

Amgen's First Quarter 2014 Revenues Increased 7 Percent To \$4.5 Billion

April 22, 2014

2014 Revenue and Adjusted EPS Guidance Reaffirmed

THOUSAND OAKS, Calif., April 22, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced financial results for the first quarter of 2014. Key results include:

- Total revenues increased 7 percent to \$4,521 million, with 5 percent product sales growth driven by Kyprolis[®] (carfilzomib), XGEVA[®] (denosumab), Prolia[®] (denosumab) and Neulasta[®] (pegfilgrastim). The first quarter includes results for Onyx Pharmaceuticals, Inc. (Onyx), which was acquired on Oct. 1, 2013.
- Adjusted operating income increased 18 percent to \$1,860 million, driven by a significant increase in the profitability of Enbrel® (etanercept) following the end of the ENBREL profit share in the fourth quarter of 2013.
- The Company generated \$1.0 billion of free cash flow, an increase of 9 percent.
- Adjusted EPS decreased 5 percent to \$1.87, due to favorable tax items in the first quarter of 2013.
- GAAP EPS were \$1.40 compared to \$1.88 and GAAP operating income was \$1,364 million compared to \$1,442 million. GAAP EPS and operating income in 2014 include non-cash amortization and other expenses for recent acquisitions.

"Strong underlying demand for our products and growth in adjusted operating income make us confident in our full-year growth outlook," said Robert A. Bradway, chairman & chief executive officer. "We continue to advance our robust late stage pipeline and expect to submit global fillings for evolocumab in 2014."

		Year	-over-Y	ear
\$Millions, except EPS and percer	ntages C	21 '14	Q1 '13 '	ΥΟΥ Δ
Total Revenues	\$	4,5213	\$ 4,238	7%
Adjusted Operating Income	\$	1,860	\$ 1,572	18%
Adjusted Net Income	\$	1,438	\$ 1,498	(4%)
Adjusted EPS	\$	1.87	\$ 1.96	(5%)
GAAP Operating Income	\$	1.3649	\$ 1,442	(5%)
GAAP Net Income			\$ 1,434	` ,
GAAP EPS	\$		\$ 1.88	, ,

References in this release to "adjusted" measures, measures presented "on an adjusted basis" or to free cash flow refer to non-GAAP financial measures. These adjustments and other items are presented on the attached reconciliations.

First Quarter 2014 Product Sales Performance

- **Total product sales** increased 5 percent year-over-year. Sales declined 9 percent on a sequential basis driven primarily by inventory draw-downs in the first quarter of this year following wholesaler and end customer inventory builds in the fourth quarter of last year, principally affecting ENBREL.
- Combined Neulasta and NEUPOGEN® (filgrastim) sales increased 3 percent year-over-year. This includes sales in new markets whose rights were reacquired effective Jan. 1, 2014.
 - Global Neulasta sales increased 5 percent year-over-year driven mainly by price.
 - o Global NEUPOGEN sales decreased 3 percent year-over-year due to lower unit demand.
- Enbrel sales decreased 5 percent year-over-year mainly driven by lower unit demand.
- Aranesp® (darbepoetin alfa) sales decreased 2 percent year-over-year due to lower unit demand.
- EPOGEN® (epoetin alfa) sales increased 6 percent year-over-year.
- Sensipar®/Mimpara® (cinacalcet) sales increased 2 percent year-over-year.
- Combined sales of **Vectibix**® (panitumumab) and **Nplate**® (romiplostim) increased 18 percent year-over-year driven mainly by higher unit demand.
- XGEVA sales increased 25 percent year-over-year driven by higher unit demand.
- Prolia sales increased 38 percent year-over-year driven by higher unit demand.
- Kyprolis sales were \$68 million.

