetics that has resulted from our acquisition of deCODE."

Harper said Amgen's late-stage pipeline is advancing with data expected from eight pivotal programs by 2016. Highlights include:

- **AMG 145:** The AMG 145 Phase 3 program will enroll more than 26,000 patients across seven studies, including the treatment of hyperlipidemia with AMG 145 in:
  - 1,700 patients at risk for cardiovascular disease who are on statin therapy;
  - 300 patients who cannot tolerate statins;
  - 600 patients as monotherapy; and
  - 300 patients with heterozygous familial hypercholesterolemia.

Results from these four Phase 3 trials are expected in 2014. Additionally, a long-term Phase 3 outcomes trial is evaluating treatment with AMG 145 in combination with statins in 22,500 patients at high cardiovascular risk with results expected in 2018.

- **Romosozumab (AMG 785):** The romosozumab program will enroll approximately 10,000 postmenopausal osteoporosis patients in two pivotal Phase 3 studies:
  - A pivotal placebo-controlled trial that will evaluate incidence of new vertebral fractures at 12 and 24 months in 6,000 patients; and
  - An active-controlled trial versus alendronate that will evaluate the incidence of clinical fracture and new vertebral fracture at 12 and 24 months in 4,000 patients.
- **Brodalumab (AMG 827):** In Phase 3 for psoriasis. Results expected in 2014.
- **AMG 416:** In Phase 2 for secondary hyperparathyroidism. Results expected in 2014.
- **Talimogene laherparepvec:** In Phase 3 for melanoma. Results expected in 2013.

- **Trebananib (AMG 386):** In Phase 3 for ovarian cancer. Results expected beginning in 2013.
- **Blinatumomab (AMG 103):** In Phase 2 for acute lymphocytic leukemia. Results expected in 2014.
- **Rilotumomab (AMG 102):** In Phase 3 for gastric cancer. Results expected in 2016.

Harper also discussed AMG 334, a calcitonin gene-related peptide (CGRP) receptor antagonist monoclonal antibody, as an example of Amgen's innovative approach to R&D.

### Transforming the Commercial Model to Drive Revenue Growth

During the meeting, Anthony C. Hooper, executive vice president of Global Commercial Operations at Amgen, reviewed how Amgen is transforming its commercial model to build on its existing strengths and to enable new opportunities. He outlined several growth opportunities, including significantly expanding Amgen's geographic footprint, leveraging strong specialty market experience, continuing to build competitive biologic primary care competencies, and creating an integrated commercial model for payers, prescribers and patients.

- **Growth and Differentiation of In-Market Products:**
  - Enbrel® (etanercept), the leading biologic in value terms within the fast-growing rheumatology and dermatology segments, continues to be the leading choice for new-to-biologic rheumatoid arthritis patients.
  - Prolia® and XGEVA® (denosumab) combined delivered \$1.2 billion in sales in 2012. This franchise is expected to exceed \$3 billion in revenues over time.
  - Growth-phase products Sensipar® (cinacalcet), Vectibix® (panitumumab), and Nplate® (romiplostim) have strong momentum and have opportunities for continued growth.
- **New Product Launches:** Amgen reviewed the commercial opportunities for both AMG 145 and romosozumab.
- **Biosimilars:** Amgen outlined plans to launch a portfolio of six new biosimilars beginning in 2017, and noted that biosimilars represent a multi-billion dollar growth opportunity for Amgen.
- **New and Emerging Markets:** Amgen expects to deliver over \$1 billion in sales in new and emerging markets by 2015 and plans to expand its operating footprint in key markets, including Japan and China. Currently, the company is exploring a partnership opportunity in Japan that will provide a stand-alone, fully-scaled subsidiary by 2020. Amgen also expects to launch its first products in the Japanese market by 2016. The company has a multi-pronged strategy for China that includes establishing an R&D presence and local manufacturing when needed, and is exploring partnerships and acquisitions to accelerate its commercial presence. Amgen also expects to launch its first products in the Chinese market by 2015.

### Strong Execution Supports Continued Financial Success

Jonathan M. Peacock, executive vice president and chief financial officer at Amgen, reviewed Amgen's results over the past 12 months, and the strategic priorities that will allow the company to successfully execute plans for broad-based growth in 2013 and into the future.

