

Shire plc  
Form 425  
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Under the Securities Act of 1933

Subject Company: Shire plc

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*For immediate release*

*July 25, 2014*

## **PRESS RELEASE**

### **AbbVie Reports Second-Quarter 2014 Financial Results**

- *Reports Second-Quarter Adjusted EPS of \$0.82, Above Previous Guidance Range of \$0.75 to \$0.77 (Reports GAAP EPS of \$0.68)*
- *Delivers Second-Quarter Revenue of \$4.926 Billion, an Increase of 5.0 Percent Over Second-Quarter 2013 (Up 4.8 Percent On an Operational Basis); Revenue Up 12.3 Percent Operationally Excluding Lipid Sales Due to Loss of Exclusivity*
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*Revenue Growth Reflects 26.2 Percent Global Reported Sales Growth from HUMIRA (Up 25.4 Percent On an Operational Basis) and Strong Growth from Other Key Products*

- *Pipeline Continues to Advance Including Phase 3 Start for ABT-888, Positive Phase 3 Data for Daclizumab, Priority Review (FDA) and Accelerated Assessment (EMA) of our HCV Program, Positive Data from Next-Generation HCV Program and ABT-414 for Glioblastoma*
- *Continues to Enhance the Company's Position and Shape AbbVie for the Long-Term with Agreement to Merge with Shire, Creating a Larger and More Diversified Biopharmaceutical Company and Driving Significant Strategic and Financial Benefits*
- *Confirms Recently-Increased 2014 Adjusted EPS Guidance Range of \$3.06 to \$3.16 (GAAP EPS Guidance Range is \$2.69 to \$2.79)*

**NORTH CHICAGO, Ill.**, July 25, 2014 AbbVie (NYSE:ABBV) today announced financial results for the second quarter ended June 30, 2014.

This was another very strong quarter for AbbVie, as we delivered sales and earnings per share above our original guidance and announced plans to merge with Shire, a strategic action that will further enhance our long-term growth prospects, said Richard A. Gonzalez, chairman and chief executive officer, AbbVie. Last month, we raised our 2014 earnings-per-share guidance, reflecting strong underlying business performance. We continue to expect positive trends for the second half of the year, as well as additional progress from our pipeline, including the expected U.S. approval of our interferon-free HCV combination.

## Second-Quarter Results

- Worldwide sales were \$4.926 billion in the second quarter, up 5.0 percent. On an operational basis, sales increased 4.8 percent, excluding a 0.2 percent favorable impact from foreign exchange rate fluctuations. Excluding sales from our lipid franchise due to the loss of exclusivity, sales increased 12.3 percent on an operational basis in the quarter.
- Second-quarter sales growth was driven primarily by the continued strength of HUMIRA. Global HUMIRA sales increased 26.2 percent, or 25.4 percent on an operational basis, excluding the impact of foreign exchange rate fluctuations. Total company sales growth was also driven by strong growth from key products including Synthroid, Sevoflurane and Duodopa.
- The adjusted gross margin ratio in the second quarter was 79.6 percent, excluding intangible asset amortization and other specified items. The gross margin ratio under U.S. generally accepted accounting principles (GAAP) was 77.4 percent.
- Adjusted selling, general and administrative (SG&A) expense was 27.1 percent of sales in the second quarter, 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 16.1 percent of sales in the quarter, reflecting funding actions in support of our mid- and late-stage pipeline and the continued pursuit of additional HUMIRA indications. On a GAAP basis, R&D was 16.9 percent of sales.
- Net interest expense was \$69 million, and the adjusted tax rate was 22.2 percent in the quarter. On a GAAP basis, the second-quarter tax rate was 23.4 percent.
- Second-quarter diluted earnings per share were \$0.68 on a GAAP basis. Adjusted diluted earnings per share, excluding intangible asset amortization expense and other specified items, were \$0.82.

## Key Events from the Second Quarter

- AbbVie announced it reached an agreement with Shire's Board of Directors for a recommended transaction to combine the two companies. The proposed combination is strategically compelling for both companies and will create a larger and more diversified biopharmaceutical company with multiple leading franchises. The new company will also have significant financial capacity for future acquisitions, investment and enhanced shareholder distributions and value creation.
- AbbVie announced the initiation of a Phase 3 clinical trial evaluating the safety and efficacy of its investigational compound, veliparib (ABT-888), when added to carboplatin and paclitaxel, two chemotherapeutic medicines, in patients with human epidermal growth factor receptor 2-(HER2) negative metastatic or locally-advanced breast cancer, containing BRCA1 and/or BRCA2 gene mutations. The trial will recruit approximately 270 patients. The primary efficacy outcome is progression-free survival. The secondary pre-specified outcome measures include overall survival, clinical benefit rate, objective response rate and duration of response. The start of this trial followed initiation of Phase 3 clinical work in two other settings: non-small cell lung cancer and neoadjuvant treatment of triple negative breast cancer.