Product Sales Detail by Product and Geographic Region

\$Millions, except percentages	Q1 '14	Q1 '13 YOY Δ
	US ROW I	OTALTOTALTOTAL
Neulasta [®] / NEUPOGEN [®]	\$1,066 \$313	31,379 \$1,338 3%

Neulasta [®]	0.50	220	1 000	1 020	5%
	852	238	1,090	1,039	
NEUPOGEN [®]	214	75	289	299	(3%)
Enbrel [®]	924	64	988	1,039	(5%)
Aranesp [®]	177	283	460	468	(2%)
EPOGEN [®]	462	0	462	435	6%
Sensipar [®] / Mimpara [®]	178	92	270	264	2%
Vectibix [®]	39	64	103	87	18%
Nplate [®]	62	51	113	96	18%
XGEVA [®] / Prolia [®]	319	156	475	365	30%
XGEVA [®]	200	79	279	223	25%
Prolia [®]	119	77	196	142	38%
Kyprolis [®]	62	6	68	0	*
Other	0	38	38	59	(36%)
Total product sales	<u>\$3,289</u> \$	1,067	\$4,356	\$4,151	5%
* Not meaningful					

Operating Expense and Tax Rate Analysis, on an Adjusted Basis

- Cost of Sales margin improved 0.5 points.
- Research & Development (R&D) expenses increased 17 percent in the first quarter of 2014, principally attributable to the addition of Onyx programs.
- Selling, General & Administrative (SG&A) expenses decreased 14 percent in the first quarter of 2014 driven primarily by a significant increase in the profitability of ENBREL following the end of the ENBREL profit share, offset partially by the addition of Onyx.

\$Millions, except percentages			
On an Adjusted Basis	Q1 '14 (Q1 '13	ΥΟΥ Δ
·			
Cost of Sales	\$684	\$671	2%
% of sales	15.7%	16.2%	(0.5) pts
% of sales (Excluding PR excise tax	x) 13.6%	14.1%	(0.5) pts
Research & Development	\$994	\$851	17%
% of sales	22.8%	20.5%	2.3 pts
Selling, General & Administrative	\$983	\$1,144	(14%)
% of sales	22.6%	27.6%	(5.0) pts
TOTAL Operating Expenses	\$2,661	2,666	(0%)
pts: percentage points			
PR: Puerto Rico			

• Tax Rate for the first quarter of 2014 excludes two significant benefits recognized in the prior year, namely the federal and state tax benefits associated with the resolution of the Company's federal audit for tax years 2007-2009 and the recognition of the full 2012 federal R&D credit in the first quarter of 2013. The federal R&D credit has not yet been extended for 2014 and is therefore not reflected in the current quarter.

On an Adjusted Basis	Q1 '14Q1 '13 YOY Δ
Tax Rate	15.4%(0.9%)16.3 pts
Tax Rate (Excluding PR excise tax cred	dits) 18.9% 4.2%14.7 pts
pts: percentage points	
PR: Puerto Rico	

Cash Flow and Balance Sheet Discussion

- The Company generated \$1.0 billion of free cash flow in the first quarter of 2014 versus \$0.9 billion in the first quarter of 2013.
- The Company's second quarter 2014 dividend of \$0.61 per share declared on March 5, 2014, will be paid on June 6, 2014, to all stockholders of record as of the close of business on May 15, 2014.
- The Company did not repurchase shares in the first quarter and has \$1.6 billion remaining under its stock repurchase authorization.

\$Billions, except shares	Q1 '14	Q1 '13	ΥΟΥ Δ
Operating Cash Flow	\$1.1	\$1.0	\$0.1
Capital Expenditures	0.2	0.2	0.0

Free Cash Flow Dividends Paid Cost of Shares Repurchased Avg. Diluted Shares (millions)	1.0 0.5 0.0 768	0.9 0.4 0.8 764	0.1 0.1 (0.8) 4
Cash and Investments*	23.2	21.3	1.9
Debt Outstanding	32.0	23.9	8.1
Stockholders' Equity	22.7	19.5	3.2
 Includes cash, cash equivalents and marke investments. Note: Numbers may not add due to roundin 	·	l long-term r	estricted