For 2013, Amgen now expects to deliver adjusted EPS of \$7.05 to \$7.35 and an adjusted tax rate of between 12 percent and 13 percent, including the benefit of the Puerto Rico Excise Tax Credit. This update to our guidance is due to federal tax settlements for prior years that resulted in an adjustment to the tax charge for those years that will be recorded in the first quarter. Peacock confirmed that the revenues and capital expenditures guidance for 2013 remains unchanged.

Peacock highlighted strong commercial execution, continued pipeline progress, increased focus on operational excellence and return on investment, recent acquisitions, and capital allocation strategy.

Peacock said Amgen expects to deliver approximately \$800 million of operating income benefit in 2014 to shareholders from the transition of the Enbrel profit share to a royalty payment. Shareholders will realize a further increase of approximately 10 percent of Enbrel sales in 2017 as a result of the termination of the royalty payment. In addition, Amgen will reallocate approximately \$1 billion in operational efficiencies over the next three years towards strategic initiatives that support the company's growth and competitive position.

Peacock detailed that Amgen has continued to execute on its capital allocation strategy focused on returning, on average, more than 60 percent of adjusted net income to shareholders through dividend growth and share repurchases. Since the April 2011 Business Review, this strategy has led to significant returns to shareholders and an improved return on equity.

A webcast of the Amgen Business Review meeting with presentation slides and video is available through [www.amgen.com](http://www.amgen.com). The webcast will be archived and available for replay at least 30 days after the event.

### About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit [www.amgen.com](http://www.amgen.com). Follow us on [www.twitter.com/amgen](https://twitter.com/amgen).

### Forward Looking Statements

This news release contains forward-looking statements that are based on management's current expectations and beliefs. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including statements regarding: the Company's

commercial, operational, capital allocation, biosimilars, geographic expansion, planned research and product development or other strategies; estimates of revenues, operating margins, capital expenditures, cash, dividend distributions, stock repurchases, tax rates, earnings per share or 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 that could cause actual results to differ materially from those described, including those risks discussed below and more fully described in our Form 10-K for the year ended Dec. 31, 2011, and in our periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen'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 the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this news release 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. 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 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 products 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 are affected by the reimbursement policies imposed by third-party payors, 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 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 and there can be no guarantee of our 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 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.

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. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Further, the scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (FDA) for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses. Only the FDA can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

**Amgen Inc.**

**Reconciliation of GAAP EPS Guidance to "Adjusted" EPS Guidance for the Year Ending December 31, 2013 (Unaudited)**

	<u>2013</u>	
<b>GAAP EPS (diluted) guidance</b>	\$ 6.71 -	\$ 7.01
<b>Known adjustments to arrive at "Adjusted" earnings:</b>		
Amortization of acquired intangible assets	(a)	0.51
Stock option expense	(b)	0.05
Non-cash interest expense associated with our convertible notes	(c)	0.02
Tax impact	(d)	<u>(0.24)</u>
<b>"Adjusted" EPS (diluted) guidance</b>	<u>\$ 7.05 -</u>	<u>\$ 7.35</u>

(a) To exclude the non-cash amortization of intangible assets acquired in prior year business combinations.

(b) To exclude stock option expense.

(c) To exclude the non-cash interest expense associated with our convertible notes.

(d)To exclude tax impact of above items and tax impact of 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, 2013  
(Unaudited)**

	<u>2013</u>	
<b>GAAP tax rate guidance*</b>	9.7%	- 10.8%
Tax rate effect of known adjustments	<u>2.3%</u>	<u>- 2.2%</u>
<b>"Adjusted" tax rate guidance*</b>	<u>12.0%</u>	<u>- 13.0%</u>

\* Includes Puerto Rico excise tax credit.

CONTACT: Amgen, Thousand Oaks  
Ashleigh Koss, 805-559-0746 (media)  
Arvind Sood, 805-447-1060 (investors)

(Logo: <http://photos.prnewswire.com/prnh/20081015/AMGENLOGO>)

SOURCE Amgen