**Key Events from the Second Quarter (continued)**

- Biogen Idec and AbbVie announced positive top-line results from the Phase 3 DECIDE trial, designed to evaluate the superiority of once-monthly, subcutaneous daclizumab high-yield process (DAC HYP) when compared to intramuscular interferon beta-1a (IFN -1a), as a potential treatment for relapsing-remitting multiple sclerosis (RRMS), the most common form of multiple sclerosis. Results showed that DAC HYP was superior on the study's primary endpoint, demonstrating a statistically significant 45 percent reduction in annualized relapse rate (ARR) compared to IFN -1a ( $p < 0.0001$ ).
- AbbVie presented interim results from a Phase 1b clinical trial of ABT-199/GDC-0199, an investigational B-cell lymphoma 2 (BCL-2) selective inhibitor, in combination with rituximab. Results showed an overall response rate of 84 percent, in patients with relapsed/refractory chronic lymphocytic leukemia (CLL). These results were presented at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO). The combination of ABT-199/GDC-0199 and rituximab is being investigated in an ongoing Phase 3 clinical trial for the treatment of relapsed/refractory CLL.
- AbbVie presented updated data from another Phase 1 study of ABT-199/GDC-0199 as a monotherapy including results from the trial arms investigating the compound as a treatment for patients with relapsed/refractory CLL and a variety of subtypes of non-Hodgkin's lymphoma (NHL), including diffuse large B-cell lymphoma (DLBCL). ABT-199/GDC-0199 as a monotherapy in patients with relapsed/refractory CLL harboring the 17p deletion is under investigation in an ongoing Phase 2 clinical trial.
- Also at ASCO, AbbVie released preliminary results from an ongoing Phase 1 study of ABT-414, an anti-epidermal growth factor receptor (EGFR) monoclonal antibody drug conjugate, in combination with temozolomide, which showed four objective responses, including one complete response, in patients with recurrent or unresectable glioblastoma multiforme. The trial was designed to evaluate the toxicities, pharmacokinetics and recommended Phase 2 dose of ABT-414 when administered every other week in combination with temozolomide in patients with recurrent or unresectable glioblastoma. Other important assessments included adverse events, pharmacokinetic parameters, objective response and tumor tissue epidermal growth factor receptor biomarkers.
- The New Drug Application for AbbVie's investigational, all-oral, interferon-free regimen for the treatment of adult patients with chronic genotype 1 hepatitis C virus (HCV) infection was accepted by the U.S. Food and Drug Administration (FDA) and granted priority review. Additionally, the Marketing Authorization Applications for AbbVie's HCV regimen were validated and are under accelerated assessment by the European Medicines Agency (EMA).
- AbbVie and Bristol-Myers Squibb announced that the FDA has granted elotuzumab, an investigational humanized monoclonal antibody, Breakthrough Therapy Designation for use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in patients who have received one or more prior therapies. Phase 3 studies are ongoing and expected to complete in 2015.
- On June 19, the AbbVie board of directors declared a quarterly cash dividend of \$0.42 per share, payable Aug. 15, 2014 to stockholders of record at the close of business on July 15, 2014.

### Full-Year 2014 Outlook

*Excluding the potential impact of the transaction with Shire, AbbVie is confirming its recently-increased diluted earnings-per-share guidance for the full-year 2014 of \$3.06 to \$3.16 on an adjusted basis, or \$2.69 to \$2.79 on a GAAP basis. AbbVie's 2014 outlook excludes any potential revenue from the expected 2014 U.S. launch of its hepatitis C (HCV) therapy. 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.*

### Third-Quarter 2014 Outlook

*Excluding the potential impact of the transaction with Shire, AbbVie is issuing diluted earnings-per-share guidance for the third-quarter 2014 of \$0.77 to \$0.79 on an adjusted basis, or \$0.68 to \$0.70 on a GAAP basis. The company's third-quarter adjusted diluted earnings-per-share excludes \$0.09 per share of intangible asset amortization expense and other specified items primarily associated with certain separation-related costs and ongoing restructuring activities.*

### UK City Code

The Full-Year 2014 Outlook and Third-Quarter 2014 Outlook constitute profit forecasts under Rule 28 of the City Code on Takeovers and Mergers issued by the Panel on Takeovers and Mergers (the **Code**).

In accordance with Rule 28.4(a) of the Code, the principal assumptions upon which the forecasts are based are included at Schedule 1 to this announcement. In accordance with Rule 28.4(b) of the Code, there is a clear distinction in Schedule 1 between assumptions which the Directors of AbbVie (or other members of AbbVie's management) can influence and those which they cannot influence.

The Third-Quarter 2014 Outlook has been reported on by PricewaterhouseCoopers LLP ( **PwC** ), the Company's reporting accountants, and by J.P. Morgan Limited ( **J.P. Morgan** ), the Company's financial advisers. Copies of their reports are included at Schedules 2 and 3 to this announcement. PwC and J.P. Morgan have given and not withdrawn their consent to publication of this announcement with the inclusion of their reports.

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The Directors of AbbVie confirm that the Full-Year 2014 Outlook remains valid and that PwC and J.P. Morgan have confirmed that their reports issued in accordance with Rule 28.1 of the Code on 23 June 2014 continue to apply. These reports are presented in the announcement titled AbbVie Raises Outlook for 2014 issued on 23 June 2014 and available on AbbVie's website at: [www.abbvieinvestor.com/phoenix.zhtml?c=251551&p=irol-disclaimer-documents](http://www.abbvieinvestor.com/phoenix.zhtml?c=251551&p=irol-disclaimer-documents).

In accordance with Rule 30.4 of the Code, a copy of this announcement will be available on AbbVie's website at [www.abbvieinvestor.com](http://www.abbvieinvestor.com).

### **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 [www.abbvie.com](http://www.abbvie.com). Follow [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](#) or [LinkedIn](#) page.

### **Conference Call**

AbbVie will host an investor conference call today at 8:00 a.m. Central time to discuss our second-quarter performance. Participating on the call will be Rick Gonzalez, chairman and chief executive officer; Bill Chase, executive vice president and chief financial officer; and Larry Peepo, vice president of investor relations. The call will be webcast through AbbVie's Web site at [www.abbvieinvestor.com](http://www.abbvieinvestor.com). Due to the UK Takeover Code, AbbVie will only be providing prepared remarks during the conference call.

### **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.

### **No Offer or Solicitation**

This release is provided for informational purposes only and does not constitute an offer to sell, or an invitation to subscribe for, purchase or exchange, any securities or the solicitation of any vote or approval in any jurisdiction, nor shall there be any sale, issuance, exchange or transfer of the securities referred to in this release in any jurisdiction in contravention of applicable law.