2014 Guidance

For the full year 2014, the Company continues to expect:

- **Total revenues** to be in the range of \$19.2 billion to \$19.6 billion and **adjusted EPS** to be in the range of \$7.90 to \$8.20. This includes an \$800 million incremental operating income contribution due to the end of the ENBREL profit share.
- Adjusted tax rate to be in the range of 15 percent to 16 percent. This assumes the federal R&D credit will be extended for 2014 and also includes the impact of the foreign tax credit associated with the Puerto Rico excise tax. The Puerto Rico excise tax credit reduces the adjusted rate by three to four percentage points.
- Capital expenditures to be approximately \$800 million.

First Quarter Product and Pipeline Update

2014 milestones for innovative pivotal programs:

Clinical Program	Lead Indication	Milestone	Timing
Evolocumab	Dyslipidemia	Phase 3 data	Achieved
Evolocumab	Dyslipidemia	Global filing	2014
Talimogene laherparepvec	Metastatic melanoma	Phase 3 data* [†]	Achieved
Blinatumomab	Relapsed/refractory ALL	Phase 2 data	Achieved
Brodalumab**	Psoriatic arthritis	Phase 3 initiation	Achieved
Brodalumab**	Psoriasis	Phase 3 data	2014
Ivabradine	Chronic heart failure	U.S. filing	Q2 2014
Kyprolis	Multiple myeloma	Phase 3 ASPIRE interim analysis* Phase 3 FOCUS data*	Q2/Q3 2014
Trebananib	Recurrent ovarian cancer	Phase 3 data* [†]	H2 2014
Velcalcetide (AMG 416)	Secondary hyperparathyroidism	Phase 3 data	H2 2014

^{*} Event driven studies

ALL = acute lymphoblastic leukemia

The Company provided the following information on selected clinical programs:

Kyprolis

• The Company stated that the event driven interim analysis of the ASPIRE study and the event driven final analysis of the FOCUS study are expected in Q2/Q3 2014.

Brodalumab

- The Company discussed the recent initiation of two Phase 3 studies in patients with psoriatic arthritis.
- The Company announced that results from the Phase 3 placebo controlled study in patients with psoriasis are expected in Q2 2014 with results from the two ustekinumab controlled studies expected in the second half of the year.

Ivabradine

• The Company announced that it was granted fast-track filing status by the FDA for chronic heart failure.

Blinatumomab

• The Company discussed a confirmatory Phase 2 study in relapsed/refractory ALL had completed and that the data will be presented at the American Society of Clinical Oncology (ASCO) 2014 Annual Meeting.

Talimogene laherparepvec

• The Company announced that the primary analysis of the overall survival secondary endpoint from a Phase 3 study in

^{**}Developed in collaboration with AstraZeneca/MedImmune

[†]Overall survival (secondary endpoint)

melanoma will be presented at the ASCO 2014 Annual Meeting.

Non-GAAP Financial Measures

In this press release, management has presented its operating results for the first quarters of 2014 and 2013 in accordance with U.S. Generally Accepted Accounting Principles (GAAP) and on an adjusted (or non-GAAP) basis. In addition, management has presented its full year 2014 EPS and tax rate guidance in accordance with GAAP and on an adjusted (or non-GAAP) basis. These non-GAAP financial measures are computed by excluding certain items related to acquisitions, cost-savings initiatives and certain other items from the related GAAP financial measures. Management has also presented Free Cash Flow (FCF), which is a non-GAAP financial measure, for the first quarters of 2014 and 2013. FCF is computed by subtracting capital expenditures from operating cash flow, each as determined in accordance with GAAP. Reconciliations for these non-GAAP financial measures to the most directly comparable GAAP financial measures are included in the press release.

