# AbbVie Reports First-Quarter 2014 Financial Results

- Reports First-Quarter Adjusted EPS of \$0.71, Up 4.4 Percent and Above Previous Guidance Range of \$0.67 to \$0.69 (Reports GAAP EPS of \$0.61)
- Delivers First-Quarter Revenue of \$4.563 Billion, an Increase of 5.4 Percent Over First-Quarter 2013 (Up 6.7 Percent On an Operational Basis)
- Revenue Growth Reflects 17.5 Percent Global Reported Sales Growth from HUMIRA (Up 18.4 Percent On an Operational Basis) and Double-Digit Growth from Other Key Products
- Delivers Significant Gross Margin Expansion and Strong Investment Spending in R&D and SG&A
- Recently Submitted U.S. Regulatory Application for Interferon-Free HCV Combination; Continues to Expect U.S. Approval in 2014; EU Submission Planned for Early May
- Pipeline Continues to Advance in 2014 With Numerous Data Milestones, Regulatory Submissions and Phase Transitions, Including Initiation of a Phase 3 Trial for Veliparib in Non-Small Cell Lung Cancer
- Confirms 2014 Adjusted EPS Guidance Range of \$3.00 to \$3.10 (GAAP EPS Range is \$2.63 to \$2.73)

NORTH CHICAGO, III., April 25, 2014 -- AbbVie (NYSE:ABBV) announced financial results for the first quarter ended March 31, 2014.

"AbbVie delivered strong first-quarter results, with sales and earnings per share above our original guidance, significant margin expansion, and increased R&D and SG&A investment to support our existing portfolio and our promising pipeline opportunities," said Richard A. Gonzalez, chairman and chief executive officer, AbbVie. "As we look ahead to the remainder of 2014, we continue to expect a significant amount of progress from our pipeline. This includes key data presentations, phase transitions, regulatory submissions, and U.S. approval of our interferon-free HCV combination in 2014."

### **First-Quarter Results**

- Worldwide sales were \$4.563 billion in the first quarter, up 5.4 percent. On an operational basis, sales increased 6.7 percent, excluding a 1.3 percent unfavorable impact from foreign exchange rate fluctuations. Excluding sales from our lipid franchise due to the loss of exclusivity, sales increased 13.5 percent on an operational basis in the quarter.
- First-quarter sales growth was driven primarily by the continued strength of HUMIRA. Global HUMIRA sales increased 17.5 percent, or 18.4 percent on an operational basis, excluding the impact of foreign exchange rate fluctuations. Total company sales growth was also driven by double-digit growth from key products including Synthroid, Creon and Duodopa.
- The adjusted gross margin ratio in the first quarter was 78.4 percent, up 220 basis points versus the prior year, excluding intangible asset amortization and other specified items. The gross margin ratio under U.S. generally accepted accounting principles (GAAP) was 75.9 percent.
- Adjusted selling, general and administrative (SG&A) expense was 27.6 percent of sales in the first quarter, up 4.6 percent versus the prior year, reflecting continued investment in our growth brands and the expected HCV launch. On a GAAP basis, SG&A was 29.4 percent of sales.
- Adjusted research and development (R&D) was 16.9 percent of sales in the quarter, up 22.0 percent versus the prior year, reflecting funding actions in support of our emerging mid- and late-stage pipeline assets and the continued pursuit of additional HUMIRA indications. On a GAAP basis, R&D was 16.9 percent of sales, up 21.8 percent.
- Net interest expense was \$65 million, and the adjusted tax rate was 22.3 percent in the quarter. On a GAAP basis, the first-quarter tax rate was 23.8 percent.

• First-quarter diluted earnings per share were \$0.61 on a GAAP basis. Adjusted diluted earnings per share, excluding intangible asset amortization expense and other specified items, were \$0.71, up 4.4 percent from first-quarter 2013.

