

PHARMACYCLICS INC
Form 425
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Subject Company: Pharmacyclics, Inc.

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PRESS RELEASE

AbbVie Reports First-Quarter 2015 Financial Results

- *Reports First-Quarter Adjusted EPS of \$0.94, Up 32.4 Percent and Exceeding Previous Guidance Range of \$0.82 to \$0.84 (Reports GAAP EPS of \$0.63)*
- *Delivers First-Quarter Revenue of \$5.040 Billion, an Increase of 17.8 Percent Over First-Quarter 2014 on an Operational Basis (Up 10.5 Percent on a Reported Basis) Driven by Strong Growth Across the Portfolio and the Launch of Viekira*
- *Revenue Growth Reflects 26.0 Percent Global Operational Sales Growth from HUMIRA (Up 18.0 Percent on a Reported Basis) and Double-Digit Operational Growth from Other Key Products*
- *Delivers Adjusted Gross Margin Expansion to 82.9 Percent of Sales; Adjusted Operating Margin Improves to 40.1 Percent of Sales*

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- *Announced Strategic Agreement to Acquire Pharmacyclics; Expects to Close the Transaction in Second-Quarter 2015*
- *Raises 2015 Adjusted EPS Guidance Range to \$4.10 to \$4.30 (GAAP EPS Range is \$3.57 to \$3.77)*

NORTH CHICAGO, Ill., April 23, 2015 AbbVie (NYSE:ABBV) announced financial results for the first quarter ended March 31, 2015.

AbbVie had an exceptional first quarter, delivering on our projection of top-tier EPS growth, as well as robust sales growth and significant margin expansion, said Richard A. Gonzalez, chairman and chief executive officer, AbbVie. We also announced the acquisition of Pharmacyclics, which will establish AbbVie as a leader in the hematologic oncology market and provide an important growth platform for the future. And, we continued to gain momentum with the launch of our HCV therapy, Viekira, and further advancement of our late stage pipeline. Certainly, 2015 is a pivotal year for AbbVie and we are off to an impressive start.

First-Quarter Results

- Worldwide sales were \$5.040 billion in the first quarter, up 10.5 percent year-over-year. On an operational basis, sales increased 17.8 percent, excluding a 7.3 percent unfavorable impact from foreign exchange rate fluctuations.
- First-quarter sales growth was driven by the continued strength of HUMIRA and other promoted products. Global HUMIRA sales increased 18.0 percent, or 26.0 percent on an operational basis, excluding the impact of foreign exchange rate fluctuations. Total company sales growth was also driven by the launch of Viekira, as well as strong operational growth from other key products including Synagis, Synthroid, Creon and Duodopa.

First-Quarter Results (continued)

- The adjusted gross margin ratio in the first quarter was 82.9 percent, excluding intangible asset amortization and other specified items. Gross margin expansion was driven by product mix, operating efficiencies and the impact of foreign exchange rates. The gross margin ratio under U.S. generally accepted accounting principles (GAAP) was 81.3 percent.
- Adjusted selling, general and administrative (SG&A) expense was 26.7 percent of sales in the first quarter. On a GAAP basis, SG&A was 29.2 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 emerging mid- and late-stage pipeline assets. On a GAAP basis, R&D was also 16.1 percent of sales.
- The adjusted operating margin in the first quarter was 40.1 percent, compared to 33.9 percent in first-quarter 2014. On a GAAP basis, the operating margin was 33.5 percent.
- Net interest expense was \$67 million on an adjusted basis and \$126 million on a GAAP basis. The adjusted tax rate was 22.3 percent in the quarter and 26.8 percent on a GAAP basis.
- Adjusted diluted earnings per share, excluding intangible asset amortization expense and other specified items, were \$0.94 in the first quarter, up 32.4 percent. Diluted earnings per share were \$0.63 on a GAAP basis.