### **Additional Information and Where to Find it**

In furtherance of the combination, AbbVie Private Limited ( Holdco ) intends to file with the SEC a registration statement on Form S-4 containing a Proxy Statement of AbbVie that will also constitute a Prospectus of Holdco relating to the Holdco Shares to be issued to Holdco Stockholders in the combination. In addition, AbbVie, Holdco and Shire may file additional documents with the SEC. INVESTORS AND SECURITY HOLDERS OF ABBVIE AND SHIRE ARE URGED TO READ THE PROXY



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STATEMENT/PROSPECTUS, AND OTHER DOCUMENTS FILED WITH THE SEC IN CONNECTION WITH THE TRANSACTION CAREFULLY AND IN THEIR ENTIRETY, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Those documents, if and when filed, as well as AbbVie's and Holdco's other public filings with the SEC may be obtained without charge at the SEC's website at [www.sec.gov](http://www.sec.gov), at AbbVie's website at [www.abbvieinvestor.com](http://www.abbvieinvestor.com) and at Shire's website at [www.shire.com](http://www.shire.com). It is expected that the Holdco shares to be issued to Shire shareholders under a scheme of arrangement will be issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Section 3(a)(10) thereof.

### **Participants in the Solicitation**

AbbVie, its directors and certain of its executive officers may be considered participants in the solicitation of proxies in connection with the transactions contemplated by the Proxy Statement/Prospectus. Information about the directors and executive officers of AbbVie is set forth in its Annual Report on Form 10-K for the year ended December 31, 2013, which was filed with the SEC on February 21, 2014, and its proxy statement for its 2014 annual meeting of stockholders, which was filed with the SEC on March 24, 2014. Other information regarding potential participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the Proxy Statement/Prospectus when it is filed.

## Forward-Looking Statements

This release contains certain forward-looking statements with respect to a combination involving AbbVie and Shire. The words believe, expect, anticipate, project and similar expressions, among others, generally identify forward-looking statements. 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, the possibility that necessary regulatory approvals or stockholder approvals will not be obtained or any of the other conditions to the combination will not be satisfied, adverse effects on the market price of AbbVie Shares and on AbbVie's or Shire's operating results because of a failure to complete the combination, failure to realise the expected benefits of the possible combination, negative effects relating to the announcement of the possible combination or any further announcements relating to the possible combination or the consummation of the possible combination on the market price of AbbVie shares or Shire shares, significant transaction costs and/or unknown liabilities, general economic and business conditions that affect the combined companies following the consummation of the possible combination, changes in global, political, economic, business, competitive, market and regulatory forces, future exchange and interest rates, changes in tax laws, regulations, rates and policies, future business combinations or disposals and competitive developments. These forward-looking statements are based on numerous assumptions and assessments made in light of AbbVie's or, as the case may be, Shire's experience and perception of historical trends, current conditions, business strategies, operating environment, future developments and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The factors described in the context of such forward-looking statements in this release could cause AbbVie's plans with respect to Shire, AbbVie's or Shire's actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements. Although it is believed that the expectations reflected in such forward-looking statements are reasonable, no assurance can be given that such expectations will prove to have been correct and persons reading this release are therefore cautioned not to place undue reliance on these forward-looking statements which speak only as at the date of this release. Additional information about economic, competitive, governmental, technological and other factors that may affect AbbVie is set forth in Item 1A, Risk Factors, in AbbVie's 2013 Annual Report on Form 10-K, which has been filed with the SEC, the contents of which are not incorporated by reference into, nor do they form part of, this release. Neither AbbVie nor Shire undertakes any obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

### Media:

Jennifer Smoter  
(847) 935-8865

Adelle Infante  
(847) 938-8745

### Investors:

Larry Peepo  
(847) 935-6722

Liz Shea  
(847) 935-2211

## AbbVie Inc.

## Key Product Sales

Quarter Ended June 30, 2014

(Unaudited)

	Sales (in millions)			% Change vs. 2Q13				
	U.S.	Int I.	Total	U.S.	International		Total	
					Operational	Reported	Operational	Reported
<b>TOTAL SALES</b>	<b>\$2,646</b>	<b>\$2,280</b>	<b>\$4,926</b>	<b>0.9%</b>	<b>9.7%</b>	<b>10.2%</b>	<b>4.8%</b>	<b>5.0%</b>
Humira	1,661	1,627	3,288	35.6	16.2	17.8	25.4	26.2
AndroGel	218	--	218	(15.6)	n/a	n/a	(15.6)	(15.6)
Kaletra	56	160	216	(15.4)	(23.5)	(24.4)	(21.5)	(22.2)
Lupron	133	53	186	(7.0)	(0.5)	(3.1)	(5.2)	(5.9)
Synthroid	166	--	166	8.7	n/a	n/a	8.7	8.7
Sevoflurane	22	132	154	20.7	12.8	11.3	13.9	12.6
Creon	110	--	110	4.1	n/a	n/a	4.1	4.1
Synagis	--	74	74	n/a	16.3	4.3	16.3	4.3
Duodopa	--	56	56	n/a	24.2	29.3	24.2	29.3
Niaspan	21	--	21	(90.9)	n/a	n/a	(90.9)	(90.9)
TriCor/Trilipix	17	--	17	(84.4)	n/a	n/a	(84.4)	(84.4)

Note: Operational growth reflects the percentage change over the prior year excluding the impact of exchange rate fluctuations.

n/a = not applicable

## AbbVie Inc.

## Key Product Sales

Six Months Ended June 30, 2014

(Unaudited)