## **Key Events from the First Quarter**

- AbbVie recently submitted its U.S. regulatory application for its interferon-free combination for patients with genotype 1 hepatitis C virus (HCV). AbbVie plans to submit applications for regulatory approval of its regimen in the European Union in early May. The company expects U.S. commercialization in 2014 and European approval in early 2015.
- AbbVie presented new data from its Phase 3 HCV program at the 2014 International Liver Congress in London, including detailed results from the SAPPHIRE-I, SAPPHIRE-II, PEARL-III, and TURQUOISE-II studies. Data from TURQUOISE-II, a global, multi-center, randomized, open-label study evaluating the efficacy and safety of 12 weeks or 24 weeks of treatment with AbbVie's regimen with ribavirin (RBV) in adult patients with genotype 1 chronic HCV infection with compensated liver cirrhosis, was presented as a late-breaker. Patients in the study achieved sustained virologic response rates 12 weeks post-treatment (SVR<sub>12</sub>) of 91.8 percent and 95.9 percent in the 12-week and 24-week treatment arms, respectively.
- AbbVie announced the initiation of a global Phase 3 clinical trial evaluating the safety and efficacy of its investigational compound, veliparib (ABT-888), in patients with previously untreated locally advanced or metastatic squamous non-small cell lung cancer (NSCLC). This randomized, placebo-controlled, doubleblind, multi-center trial will recruit approximately 900 patients, and the primary efficacy outcome of the trial is overall survival. Veliparib is a PARP inhibitor being evaluated in multiple tumor types.
- At the recent Conference on Retroviruses and Opportunistic Infections (CROI), AbbVie presented data on its next-generation HCV assets, ABT-493 and ABT-530, showing balanced pan-genotypic coverage. These next-generation assets are currently in Phase 2 development. AbbVie also presented the first detailed results from the pivotal Phase 3 study, PEARL-III. PEARL-III evaluated the efficacy and safety of 12 weeks of treatment with AbbVie's investigational therapy with or without RBV in non-cirrhotic, adult patients with chronic genotype 1b HCV infection who were new to treatment.
- AbbVie announced the initiation of a pivotal Phase 3 clinical trial that will evaluate the use of HUMIRA as
  a treatment for fingernail psoriasis in patients with moderate to severe chronic plaque psoriasis, an area
  of unmet need. Currently there are no approved treatments for fingernail psoriasis. The 26-week clinical
  trial is a multinational, double-blind, placebo-controlled study that is expected to enroll 200 patients with
  moderate to severe chronic plaque psoriasis with fingernail psoriasis. It will be conducted at
  approximately 32 sites worldwide.
- AbbVie announced plans to establish operations in Singapore for small molecule and biologics active drug substance manufacturing. When completed, the facility will provide manufacturing capacity for compounds within AbbVie's oncology and immunology pipeline to serve markets globally. The investment will establish AbbVie's manufacturing presence in Asia.
- On February 20, the AbbVie board of directors increased the company's quarterly cash dividend by 5 percent from \$0.40 per share to \$0.42 per share. The cash dividend is payable May 15, 2014 to stockholders of record at the close of business on April 15, 2014.

## Full-Year 2014 Outlook

AbbVie is confirming its diluted earnings-per-share guidance for the full-year 2014 of \$3.00 to \$3.10 on an adjusted basis, or \$2.63 to \$2.73 on a GAAP basis. The company's 2014 adjusted diluted earnings-per-share guidance excludes \$0.37 per share of intangible asset amortization expense and other specified items primarily associated with certain separation-related costs and ongoing restructuring activities. AbbVie continues to expect 2014 revenue of approximately \$19 billion, excluding any potential revenue from the expected 2014 U.S. launch of its HCV therapy.

### About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. AbbVie employs approximately 25,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit <a href="https://www.abbvie.com">www.abbvie.com</a>. Follow <a href="mailto:openiclosure">openiclosure</a> in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit <a href="https://www.abbvie.com">www.abbvie.com</a>. Follow <a href="mailto:openiclosure">openiclosure</a> in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit <a href="mailto:openiclosure">openiclosure</a> in more than 170 countries. Follow <a href="mailto:openiclosure">openiclosure</a> in more than 170 countries.

#### **Conference Call**

AbbVie will host an investor conference call today at 8:00 a.m. Central time to discuss our first-quarter performance. Participating on the call will be Rick Gonzalez, chairman and chief executive officer; Bill Chase, executive vice president and chief financial officer; Laura Schumacher, executive vice president, business development, external affairs and general counsel; Scott Brun, vice president of clinical development; and Larry Peepo, vice president of investor relations. The call will be webcast through AbbVie's Investor Relations Web site at www.abbvieinvestor.com. An archived edition of the call will be available after 11:00 a.m. Central time.

### **Non-GAAP Financial Results**

Financial results for 2013 and 2014 are presented on both a reported and a non-GAAP basis. Reported results were prepared in accordance with GAAP and include all revenue and expenses recognized during the period. Non-GAAP results adjust for certain non-cash items and for factors that are unusual or unpredictable, and exclude those costs, expenses, and other specified items presented in the reconciliation tables later in this release. AbbVie's management believes non-GAAP financial measures provide useful information to investors regarding AbbVie's results of operations and assist management, analysts, and investors in evaluating the performance of the business. Non-GAAP financial measures should be considered in addition to, and not as a substitute for, measures of financial performance prepared in accordance with GAAP. The company's 2014 financial guidance is also being provided on both a reported and a non-GAAP basis.

### **Forward-Looking Statements**

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," in AbbVie's 2013 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

### AbbVie Inc. Key Product Sales Quarter Ended March 31, 2014 (Unaudited)

						% Change vs.	IQ13	
	Sales (in millions)			_	Interna	ational	Total	
	<u>U.S.</u>	<u>Int'l.</u>	<u>Total</u>	<u>U.S.</u>	<b>Operational</b>	Reported	Operational	Reported
TOTAL SALES	5 \$2,226	\$2,337	\$4,563	4.9%	8.5%	5.9%	6.7%	5.4%
Humira	1,192	1,445	2,637	24.7	13.9	12.2	18.4	17.5
Synagis		354	354	n/a	9.3	2.7	9.3	2.7
AndroGel	254		254	6.0	n/a	n/a	6.0	6.0
Kaletra	54	141	195	2.2	(12.6)	(15.5)	(9.1)	(11.3)
Lupron	140	49	189	11.8	(8.2)	(13.5)	5.6	3.9
Synthroid	157		157	31.5	n/a	n/a	31.5	31.5