Key Events from the First Quarter

- On March 4, AbbVie and Pharmacyclics, Inc. announced a definitive agreement under which AbbVie will acquire Pharmacyclics and its flagship asset IMBRUVICA (ibrutinib), a highly effective treatment for hematologic malignancies. The acquisition accelerates AbbVie's clinical and commercial presence in oncology, strengthens its already robust pipeline, and establishes a leadership position in hematological oncology – an attractive and rapidly growing market approaching \$24 billion globally. The acquisition adds to AbbVie's complementary pipeline and strong growth prospects. Under the terms of the transaction, AbbVie will pay \$261.25 per share comprised of a mix of cash and AbbVie equity. The transaction values

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Pharmacyclics at approximately \$21 billion and was approved by the Boards of Directors of both companies.

- Biogen and AbbVie announced that the European Medicines Agency (EMA) has validated the companies' Marketing Authorisation Application (MAA) for ZINBRYTA (daclizumab high-yield process) for the treatment of relapsing forms of multiple sclerosis (MS) in the European Union. Validation confirms that the submission is complete and signifies the initiation of the review process by the EMA's Committee for Medicinal Products for Human Use. The MAA included results from two clinical trials, DECIDE and SELECT, in which ZINBRYTA 150 mg was administered subcutaneously every four weeks in people with relapsing-remitting MS.

Key Events from the First Quarter (continued)

- The U.S. Food and Drug Administration (FDA) has accepted AbbVie's New Drug Application and granted priority review for the company's two direct-acting antiviral treatment of ombitasvir, paritaprevir, ritonavir (OBV/PTV/r) with ribavirin (RBV) for the treatment of adults with chronic genotype 4 (GT4) hepatitis C virus (HCV) infection. AbbVie's regimen is the first all-oral, interferon-free therapy being evaluated by the FDA for patients with chronic GT4 HCV infection. The FDA granted priority review for the regimen based in part on data from the PEARL-I study, which demonstrated up to 100 percent sustained virologic response rates at 12 weeks post-treatment with no discontinuations due to adverse events.
- AbbVie submitted a New Drug Application to the Japanese Ministry of Health, Labour and Welfare seeking approval for the company's investigational, all-oral, RBV and interferon-free, 12-week, two direct-acting antiviral treatment oOBV/PTV/r, dosed once daily. The submission, which has been granted priority review, is for the treatment of patients with genotype 1 (GT1) HCV infection, and is based on the Phase 3 GIFT-I study. In Japan, approximately 1.5 to 2 million people are living with HCV. GT1 is the most common HCV genotype in Japan with 60 to 70 percent of patients infected and, of those, about 95 percent are infected with the GT1b sub-type.
- AbbVie announced preliminary results from a Phase 2b study of ABT-493 and ABT-530, the company's ongoing HCV pipeline development program which focuses on investigating a pan-genotypic, RBV-free, once-daily treatment that may also allow for treatment durations of as little as eight weeks. Results from this study in non-cirrhotic GT1 patients (n=79) receiving the RBV-free recommended regimen for 12 weeks demonstrated a sustained virologic response rate at four weeks post treatment (SVR4) of 99 percent (n=78/79). These results included both GT1a and GT1b, treatment-naïve and pegylated-interferon and RBV prior null responders. To date, the most common (>5 percent) adverse reactions were fatigue, headache, nausea, diarrhea and anxiety. Data from these Phase 2b studies of ABT-493 and ABT-530 will be released at future medical congresses.
- AbbVie recently received a Commission Decision in Europe regarding compliance with its Pediatric Investigation Plan for HUMIRA, which ensures that necessary data are obtained through studies in children. As a result of this positive decision, the company will now seek an extension from each Member State where a Supplementary Protection Certificate is held. Once approved, this will extend the HUMIRA composition of matter patent by six months.
- The European Commission (EC) has granted marketing authorization for HUMIRA for the treatment of severe chronic plaque psoriasis in children and adolescents from four years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies. With the EC decision, HUMIRA now has approval for use in this indication in all member states of the European Union. The marketing authorization is based on the positive results of a Phase 3 study, which will be presented at an upcoming medical meeting.

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- AbbVie entered into an exclusive worldwide license agreement with C2N Diagnostics, a privately held protein diagnostic and therapeutic discovery company, to develop and commercialize a portfolio of anti-tau antibodies for the treatment of Alzheimer's Disease and other neurological disorders.