	Sales (in millions)			% Change vs. 6M13				
	U.S.	Int I.	Total	U.S.	International		Total	
					Operational	Reported	Operational	Reported
<b>TOTAL SALES</b>	<b>\$4,872</b>	<b>\$4,617</b>	<b>\$9,489</b>	<b>2.7%</b>	<b>9.1%</b>	<b>8.0%</b>	<b>5.7%</b>	<b>5.2%</b>
Humira	2,853	3,072	5,925	30.8	15.1	15.1	22.2	22.2
AndroGel	472	--	472	(5.2)	n/a	n/a	(5.2)	(5.2)
Synagis	--	428	428	n/a	10.5	3.0	10.5	3.0
Kaletra	110	301	411	(7.7)	(18.6)	(20.4)	(16.0)	(17.4)
Lupron	273	102	375	1.7	(4.4)	(8.4)	--	(1.2)
Synthroid	323	--	323	18.7	n/a	n/a	18.7	18.7
Sevoflurane	41	255	296	18.5	9.0	6.4	10.2	7.9
Creon	217	--	217	10.7	n/a	n/a	10.7	10.7
Duodopa	--	108	108	n/a	26.6	30.6	26.6	30.6
Niaspan	68	--	68	(83.8)	n/a	n/a	(83.8)	(83.8)
TriCor/Trilipix	40	--	40	(83.0)	n/a	n/a	(83.0)	(83.0)

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 Six Months Ended June 30, 2014 and 2013

(Unaudited) (In millions, except per share data)

	Second Quarter Ended June 30		Six Months Ended June 30	
	2014	2013	2014	2013
Net sales	\$4,926	\$4,692	\$9,489	\$9,021
Cost of products sold	1,113	1,054	2,213	2,207
Selling, general and administrative	1,448	1,406	2,788	2,643
Research and development	834	709	1,606	1,343
Acquired in-process research and development	16	70	16	70
Total operating cost and expenses	3,411	3,239	6,623	6,263
Operating earnings	1,515	1,453	2,866	2,758
Interest expense, net	69	75	134	141
Net foreign exchange loss	5	14	8	29
Other (income) expense, net	8	(4)	5	(19)
Earnings before income tax expense	1,433	1,368	2,719	2,607
Income tax expense	335	300	641	571
Net earnings	\$1,098	\$1,068	\$2,078	\$2,036
Diluted earnings per share	\$0.68	\$0.66	\$1.29	\$1.27
Diluted earnings per share, excluding specified items	\$0.82	\$0.82	\$1.53	\$1.50 a)
Average diluted shares outstanding	1,608	1,609	1,608	1,605

a) Refer to the Reconciliation of GAAP Reported to Non-GAAP Adjusted Information for further details.

Note: The computation of diluted earnings per share for the quarter and six months ended June 30, 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 June 30, 2014

(Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

	2Q14		Diluted EPS
	Pre-tax	Earnings After-tax	
<b>As reported (GAAP)</b>	<b>\$1,433</b>	<b>\$1,098</b>	<b>\$0.68</b>
Adjusted for specified items:			
Intangible asset amortization	99	69	0.04
Separation costs	110	96	0.06
R&D	40	40	0.02
Acquired IPR&D	16	16	0.01
Restructuring/Other	12	11	0.01
<b>As adjusted (non-GAAP)</b>	<b>\$1,710</b>	<b>\$1,330</b>	<b>\$0.82</b>

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. R&D is associated with a milestone payment for a previously-announced collaboration. Acquired IPR&D reflects an upfront payment related to a licensing arrangement with a third party. Restructuring/Other is associated with previously announced restructuring activities.

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

Cost of products sold	2Q14		
	SG&A	R&D	Acquired IPR&D

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<b>As reported (GAAP)</b>	<b>\$1,113</b>	<b>\$1,448</b>	<b>\$834</b>	<b>\$16</b>
Adjusted for specified items:				
Intangible asset amortization	(99)	--	--	--
Separation costs	(3)	(106)	(1)	--
R&D	--	--	(40)	--
Acquired IPR&D	--	--	--	(16)
Restructuring/Other	(6)	(6)	--	--
<b>As adjusted (non-GAAP)</b>	<b>\$1,005</b>	<b>\$1,336</b>	<b>\$793</b>	<b>--</b>

3. The adjusted tax rate for the second quarter of 2014 was 22.2 percent, as detailed below:

	2Q14		
	Pre-tax income	Income taxes	Tax rate
<b>As reported (GAAP)</b>	<b>\$1,433</b>	<b>\$335</b>	<b>23.4%</b>
Specified items	277	45	16.2%
<b>As adjusted (non-GAAP)</b>	<b>\$1,710</b>	<b>\$380</b>	<b>22.2%</b>



## AbbVie Inc.

## Reconciliation of GAAP Reported to Non-GAAP Adjusted Information

Quarter Ended June 30, 2013

(Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

	2Q13		Diluted EPS
	Pre-tax	Earnings After-tax	
<b>As reported (GAAP)</b>	<b>\$1,368</b>	<b>\$1,068</b>	<b>\$0.66</b>
Adjusted for specified items:			
Intangible asset amortization	136	98	0.06
Separation costs	67	42	0.03
Acquired IPR&D	70	70	0.04
Restructuring/Other	57	41	0.03
<b>As adjusted (non-GAAP)</b>	<b>\$1,698</b>	<b>\$1,319</b>	<b>\$0.82</b>

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 collaboration with Alvine Pharmaceuticals. Restructuring/Other is primarily associated with previously announced restructuring activities.

