

AbbVie Reports Third-Quarter 2013 Financial Results

NORTH CHICAGO, Ill., Oct. 25, 2013 --

- *Reports Third-Quarter Adjusted EPS of \$0.82, Above Previous Guidance Range; GAAP EPS of \$0.60*
- *Raises 2013 Adjusted EPS Guidance to \$3.11-\$3.13, GAAP EPS Guidance of \$2.54-\$2.56*
- *Delivers Revenue of \$4.658 Billion, an Increase of 3.3 Percent (Up 3.6 Percent Excluding Foreign Exchange); Revenue Up 10.9 Percent Excluding Exchange and TriCor/Trilipix Due to Loss of Exclusivity*
- *Revenue Growth Reflects 19.1 Percent Global Sales Growth from HUMIRA and Strong Growth from Other Products Including Synthroid, Creon, Zemplar and Duodopa*
- *Strong R&D Investment Supports Pipeline Advancements Including the Initiation of a Large Single-Agent Study of ABT-199 in CLL, Start of a Second Phase 3 Study of Elagolix in Endometriosis, and Significant Progress Toward the Completion of our Comprehensive Global Phase 3 HCV Program*
- *Continues to Enhance Early-Stage Pipeline with Two New Collaborations in Inflammatory Diseases and Cystic Fibrosis*

AbbVie (NYSE: ABBV) today announced financial results for the third quarter ended Sept. 30, 2013.

"Our third-quarter performance demonstrates the strength and durability of our product portfolio and the continued execution of our key strategic priorities as an independent biopharmaceutical company," said Richard A. Gonzalez, chairman and chief executive officer, AbbVie. "Our mid- to late-stage pipeline contains a number of potentially significant opportunities, and we look forward to a series of milestones across our pipeline in the coming months."

Third-Quarter Results

- Worldwide sales were \$4.658 billion in the third quarter, up 3.3 percent. On an operational basis, sales increased 3.6 percent, excluding a 0.3 percent unfavorable impact from foreign exchange rate fluctuations. Sales increased in the quarter despite the decline in TriCor/Trilipix sales due to the loss of exclusivity. Excluding TriCor/Trilipix sales and foreign exchange, sales increased 10.9 percent in the quarter.
- Sales growth was driven by the continued strength of HUMIRA. Global HUMIRA sales increased 19.1 percent on both a reported and operational basis. U.S. HUMIRA sales grew 22.3 percent. Total company sales growth was also driven by strong growth from other products including Synthroid, Creon, Zemplar and Duodopa.
- Third-quarter adjusted gross margin ratio was 79.7 percent, excluding intangible asset amortization and other specified items. Gross margin strength in the quarter was driven by operational efficiencies and product mix, including strong HUMIRA sales and better-than-expected lipid performance despite loss of exclusivity. The gross margin ratio under U.S. generally accepted accounting principles (GAAP) was 76.6 percent.
- Adjusted selling, general and administrative (SG&A) expense was 26.1 percent of sales in the third quarter, reflecting continued investment in our growth brands. On a GAAP basis, SG&A was 27.1 percent of sales.
- Adjusted research and development (R&D) was 15.2 percent of sales in the quarter, 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 15.3 percent of sales.
- Net interest expense was \$69 million, and the adjusted tax rate was 22.3 percent in the quarter. On a GAAP basis, the third-quarter tax rate was 25.0 percent.
- Third-quarter diluted earnings per share were \$0.60 on a GAAP basis. Adjusted diluted earnings per share, excluding intangible asset amortization expense and other specified items, were \$0.82, above the company's previous guidance range.

Key Events from the Third Quarter

- In the quarter we made significant progress toward the completion of our Phase 3 interferon-free hepatitis C program. AbbVie's Phase 3 program, which includes six trials in more than 2,000 patients and trial sites in 30 countries, represents the largest interferon-free HCV registrational program conducted to date. This comprehensive program was designed to characterize the performance of AbbVie's 3-DAA regimen across genotype 1 populations and includes independent studies in difficult to treat patients. We expect to begin reporting the initial results from these studies in the fourth quarter and into early next year, supporting registration submissions in the second quarter of 2014.
- New data from AbbVie's Phase 2 hepatitis C clinical development program will be presented at the Liver Meeting, the annual meeting of the American Association for the Study of Liver Diseases (AASLD) in Washington, D.C., beginning next week. Abstracts presented will include additional analyses from the Phase 2b AVIATOR study. The data examine sustained virologic response (SVR) concordance, patient adherence to the regimen, patient reported outcomes and the impact of ribavirin dose reduction.