Key Events from the First Quarter (continued)

- AbbVie announced that the FDA approved DUOPA (carbidopa and levodopa) enteral suspension for the treatment of motor fluctuations for people with advanced Parkinson's disease. DUOPA is administered using a small, portable infusion pump that delivers carbidopa and levodopa directly into the small intestine for 16 continuous hours via a procedurally-placed tube. In a clinical trial, patients treated with DUOPA experienced significantly greater improvement in "off" time (periods of poor mobility, slowness and stiffness) than patients treated with oral carbidopa-levodopa immediate release tablets.
- On February 19, the AbbVie board of directors increased the company's quarterly cash dividend by 4 percent from \$0.49 per share to \$0.51 per share. The cash dividend is payable May 15, 2015 to stockholders of record at the close of business on April 15, 2015. Since the company's inception in 2013, AbbVie has increased its dividend by 28 percent.

Full-Year 2015 Outlook

Today, AbbVie is raising its adjusted diluted earnings-per-share guidance for the full-year 2015 to \$4.10 to \$4.30 from \$4.05 to \$4.25. The company's 2015 adjusted diluted earnings-per-share guidance excludes \$0.53 per share of intangible asset amortization expense, deal costs, integration, and other specified items, and includes \$0.20 of dilution related to the Pharmacyclics acquisition. AbbVie's diluted earnings-per-share guidance is \$3.57 to \$3.77 on a GAAP basis, excluding certain transaction related costs to be quantified following the close of the Pharmacyclics acquisition.

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 more than 26,000 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](#) on Twitter or view careers on our [Facebook](#) or [LinkedIn](#) page.

Conference Call

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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; Mike Severino, executive vice president, research and development and chief scientific officer; 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 2014 and 2015 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 2015 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, the likelihood that the Pharmacyclics transaction is consummated and the expected benefits of the transaction, 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 2014 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.

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Important Additional Information

This press release does not constitute an offer to purchase, or a solicitation of an offer to sell, shares of common stock of Pharmacyclics, nor is it a substitute for the Registration Statement on Form S-4 and tender offer materials that AbbVie filed with the Securities and Exchange Commission (SEC) on March 23, 2015, each as amended.

Investors and security holders of Pharmacyclics are urged to read the tender offer statement on Schedule TO, filed on March 23, 2015 (as amended, the Schedule TO), the Registration Statement on Form S-4, as filed on March 23, 2015 (as amended, the Registration Statement), and the solicitation/recommendation statement filed by Pharmacyclics on Schedule 14D-9, filed on March 23, 2015 (as amended, the Schedule 14D-9). The tender offer materials (including an offer to purchase, letter of transmittal and related tender offer documents), the Registration Statement and the Schedule 14D-9 contain important information which should be read carefully before any decisions are made with respect to the Offer.

In addition to the Schedule TO, the Schedule 14D-9 and the Registration Statement described above, AbbVie and Pharmacyclics file annual, quarterly and current reports, proxy statements and other information with the SEC. The Schedule TO, the Schedule 14D-9, the Registration Statement and any other relevant materials, and any other documents filed with the SEC by AbbVie or Pharmacyclics, are available without charge at the SEC s website at www.sec.gov, or from the companies websites, at www.abbvieinvestor.com and <http://www.pharmacyclics.com>, respectively.

Free copies of the exchange offer materials (including the Registration Statement and the Schedule TO) are also available on AbbVie s website at www.abbvieinvestor.com and copies of the Schedule 14D-9 are available on Pharmacyclics website <http://www.pharmacyclics.com>. Copies of the exchange offer materials (including the Registration Statement and the Schedule TO) may also be obtained free of charge from Georgeson Inc., the information agent for the exchange offer, by calling, toll-free, (888) 680-1528 or emailing PCYC@georgeson.com.

AbbVie Inc.