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

	2Q13				
	Cost of products sold	SG&A	R&D	Acquired IPR&D	Other (income) expense
<b>As reported (GAAP)</b>	<b>\$1,054</b>	<b>\$1,406</b>	<b>\$709</b>	<b>\$70</b>	<b>(\$4)</b>
Adjusted for specified items:					

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Intangible asset amortization	(136)	--	--	--	--
Separation costs	(4)	(60)	(3)	--	--
Acquired IPR&D	--	--	--	(70)	--
Restructuring/Other	(7)	(36)	(11)	--	(3)
<b>As adjusted (non-GAAP)</b>	<b>\$907</b>	<b>\$1,310</b>	<b>\$695</b>	<b>--</b>	<b>(\$7)</b>

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

	2Q13		
	Pre-tax	Income	
	income	taxes	Tax rate
<b>As reported (GAAP)</b>	<b>\$1,368</b>	<b>\$300</b>	<b>21.9%</b>
Specified items	330	79	23.9%
<b>As adjusted (non-GAAP)</b>	<b>\$1,698</b>	<b>\$379</b>	<b>22.3%</b>

## AbbVie Inc.

## Reconciliation of GAAP Reported to Non-GAAP Adjusted Information

Six Months Ended June 30, 2014

(Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

	6M14		Diluted EPS
	Pre-tax	After-tax	
<b>As reported (GAAP)</b>	<b>\$2,719</b>	<b>\$2,078</b>	<b>\$1.29</b>
Adjusted for specified items:			
Intangible asset amortization	209	148	0.09
Separation costs	190	184	0.11
R&D	40	40	0.02
Acquired IPR&D	16	16	0.01
Restructuring/Other	16	14	0.01
<b>As adjusted (non-GAAP)</b>	<b>\$3,190</b>	<b>\$2,480</b>	<b>\$1.53</b>

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. R&D is associated with a milestone payment for a previously-announced collaboration. Acquired IPR&D reflects an upfront payment related to a licensing arrangement with a third party. Restructuring/Other is associated with previously announced restructuring activities.

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

	6M14			
	Cost of products sold	SG&A	R&D	Acquired IPR&D
<b>As reported (GAAP)</b>	<b>\$2,213</b>	<b>\$2,788</b>	<b>\$1,606</b>	<b>\$16</b>

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Adjusted for specified items:				
Intangible asset amortization	(209)	--	--	--
Separation costs	(6)	(182)	(2)	--
R&D	--	--	(40)	--
Acquired IPR&D	--	--	--	(16)
Restructuring/Other	(7)	(9)	--	--
<b>As adjusted (non-GAAP)</b>	<b>\$1,991</b>	<b>\$2,597</b>	<b>\$1,564</b>	<b>--</b>

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

	Pre-tax	6M14 Income	Tax rate
	income	taxes	
<b>As reported (GAAP)</b>	<b>\$2,719</b>	<b>\$641</b>	<b>23.6%</b>
Specified items	471	69	14.6%
<b>As adjusted (non-GAAP)</b>	<b>\$3,190</b>	<b>\$710</b>	<b>22.3%</b>

## AbbVie Inc.

## Reconciliation of GAAP Reported to Non-GAAP Adjusted Information

Six Months Ended June 30, 2013

(Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

	6M13		Diluted EPS
	Pre-tax	Earnings After-tax	
<b>As reported (GAAP)</b>	<b>\$2,607</b>	<b>\$2,036</b>	<b>\$1.27</b>
Adjusted for specified items:			
Intangible asset amortization	271	196	0.12
Separation costs	101	64	0.04
Acquired IPR&D	70	70	0.04
Restructuring/Other	56	48	0.03
<b>As adjusted (non-GAAP)</b>	<b>\$3,105</b>	<b>\$2,414</b>	<b>\$1.50</b>

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 collaboration with Alvine Pharmaceuticals. 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:

Cost of products sold	SG&A	R&D	6M13	Net foreign exchange	Other (income) expense
			Acquired IPR&D		

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<b>As reported (GAAP)</b>	<b>\$2,207</b>	<b>\$2,643</b>	<b>\$1,343</b>	<b>\$70</b>	loss <b>\$29</b>	<b>(\$19)</b>
Adjusted for specified items:						
Intangible asset amortization	(271)	--	--	--	--	--
Separation costs	(7)	(89)	(5)	--	--	--
Acquired IPR&D	--	--	--	(70)	--	--
Restructuring/Other	10	(38)	(11)	--	(11)	(6)
<b>As adjusted (non-GAAP)</b>	<b>\$1,939</b>	<b>\$2,516</b>	<b>\$1,327</b>	<b>--</b>	<b>\$18</b>	<b>(\$25)</b>

3. The adjusted tax rate for the first half of 2013 was 22.3 percent, as detailed below:

	6M13		
	Pre-tax income	Income taxes	Tax rate
<b>As reported (GAAP)</b>	<b>\$2,607</b>	<b>\$571</b>	<b>21.9%</b>
Specified items	498	120	24.1%
<b>As adjusted (non-GAAP)</b>	<b>\$3,105</b>	<b>\$691</b>	<b>22.3%</b>

## Questions & Answers

To provide investors with more insight into AbbVie's business and answer ongoing questions while we operate under the UK Takeover Code, we have expanded our earnings news release to include the following Q&A section.

### Financial Questions

**Q) What is the expected level of sales growth for the remainder of 2014?**

A) We are forecasting low- to mid-single-digit operational sales growth in both the third and fourth quarters of 2014. As a reminder, our 2014 outlook excludes any potential revenue from the expected 2014 U.S. launch of our HCV therapy.

**Q) What is the expected gross margin profile for the remainder of 2014?**

A) We expect the third-quarter gross margin ratio to be approximately 79 percent. For the fourth quarter, the ratio is expected to be somewhat lower than the third quarter driven by product mix, particularly an increase in lower-margin Synagis sales.

**Q) How will investment in SG&A impact AbbVie's second-half 2014 results, particularly in light of the anticipated HCV approval and launch?**

A) As noted on our fourth-quarter earnings conference call in January, we are forecasting a higher level of SG&A expense in 2014 compared to 2013, driven primarily by investments we are making for the upcoming launch of our HCV regimen in the U.S. and Europe. For the third quarter, we expect a modest sequential increase in absolute SG&A expense from the second quarter. For the fourth quarter, given the proximity to the U.S. HCV launch, we'd expect a more meaningful sequential increase in absolute SG&A expense from the third-quarter level. This has been reflected in our recently-increased adjusted earnings-per-share guidance.