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 core business activities by facilitating comparisons of results of core business operations among current, past and future periods. In addition, the Company believes that excluding the non-cash amortization of intangible assets, including developed product technology rights, 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. 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 press release in connection with its own budgeting and financial planning. 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 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 involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended Dec. 31, 2013, and in any subsequent periodic reports on Form 10-Q and Form 8-K. 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. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign), and difficulties or delays in manufacturing our products. In addition, sales of our products are affected by 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. 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. 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. 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, we compete with other companies with respect to some 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. Our efforts to integrate the operations of companies we have acquired may not be successful. 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.

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

Three months ended March 31, 2014 2013

Revenues: Product sales

Other revenues	165	87
Total revenues	4,521	4,238
Operating expenses:		
Cost of sales	1,090	744
Research and development	1,027	878
Selling, general and administrative	1,023	1,158
Other	17	16
Total operating expenses	3,157	2,796
Operating income	1,364	1,442
Interest expense, net	259	263
Interest and other income, net	99	164
Income before income taxes	1,204	1,343
Provision (benefit) for income taxes	131	(91)
Net income	\$ 1,073	\$ 1,434
Earnings per share:		
Basic	\$ 1.42	\$ 1.91
Diluted	\$ 1.40	\$ 1.88
Average shares used in calculation of earnings per share:		
Basic	757	751
Diluted	768	764

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

		rch 31, De 2014	cember 31, 2013
Assets			
Current assets:			
Cash, cash equivalents and marketable securities	\$	19,802 \$	19,401
Trade receivables, net		2,514	2,697
Inventories		2,966	3,019
Other current assets		3,020	2,250
Total current assets		28,302	27,367
Property, plant and equipment, net		5,365	5,349
Intangible assets, net		13,566	13,262
Goodwill		14,832	14,968
Restricted investments		3,414	3,412
Other assets		1,525	1,767
Total assets	\$	67,004 \$	66,125
Liabilities and Stockholders' Equity Current liabilities:			
Accounts payable and accrued liabilities	\$	5,698 \$	5,442
Current portion of long-term debt	Ψ	2,505	2,505
Total current liabilities		8,203	7,947
Long-term debt		29,519	29,623
Other non-current liabilities		6,541	6,459
Stockholders' equity		22,741	22,096
Total liabilities and stockholders' equity	\$	67,004 \$	66,125
Shares outstanding		757	755

GAAP to Adjusted Reconciliations (In millions) (Unaudited)

	Three mo		
	2014	2	013
GAAP cost of sales	\$ 1,090	\$	744
Adjustments to cost of sales:	ψ .,σσσ	Ψ	
Acquisition-related expenses (a)	(404)		(71)
Stock option expense Total adjustments to cost of sales	(2)		(2)
Adjusted cost of sales	\$ 684	\$	671
Adjusted 60st of suites		-	
GAAP research and development expenses	\$ 1,027	\$	878
Adjustments to research and development expenses:	* /-	Ť	
Acquisition-related expenses (b)	(31)		(22)
Stock option expense	(2)		(5) (27)
Total adjustments to research and development expenses Adjusted research and development expenses	\$ 994	\$	851
Aujusteu research and development expenses	Ψ 001	Ψ	
GAAP selling, general and administrative expenses	\$ 1,023	\$	1,158
Adjustments to selling, general and administrative expenses:	Ψ 1,020	Ψ	1,100
Acquisition-related expenses (b)	(38)		(10)
Stock option expense	(2)		(4)
Total adjustments to selling, general and administrative expenses	(40) \$ 983	\$	(14) 1,144
Adjusted selling, general and administrative expenses	φ 903	Ψ	1,144
GAAP operating expenses	\$ 3,157	\$	2,796
Adjustments to operating expenses:	Ψ 0,101	Ψ	2,700
Adjustments to cost of sales	(406)		(73)
Adjustments to research and development expenses	(33)		(27)
Adjustments to selling, general and administrative expenses Certain charges pursuant to our efforts to improve cost efficiencies in our operations (c)	(40) (15)		(14) -
Other (d)	(2)		(16)
Total adjustments to operating expenses	(496)		(130)
Adjusted operating expenses	\$ 2,661	\$	2,666
GAAP operating income Adjustments to operating expenses	\$ 1,364 496	\$	1,442 130
Adjusted operating income	\$ 1,860	\$	1,572
Adjusted operating mounts			
GAAP income before income taxes	\$ 1,204	\$	1,343
Adjustments to income before income taxes:			
Adjustments to operating expenses	496		130
Non-cash interest expense associated with our convertible notes Total adjustments to income before income taxes	496		12 142
Adjusted income before income taxes	\$ 1,700	\$	1,485
Aujusteu ilicollie belore ilicollie taxes	Ψ .,.σσ	<u> </u>	.,
GAAP provision/(benefit) for income taxes	\$ 131	\$	(91)
Adjustments to provision/(benefit) for income taxes:	•	*	(-1)
Income tax effect of the above adjustments (e)	131		40
Other income tax adjustments (f)	121		38
Total adjustments to provision/(benefit) for income taxes	131 \$ 262	\$	(13)
Adjusted provision/(benefit) for income taxes	Ψ 202	Ψ	(13)
GAAP net income	\$ 1,073	\$	1,434
Adjustments to net income:	4 1,070	Ψ	.,
Adjustments to income before income taxes, net of the income tax effect of the above adjustments	365		102
Other income tax adjustments (f)	-		(38)