- AbbVie presented Phase 2 data evaluating the efficacy of HUMIRA in patients with hidradenitis suppurativa (HS), a chronic inflammatory skin disease, at the European Dermatology and Venereology (EADV) meeting in Istanbul, Turkey. The post-hoc analysis found that HUMIRA induced a significant response rate in adult patients with moderate-to-severe HS at week 16 versus placebo. HUMIRA is the first therapy to enter Phase 3 studies in HS. Two fully-enrolled Phase 3 clinical trials are underway to evaluate the safety and efficacy of HUMIRA in approximately 600 adult HS patients.
- AbbVie recently initiated a large single-agent study of our Bcl-2 inhibitor, ABT-199, in previously-treated chronic lymphocytic leukemia (CLL) patients with the 17p deletion. Data from this study will likely read out at the end of 2014. ABT-199 is being developed in collaboration with Roche. In addition, we started the second Phase 3 pivotal trial to evaluate elagolix for the treatment of endometriosis. The second Phase 3 trial is similar in design to the initial Phase 3 trial, which is scheduled to provide top-line data in the second half of 2014.
- With partner Biogen Idec, AbbVie presented data from sub-analyses of the Phase 2 SELECT and SELECTION studies evaluating daclizumab. Daclizumab High-Yield Process (DAC HYP) is being developed as a once-monthly subcutaneous injection for patients with relapsing/remitting multiple sclerosis (MS). DAC HYP is believed to target the activated immune cells that can play a key role in MS without causing general immune cell depletion. A second registrational study, the DECIDE trial, is expected to complete in mid-2014, supporting a potential regulatory submission by year-end 2014.
- AbbVie and Ablynx announced a global license agreement to develop and commercialize ALX-0061 to treat inflammatory diseases including rheumatoid arthritis (RA) and systemic lupus erythematosus. ALX-0061 is Ablynx's proprietary anti-IL-6R Nanobody that successfully completed a Phase 2a study in Feb. 2013 reporting strong efficacy and safety data in patients with moderately to severely active RA on a stable background of methotrexate. ALX-0061 targets the interleukin 6 pathway via the IL-6 receptor, which plays a key role in the inflammatory process in RA.
- AbbVie and Galapagos announced a global alliance to discover, develop and commercialize novel potentiator and combination therapies for cystic fibrosis (CF) that address the main mutations in CF patients, including F508del and G551D, with the aim to initiate Phase 1 studies at the end of 2014.
- On Sept. 19, the board of directors of AbbVie declared a quarterly cash dividend of \$0.40 per share, payable Nov. 15, 2013 to stockholders of record at the close of business on Oct. 15, 2013. AbbVie was named to the S&P 500 Dividend Aristocrats Index.

Raising Full-Year 2013 Outlook

AbbVie is raising its diluted earnings-per-share guidance for the full-year 2013 to \$3.11 to \$3.13 (from \$3.07 to \$3.13) on an adjusted basis, or \$2.54 to \$2.56 on a GAAP basis. The company's 2013 adjusted diluted earnings-per-share guidance excludes \$0.57 per share of intangible asset amortization expense, acquired in-process research and development, and other specified items primarily associated with certain separation-related costs and ongoing restructuring activities.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott. 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. In 2013, AbbVie employs approximately 21,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](https://www.facebook.com/abbvie) or [LinkedIn](https://www.linkedin.com/company/abbvie) page.

Conference Call

AbbVie will host an investor conference call today at 8:00 a.m. Central time to discuss our third-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 of 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 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 2013 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 2012 Annual Report on Form 10-K/A, 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 September 30, 2013
(Unaudited)

	Sales (in millions)			% Change vs. 3Q12					
				International			Total		
	U.S.	Int'l.	Total	U.S.	Operational	Reported	Operational	Reported	
TOTAL SALES	\$2,616	\$2,042	\$4,658	(1.8%)	11.6%	10.8%	3.6%	3.3%	
Humira	1,389	1,381	2,770	22.3	16.0	16.1	19.1	19.1	
AndroGel	248	--	248	(11.1)	n/a	n/a	(11.1)	(11.1)	
Kaletra	63	174	237	(11.3)	(11.2)	(11.2)	(11.2)	(11.2)	
Niaspan	201	--	201	(13.4)	n/a	n/a	(13.4)	(13.4)	
Lupron	141	55	196	6.8	(1.7)	(3.5)	4.2	3.7	
Synthroid	161	--	161	22.9	n/a	n/a	22.9	22.9	
Sevoflurane	19	119	138	(5.0)	6.1	3.5	4.4	2.2	
Creon	101	--	101	9.8	n/a	n/a	9.8	9.8	
Zemplar	57	43	100	9.6	7.7	10.3	8.8	9.9	
Synagis	--	98	98	n/a	15.6	2.1	15.6	2.1	
Duodopa	--	46	46	n/a	18.9	24.3	18.9	24.3	
TriCor/Trilipix	39	--	39	(88.3)	n/a	n/a	(88.3)	(88.3)	