**Q) What level of R&D spend do you expect in second-half 2014?**

A) We currently have a significant number of Phase 3 programs in active development including exciting opportunities in oncology, HCV, immunology and other areas that warrant investment. As a result, we expect R&D expense to be above 16 percent of sales for the full-year 2014, reflecting a meaningful increase in R&D spending over the prior year. For the third quarter, we expect a sequential increase in absolute R&D investment from the second-quarter level. For the fourth quarter, we are forecasting a more modest sequential increase from the third-quarter level. This has been reflected in our recently-increased adjusted earnings-per-share guidance.

## Questions & Answers (continued)

### Marketed Product Performance Questions

**Q) What factors impacted HUMIRA performance in second-quarter 2014?**

A) In the United States, HUMIRA sales increased 35.6 percent, driven by continued market expansion, share gains, and particularly strong growth in gastroenterology. Second quarter wholesaler inventory levels remain at roughly two weeks, consistent with the first quarter. Growth in the second quarter benefitted from retail buying patterns and a favorable comparison to the prior year. We expect third-quarter HUMIRA sales growth in the U.S. to be reflective of underlying product demand and pricing trends, partially offset by a reduction in retail buying patterns. As a result, we are forecasting high-teens growth for HUMIRA in the U.S. in the third quarter.

Internationally, HUMIRA sales grew 16.2 percent on an operational basis and 17.8 percent on a reported basis. International growth continues to be driven by the uptake of new indications, share gains and double-digit market growth in most key countries. Performance in the quarter also benefitted modestly from the timing of international shipments. We are forecasting low double-digit growth for HUMIRA internationally in the third quarter driven by strong underlying trends, partially offset by the timing of shipments in international markets.

On a global basis, we continue to expect double-digit sales growth for HUMIRA in 2014.

**Q) What impacted AndroGel sales in the second quarter?**

A) AndroGel sales were \$218 million, down 15.6 percent from the prior year quarter. We continue to see a notable slowdown in the market, with overall prescriptions down more than 20 percent in recent months. We expect these market trends to continue.

**Q) What impacted Kaletra sales in the second quarter?**

A) Global Kaletra sales in the quarter were \$216 million, down 21.5 percent on an operational basis. This performance has been driven by increasing competition in the HIV marketplace and is in line with our plan expectations for the product.

**Q) What impacted Synthroid sales in the second quarter?**

A) U.S. sales of Synthroid were \$166 million, up 8.7 percent year-over-year. Synthroid maintains strong brand loyalty and market leadership, despite the entry of generics into the market many years ago. The overall market has experienced low-single digit growth, with Synthroid growth outpacing the market, including product pricing trends.

**Q) What impacted Lupron sales in the second quarter?**

A) Global Lupron sales were \$186 million, down 5.2 percent on an operational basis. Lupron continues to hold a leadership position and maintains significant share of the market. Performance this quarter is roughly in line with our full-year expectations for Lupron, and is also consistent with recent market trends.





## Questions & Answers (continued)

**Q) What impacted Sevoflurane sales in the second quarter?**

A) Global Sevoflurane sales were \$154 million in the quarter, up 13.9 percent on an operational basis. Performance in the quarter was driven by strong international execution, including key account retention, and underlying volume trends.

**Q) What impacted Creon sales in the second quarter?**

A) U.S. Creon sales were \$110 million in the quarter, up 4.1 percent. Creon maintains its leadership position in the pancreatic enzyme market, where the product continues to capture the vast majority of new prescription starts.

**Q) What impacted Synagis sales in the second quarter?**

A) Sales of Synagis were \$74 million in the second quarter, up 16.3 percent on an operational basis. Synagis, which protects at-risk infants from severe respiratory disease, is a seasonal product with the majority of sales in the first and fourth quarters of the year. Growth in the quarter was driven by continued product uptake and strong commercial execution.

**Q) What impacted Duodopa sales in the second quarter?**

A) Sales of Duodopa, our therapy for advanced Parkinson's disease approved in Europe and other international markets, were \$56 million, up 24.2 percent on an operational basis this quarter. Performance in the quarter is in line with recent trends and our full-year outlook for the product.

**Q) What impacted Dyslipidemia sales in the second quarter?**

A) Sales of Niaspan were \$21 million and TriCor/Trilipix sales were \$17 million, both down significantly due to generic competition. We expect these trends to continue for the remainder of 2014.

### Pipeline Questions

**Q) What are the upcoming milestones from the AbbVie pipeline?**

A) We expect a number of pipeline milestones over the next 6-9 months including data presentations, clinical trial advancements and regulatory actions. These include:

- Commercialization of HCV therapy in U.S. (late 2014) and EU (early 2015)
- Veliparib NSCLC Phase 2b data presentation at ESMO
- Veliparib BRCA breast Phase 2b data presentation
- Elagolix (endometriosis) Phase 3 data readout

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- Daclizumab regulatory submissions
- HUMIRA Hidradenitis Suppurativa Phase 3 data readout and regulatory submissions
- ABT-199 AML Phase 1 data presentation
- ABT-199 CLL (17P del) Phase 2 data readout
- Japan HCV Phase 3 data readout and regulatory submission