Sevoflurane	19	123	142	15.9	5.2	1.5	6.5	3.2
Creon	107		107	18.4	n/a	n/a	18.4	18.4
Duodopa		52	52	n/a	29.4	32.2	29.4	32.2
Niaspan	47		47	(75.0)	n/a	n/a	(75.0)	(75.0)
TriCor/Trilipix	23		23	(81.8)	n/a	n/a	(81.8)	(81.8)

Note: "Operational" growth reflects the percentage change over the prior year excluding the impact of exchange rate fluctuations. n/a = not applicable

# AbbVie Inc. Consolidated Statements of Earnings Quarter Ended March 31, 2014 and 2013 (Unaudited) (In millions, except per share data)

	2014	2013
Net sales	\$4,563	\$4,329
Cost of products sold Selling, general and	1,100	1,153
administrative	1,340	1,237
Research and development	772	634
Total operating cost and expenses	3,212	3,024
Operating earnings	1,351	1,305
Interest expense, net	65	66
Net foreign exchange loss	3	15
Other income, net	(3)	(15)
Earnings before income tax expense	1,286	1,239
Income tax expense	306	271
Net earnings	\$980_	\$968
Diluted earnings per share	\$0.61	\$0.60
Diluted earnings per share, excluding specified items	\$0.71	\$0.68 a)
Average diluted shares outstanding	1,609	1,605

a) Note: Refer to the Reconciliation of GAAP Reported to Non-GAAP Adjusted Information for further details. The computation of diluted earnings per share for the quarter ended March 31, 2014 was calculated pursuant to the two-class method which requires the allocation of net earnings between common stockholders and participating security holders.

# AbbVie Inc. Reconciliation of GAAP Reported to Non-GAAP Adjusted Information Quarter Ended March 31, 2014 (Unaudited) (In millions, except per share data)

# 1. Specified items impacted results as follows:

	1Q14		
	Earnings		Diluted
	Pre-tax	After-tax	EPS
As reported (GAAP)	\$1,286	\$980	\$0.61
Adjusted for specified items:			
Intangible asset amortization	110	80	0.05
Separation costs	80	88	0.05
Restructuring/Other	4	2	0.00

As adjusted (non-GAAP) \$1,480 \$1,150 \$0.71

Intangible asset amortization reflects costs recognized as a result of licensing and acquisition activities. Separation costs are expenses related to the separation of AbbVie from Abbott. Restructuring/Other is primarily associated with previously announced restructuring activities.

2. The impact of the specified items by line item was as follows:

	1(	Q14	
	Cost of		
	products sold	SG&A	R&D
As reported (GAAP)	\$1,100	\$1,340	\$772
Adjusted for specified items:			
Intangible asset amortization	(110)		
Separation costs	(2)	(77)	(1)
Restructuring/Other	(2)	(2)	
As adjusted (non-GAAP)	\$986	\$1,261	\$771

3. The adjusted tax rate for the first quarter of 2014 was 22.3 percent, as detailed below:

		1Q14		
	Pre-tax	Income		
	income	taxes	Tax rate	
As reported (GAAP)	\$1,286	\$306	23.8%	
Specified items	194	24	12.4%	
As adjusted (non-GAAP)	\$1,480	\$330	22.3%	

AbbVie Inc.

Reconciliation of GAAP Reported to Non-GAAP Adjusted Information
Quarter Ended March 31, 2013
(Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

	1Q13				
	Earnii	Diluted			
	Pre-tax	After-tax	EPS		
As reported (GAAP)	\$1,239	\$968	\$0.60		
Adjusted for specified items:					
Intangible asset amortization	135	98	0.06		
Separation costs	34	22	0.01		
Restructuring/Other	(1)	7	0.01		
As adjusted (non-GAAP)	\$1,407	\$1,095	\$0.68		

Intangible asset amortization reflects costs recognized as a result of licensing and acquisition activities. Separation costs are expenses related to the separation of AbbVie from Abbott. Restructuring/Other is primarily associated with previously announced restructuring activities and the impact of the Venezuelan currency devaluation.

2. The impact of the specified items by line item was as follows:

			1G	113	
	Cost of products sold	SG&A	R&D	Net foreign exchange loss	Other income, net
As reported (GAAP)	\$1,153	\$1,237	\$634	\$15	(\$15)
Adjusted for specified items: Intangible asset amortization	(135)				
Separation costs	(3)	(29)	(2)		
Restructuring/Other	17	(2)		(11)	(3)
As adjusted (non-GAAP)	\$1,032	\$1,206	\$632	\$4	(\$18)

3. The adjusted tax rate for the first quarter of 2013 was 22.2 percent, as detailed below:

_		1Q13	
	Pre-tax	Income	
	income	taxes	Tax rate
	\$1,239	\$271	21.9%
	168	41	24.4%
_	\$1,407	\$312	22.2%

As reported (GAAP)
Specified items
As adjusted (non-GAAP)

# SOURCE AbbVie

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