Amgen Inc.
GAAP to Adjusted Reconciliations
(In millions, except per share data)
(Unaudited)

The following table presents the computations for GAAP and Adjusted diluted EPS:

•	Three months endedThree months ende								
	March 31, 2014				March 31, 2013				
	GAAP Adjusted		G	AAP	Αdjι	ısted			
Net income	\$	1,073	\$	1,438	\$	1,434	\$	1,498	
Weighted-average shares for diluted EPS		768		768		764		764	
Diluted EPS	\$	1.40	\$	1.87	\$	1.88	\$	1.96	

- (a) The adjustments related primarily to non-cash amortization of intangible assets, including developed product technology rights, acquired in business combinations. The 2014 adjustments also include a \$99 million charge related to the closing of an agreement associated with our acquiring the licenses to filgrastim and pegfilgrastim effective January 1, 2014.
- (b) The adjustments related primarily to non-cash amortization of intangible assets acquired in business combinations.
- (c) The adjustments related primarily to severance expenses.
- (d) The 2013 adjustments related primarily to various legal proceedings.
- (e)The tax effect of the adjustments between our GAAP and Adjusted 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 stock option expense, depends on whether the amounts are deductible in the tax jurisdictions where the expenses are incurred or the asset is located 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 ended March 31, 2014 and 2013, were 26.4% and 28.2%, respectively.
- (f) The adjustments in 2013 related to resolving certain non-routine transfer-pricing and acquisition-related issues with tax authorities.

Amgen Inc. Reconciliations of Free Cash Flow (In millions) (Unaudited)

	Three months ended March 31,	
	2014	2013
Operating Cash Flow	\$ 1,142	\$ 1,049
Capital Expenditures	(172)	(158)
Free Cash Flow	\$ 970	\$ 891

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

	2014	
_		

Known adjustments to arrive at Adjusted earnings*:

 Acquisition-related expenses
 (a)
 1.24

 Other
 (b)
 0.01

 Adjusted diluted EPS guidance
 \$ 7.90-\$ 8.20

- * The known adjustments are presented net of their related tax impact which amount to approximately \$0.63 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 include stock option expense, cost savings initiatives and various legal proceedings.

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

2014

GAAP tax rate guidance

11%-12%

Tax rate effect of known adjustments discussed above 4%

Adjusted tax rate guidance

15%-16%

CONTACT: Amgen, Thousand Oaks Kristen Davis, 805-447-3008 (media) Arvind Sood, 805-447-1060 (investors)



Logo - http://photos.prnewswire.com/prnh/20081015/AMGENLOGO

SOURCE Amgen