## Questions & Answers (continued)

### Shire Transaction Questions

- Q) When do you anticipate providing additional details regarding various aspects of the financial impact of the Shire transaction, including accretion profile and synergies?**
- A) We will comment further on our plans in the transaction documents in the fall. It is expected that the transaction will be completed in the fourth quarter of 2014. Comments made to date include the following:
- AbbVie expects the transaction to be accretive to AbbVie's adjusted EPS in the first year following the completion, growing to above \$1.00 per share by 2020, with material ongoing financial and operating benefits.
- Note: Adjusted EPS excludes intangible asset amortization expense and purchase accounting adjustments and other specified items. The statement that the Transaction is earnings accretive should not be construed as a profit forecast and is therefore not subject to the requirements of Rule 28 of the Code. It should not be interpreted to mean that the earnings per share in any future financial period will necessarily match or be greater than those for the relevant preceding financial period.
- Q) What is the expected tax rate for AbbVie following the Shire transaction?**
- A) The AbbVie Board expects the transaction to reduce New AbbVie's effective tax rate to approximately 13 percent by 2016 and provide New AbbVie with access to its global cash flows.
- Q) What is the expected impact to AbbVie's credit ratings following the Shire transaction?**
- A) New AbbVie intends to maintain its investment grade rating profile following the transaction.
- Q) What are AbbVie's plans for dividend growth and share repurchase following the Shire transaction?**
- A) It is AbbVie's intent, upon completion of the transaction, to maintain a strong commitment to a growing dividend and to implement a significant share repurchase program.
- Q) When do you anticipate providing 2015 financial guidance, inclusive of the Shire impact?**
- A) We have typically provided guidance for the coming year on our fourth-quarter earnings conference call. We expect to do something similar for our 2015 guidance.
- Q) Do you anticipate New AbbVie will be included in the S&P 500?**
- A) It is intended that the New AbbVie shares will be listed on the New York Stock Exchange. As a result, we expect that New AbbVie will be included in the S&P 500.
- Q) Which countries have been identified as requiring approval as a condition of the Shire transaction?**
- A)

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Principal countries in which approvals are required or potentially required include: United States, Canada, Ukraine, Israel, Russia and the European Union.

## Questions & Answers (continued)

**Q) What are the tax implications of the Shire transaction for shareholders of both companies?**

- A) It is expected that Shire Shareholders who are resident in the UK for tax purposes will generally not be charged to tax in the UK in respect of that element of the consideration provided to them in the form of shares in New AbbVie, but that any cash consideration received by such shareholders for their Shire Shares will crystallise a disposal for such shareholders for the purposes of UK tax on chargeable gains and may, depending on the circumstances of such shareholders, give rise to a charge to UK capital gains tax or UK corporation tax.

It is expected that, for U.S. federal income tax purposes, the Transaction generally will be taxable to U.S. shareholders of both AbbVie and Shire. The tax consequences of the Transaction may vary based on an individual shareholder's circumstances, and a more complete description of the anticipated tax consequences of the Transaction will be made available in the Scheme Circular and the AbbVie Proxy Statement.

This information is intended to be general guidance only and does not take into account individual investors' specific circumstances or constitute tax advice to any investor. Investors who require further information about the tax consequences of the transaction are urged to seek tax advice from appropriately qualified tax advisors.

**Schedule 1**

**Profit Forecast for AbbVie Inc for the Financial Year ended December 31, 2014 and for three months ended September 30, 2014**

In accordance with Rule 28.4(a) of the Code, the principal assumptions upon which the profit forecast is based are included in this Schedule 1 to the announcement. In accordance with Rule 28.4(b) of the Code, there is a clear distinction made between assumptions which the Directors of AbbVie (or other members of AbbVie's management) can influence and those which they cannot influence.

**1. General**

AbbVie today made the following statements in its Second-Quarter 2014 Financial Results Announcement:

Full-Year 2014 Outlook

*Excluding the potential impact of the transaction with Shire, AbbVie is confirming its recently-increased diluted earnings-per-share guidance for the full-year 2014 of \$3.06 to \$3.16 on an adjusted basis, or \$2.69 to \$2.79 on a GAAP basis. AbbVie's 2014 outlook excludes any potential revenue from the expected 2014 U.S. launch of its hepatitis C (HCV) therapy. 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.*

Third-Quarter 2014 Outlook

*Excluding the potential impact of the transaction with Shire, AbbVie is issuing diluted earnings-per-share guidance for the third-quarter 2014 of \$0.77 to \$0.79 on an adjusted basis, or \$0.68 to \$0.70 on a GAAP basis. The company's third-quarter adjusted diluted earnings-per-share excludes \$0.09 per share of intangible asset amortization expense and other specified items primarily associated with certain separation-related costs and ongoing restructuring activities.*

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The above statements for the financial year ending December 31, 2014 and the three months ending September 30, 2014 constitute profit forecasts for the purposes of the Code (the **AbbVie Profit Forecast** ).

In the above statements, adjusted diluted earnings per share is defined as net earnings attributable to AbbVie divided by the weighted average number of diluted shares for the year. The computation of weighted average shares for diluted earnings per share adds back incremental shares from assumed conversions of stock options, net of assumed share repurchases and LTIP shares to the weighted average shares of basic earnings per shares.

### **2. Basis of preparation**

The AbbVie Profit Forecast has been prepared on a basis consistent with the accounting policies for AbbVie which are in accordance with generally accepted accounting standards in the U.S. and those which AbbVie anticipates will be applicable for the full year ending December 31, 2014.

AbbVie has prepared the AbbVie Profit Forecast based on unaudited interim financial results for the six months ended June 30, 2014 and a forecast to September 30, 2014 and December 31, 2014.



**3. Assumptions**

AbbVie has prepared the AbbVie Profit Forecast on the basis of the following assumptions:

***Factors outside the influence or control of AbbVie and its Directors***

- There will be no material change to the existing prevailing global macroeconomic and political conditions during the year ended December 31, 2014.
- The Euro, British pound and Japanese yen and other exchange rates, and inflation and tax rates in AbbVie's principal markets will remain materially unchanged from the prevailing rates.
- There will be no material change in legislation or regulatory requirements impacting on AbbVie's operations or its accounting policies.
- There will be no material change in AbbVie's labour costs, including medical and pension and other post-retirement benefits driven by external parties or regulations.
- There will be no material adverse events that will have a significant impact on AbbVie's financial performance.