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

AbbVie Inc.
Key Product Sales
Nine Months Ended September 30, 2013
(Unaudited)

	Sales (in millions)			% Change vs. 9M12					
				International			Total		
	U.S.	Int'l.	Total	U.S.	Operational	Reported	Operational	Reported	
TOTAL SALES	\$7,363	\$6,316	\$13,679	--	10.4%	8.7%	4.6%	3.8%	
Humira	3,569	4,051	7,620	20.4	13.0	11.9	16.3	15.7	
AndroGel	746	--	746	(5.2)	n/a	n/a	(5.2)	(5.2)	
Kaletra	181	553	734	(7.7)	(1.4)	(2.5)	(3.0)	(3.8)	
Niaspan	619	--	619	(2.4)	n/a	n/a	(2.4)	(2.4)	
Lupron	410	166	576	(1.0)	(4.0)	(5.1)	(1.9)	(2.2)	
Synagis	--	513	513	n/a	9.9	1.4	9.9	1.4	
Synthroid	433	--	433	13.1	n/a	n/a	13.1	13.1	
Sevoflurane	54	358	412	1.9	(6.4)	(8.4)	(5.4)	(7.2)	
Creon	297	--	297	19.8	n/a	n/a	19.8	19.8	
Zemplar	161	127	288	--	9.5	10.4	3.9	4.3	
TriCor/Trilipix	274	--	274	(69.5)	n/a	n/a	(69.5)	(69.5)	
Duodopa	--	129	129	n/a	16.6	19.4	16.6	19.4	

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 and Nine Months Ended September 30, 2013 and 2012
(Unaudited) (In millions, except per share data)

	Third Quarter Ended September 30		Nine Months Ended September 30	
	2013	2012	2013	2012
Net sales	\$4,658	\$4,508	\$13,679	\$13,174
Cost of products sold	1,092	1,014	3,299	3,243
Selling, general and administrative	1,261	1,085	3,904	3,578
Research and development	714	813	2,057	2,097
Acquired in-process research and development	220	--	290	260
Total operating cost and expenses	3,287	2,912	9,550	9,178
Operating earnings	1,371	1,596	4,129	3,996
Interest (income) expense, net	69	(1)	210	(4)
Net foreign exchange (gain) loss	11	6	40	27
Other (income) expense, net	5	(13)	(14)	(39)
Earnings before income tax	1,286	1,604	3,893	4,012
Income tax expense	322	19	893	277
Net earnings	\$964	\$1,585	\$3,000	\$3,735
Diluted earnings per share	\$0.60	\$1.01	\$1.86	\$2.37
Average diluted shares outstanding	1,605	1,577	1,602	1,577

Note: On Jan. 1, 2013, Abbott Laboratories distributed 1,577 million shares of AbbVie common stock to Abbott's shareholders in connection with the separation of AbbVie from Abbott. The computation of diluted earnings per share for the quarter and nine months ended Sept. 30, 2012 was calculated using the shares distributed on Jan. 1, 2013.

AbbVie Inc.
Reconciliation of GAAP Reported to Non-GAAP Adjusted Information
Quarter Ended September 30, 2013
(Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

	3Q13		
	Earnings		Diluted EPS
	Pre-tax	After-tax	
As reported (GAAP)	\$1,286	\$964	\$0.60
Adjusted for specified items:			
Intangible asset amortization	137	98	0.06
Separation costs	51	33	0.02
Acquired IPR&D	220	220	0.13
Restructuring/Other	14	12	0.01
As adjusted (non-GAAP)	\$1,708	\$1,327	\$0.82

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. Acquired IPR&D reflects the upfront payment related to the previously announced collaborations with Ablynx and Galapagos. Restructuring/Other is primarily associated with previously announced restructuring activities.

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

	3Q13				
	Cost of products sold	SG&A	R&D	Acquired IPR&D	Other (income) expense
As reported (GAAP)	\$1,092	\$1,261	\$714	\$220	\$5
Adjusted for specified items:					
Intangible asset amortization	(137)	--	--	--	--
Separation costs	(4)	(46)	(1)	--	--
Acquired IPR&D	--	--	--	(220)	--
Restructuring/Other	(7)	--	(4)	--	(3)
As adjusted (non-GAAP)	\$944	\$1,215	\$709	--	\$2

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

	3Q13		
	Pre-tax income	Income taxes	Tax rate
As reported (GAAP)	\$1,286	\$322	25.0%
Specified items	422	59	14.0%
As adjusted (non-GAAP)	\$1,708	\$381	22.3%

SOURCE AbbVie

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