Key Product Sales

Quarter Ended March 31, 2015

(Unaudited)

	Sales (in millions)			% Change vs. 1Q14				
	<u>U.S.</u>	<u>Int. I.</u>	<u>Total</u>	<u>U.S.</u>	<u>International</u> <u>Operational</u>	<u>Reported</u>	<u>Total</u> <u>Operational</u>	<u>Reported</u>
TOTAL SALES	\$2,650	\$2,390	\$5,040	19.1%	16.5%	2.3%	17.8%	10.5%
Humira	1,664	1,447	3,111	39.6	14.8	0.2	26.0	18.0
Synagis	--	335	335	n/a	8.0	(5.5)	8.0	(5.5)
Viekira	138	93	231	n/m	n/m	n/m	n/m	n/m
Lupron	150	42	192	7.0	(5.1)	(14.2)	3.8	1.5
Synthroid	186	--	186	18.8	n/a	n/a	18.8	18.8
Kaletra	41	139	180	(23.8)	13.1	(1.7)	3.1	(7.7)
AndroGel	153	--	153	(39.8)	n/a	n/a	(39.8)	(39.8)
Creon	127	--	127	18.8	n/a	n/a	18.8	18.8
Sevoflurane	18	108	126	(2.8)	(1.1)	(12.1)	(1.3)	(10.9)
Duodopa	n/m	53	53	n/m	18.9	1.2	19.5	1.8

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

n/a = not applicable

n/m = not meaningful

AbbVie Inc.

Consolidated Statements of Earnings

Quarter Ended March 31, 2015 and 2014

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

	2015	2014
Net sales	\$5,040	\$4,563
Cost of products sold	942	1,100
Selling, general and administrative	1,473	1,340
Research and development	811	772
Acquired in-process research and development	127	--
Total operating cost and expenses	3,353	3,212
Operating earnings	1,687	1,351
Interest expense, net	126	65
Net foreign exchange loss	164	3
Other (income) expense, net	1	(3)
Earnings before income tax expense	1,396	1,286
Income tax expense	374	306
Net earnings	\$1,022	\$980
Diluted earnings per share	\$0.63	\$0.61
Diluted earnings per share, excluding specified items	\$0.94	\$0.71 a)
Average diluted shares outstanding	1,608	1,609

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

AbbVie Inc.

Reconciliation of GAAP Reported to Non-GAAP Adjusted Information

Quarter Ended March 31, 2015

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

1. Specified items impacted results as follows:

	1Q15		
	Earnings		Diluted
	Pre-tax	After-tax	EPS
As reported (GAAP)	\$1,396	\$1,022	\$0.63
Adjusted for specified items:			
Intangible asset amortization	68	52	0.03
Separation costs	104	89	0.05
Acquired IPR&D	127	127	0.08
Shire termination	170	170	0.11
Other	95	63	0.04
As adjusted (non-GAAP)	\$1,960	\$1,523	\$0.94

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 primarily reflects the C2N collaboration. Shire termination reflects the completed liquidation of remaining foreign currency positions related to the terminated Shire transaction, as communicated in the fourth quarter. Other is primarily associated with restructuring activities and interest expense for the Pharmacyclics acquisition.

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

	1Q15				
	Cost of products sold	SG&A	IPR&D	Foreign exchange (gain)/loss	Interest expense
As reported (GAAP)	\$942	\$1,473	\$127	\$164	\$126
Adjusted for specified items:					
Intangible asset amortization	(68)	--	--	--	--
Separation costs	(3)	(101)	--	--	--

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Acquired IPR&D	--	--	(127)	--	--
Shire termination	--	--	--	(170)	--
Other	(9)	(27)	--	--	(59)
As adjusted (non-GAAP)	\$862	\$1,345	--	(\$6)	\$67

3. The adjusted tax rate for the first quarter of 2015 was 22.3 percent, as detailed below:

	Pre-tax income	1Q15 Income taxes	Tax rate
As reported (GAAP)	\$1,396	\$374	26.8%
Specified items	564	63	11.2%
As adjusted (non-GAAP)	\$1,960	\$437	22.3%

AbbVie Inc.

Reconciliation of GAAP Reported to Non-GAAP Adjusted Information

Quarter Ended March 31, 2014

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

4. 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.

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

	1Q14		
	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

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

	Pre-tax income	1Q14 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%