***Factors within the influence or control of AbbVie and its Directors***

- The AbbVie Profit Forecast excludes any material acquisitions or disposals in the year ended December 31, 2014.
- This AbbVie Profit Forecast excludes any future one-time costs associated with the proposed transaction with Shire plc, which will be quantified at a later date.
- Current separation plans and costs as part of the Transition Service Agreement with Abbott will conclude materially as AbbVie would reasonably expect based on AbbVie's past experience.
- The AbbVie Profit Forecast excludes any potential revenue from the expected 2014 U.S. launch of its HCV therapy.
- There will be no material change in the weighted average number of diluted shares in issue.
- There will be no material change in the present management or control of AbbVie or its existing operational strategy.

**Schedule 2**

**Report of PricewaterhouseCoopers pursuant to Rule 28.1(a)(i) of the City Code on Takeovers and Mergers**

The Directors (the **Directors** )

AbbVie Inc.

1 North Waukegan Road

North Chicago

Illinois 60064

United States of America

J.P. Morgan Limited (the **Financial Adviser** )

25 Bank Street

Canary Wharf

London

E14 5JP

July 25, 2014

Dear Sirs

**AbbVie Inc**

## Edgar Filing: Shire plc - Form 425

We report on the profit forecast comprising the statement by AbbVie Inc. (the **Company** ) and its subsidiaries (together the **Group** ) in relation to the third quarter guidance for the three months ending September 30, 2014 (the **Profit Forecast** ). The Profit Forecast and the material assumptions, upon which it is based, are set out on Schedule 1 of the announcement issued by the Company dated July 25, 2014 (the **Document** ).

This report is required by Rule 28.1(a)(i) of the City Code on Takeovers and Mergers issued by the Panel on Takeovers and Mergers (the **City Code** ) and is given for the purpose of complying with that rule and for no other purpose.

### Responsibilities

It is the responsibility of the Company and the directors of the Company (the **Directors** ) to prepare the Profit Forecast in accordance with the requirements of the City Code.

It is our responsibility to form an opinion as required by Rule 28.1(a)(i) of the City Code as to the proper compilation of the Profit Forecast and to report that opinion to you.

Save for any responsibility which we may have to those persons to whom this report is expressly addressed and for any responsibility arising under Rule 28.1(a)(i) of the City Code to any person as and to the extent therein provided, to the fullest extent permitted by law we do not assume any responsibility and will not accept any liability to any other person for any loss suffered by any such other person as a result of, arising out of, or in connection with this report or our statement, required by and given solely for the purposes of complying with Rule 23.3(b) of the City Code, consenting to its inclusion in the Document.

### **Basis of Preparation of the Profit Forecast**

The Profit Forecast has been prepared on the basis stated in Schedule 1 of the Document and is based on the unaudited interim financial results for the six months ended June 30, 2014 and a forecast to September 30, 2014. The Profit Forecast is required to be presented on a basis consistent with the accounting policies of the Group.

### **Basis of Opinion**

We conducted our work in accordance with the Standards for Investment Reporting issued by the Auditing Practices Board in the United Kingdom. Our work included evaluating the basis on which the historical financial information included in the Profit Forecast has been prepared and considering whether the Profit Forecast has been accurately computed based upon the disclosed assumptions and the accounting policies of the Group. Whilst the assumptions upon which the Profit Forecast are based are solely the responsibility of the Company and the Directors, we considered whether anything came to our attention to indicate that any of the assumptions adopted by the Company and the Directors which, in our opinion, are necessary for a proper understanding of the Profit Forecast have not been disclosed or if any material assumption made by the Company and the Directors appears to us to be unrealistic.

We planned and performed our work so as to obtain the information and explanations we considered necessary in order to provide us with reasonable assurance that the Profit Forecast has been properly compiled on the basis stated.

Since the Profit Forecast and the assumptions on which it is based relate to the future and may therefore be affected by unforeseen events, we can express no opinion as to whether the actual results reported will correspond to those shown in the Profit Forecast and differences may be material.

Our work has not been carried out in accordance with auditing standards generally accepted in the United States of America or auditing standards of the Public Company Accounting Oversight Board (United States) and accordingly should not be relied upon as if it had been carried out in accordance with those standards.

### **Opinion**

In our opinion, the Profit Forecast has been properly compiled on the basis stated and the basis of accounting used is consistent with the accounting policies of the Group.

Yours faithfully

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP

Chartered Accountants

**Schedule 3**

**Report of J.P. Morgan pursuant to Rule 28.1(a)(ii) of the City Code on Takeovers and Mergers**

The Directors (the **Directors** )

AbbVie Inc.

1 North Waukegan Road

North Chicago

Illinois 60064

United States of America

25 July 2014

Dear Sirs

**Report by the financial adviser to AbbVie Inc. (the Company )**

We refer to the profit forecast comprising the statement by the Company and its subsidiaries in relation to the third quarter guidance for the three months ending 30 September 2014 made by the Company in the announcement issued by the Company on 25 July 2014 (the **Profit Forecast** ).

We have discussed the Profit Forecast and the bases and assumptions on which it has been prepared with duly authorized executive officers of the Company (acting on behalf of the Company) and with PricewaterhouseCoopers LLP ( **PwC** ), the Company's reporting accountants. We have also discussed the accounting policies and calculations for the Profit Forecast with PwC and we have considered their letter of today's date addressed to you and ourselves on this matter. We have relied upon the accuracy and completeness of all the financial and other information discussed with us and have assumed such accuracy and completeness for the purposes of delivering this letter.

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This letter to you is provided solely in connection with our obligation under Rule 28.1(a) (ii) of the City Code on Takeovers and Mergers and for no other purpose. We accept no responsibility and, to the fullest extent permitted by law, exclude all liability to any other person other than to you, in your capacity as directors of the Company, in respect of this letter or the work undertaken in connection with this letter.

On the basis of the foregoing, we consider that the Profit Forecast referred to above, for which the Company and the Directors are solely responsible, has been prepared with due care and consideration.

Yours faithfully,

/s/ J.P. Morgan Limited

J.P. Morgan Limited