
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **April 25, 2019**

ABBVIE INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other Jurisdiction
of Incorporation)

001-35565
(Commission File Number)

32-0375147
(IRS Employer
Identification No.)

1 North Waukegan Road
North Chicago, Illinois 60064-6400
(Address of principal executive offices)(Zip Code)

Registrant's telephone number, including area code: **(847) 932-7900**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On April 25, 2019, AbbVie Inc. issued a press release announcing financial results for the first quarter ended March 31, 2019. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Exhibit
99.1	Press Release dated April 25, 2019 (furnished pursuant to Item 2.02).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ABBVIE INC.

Date: April 25, 2019

By: /s/ Robert A. Michael

Robert A. Michael
Senior Vice President,
Chief Financial Officer

PRESS RELEASE

AbbVie Reports First-Quarter 2019 Financial Results

- Reports First-Quarter Diluted EPS of \$1.65 on a GAAP Basis; Adjusted Diluted EPS of \$2.14 Reflects Growth of 14.4 Percent
- First-Quarter Net Revenues Were \$7.828 Billion, an Increase of 0.4 Percent on an Operational Basis, Excluding a 1.7 Percent Unfavorable Impact From Foreign Exchange
- First-Quarter U.S. HUMIRA Net Revenues Were \$3.215 Billion, an Increase of 7.1 Percent; Internationally, HUMIRA Net Revenues Were \$1.231 Billion, a Decrease of 23.0 Percent on an Operational Basis, Excluding a 4.9 Percent Unfavorable Impact From Foreign Exchange, Due to Biosimilar Competition
- First-Quarter Global Net Revenues From the Hematologic Oncology Portfolio Were \$1.173 Billion, an Increase of 43.2 Percent on an Operational Basis, Excluding a 0.4 Percent Unfavorable Impact From Foreign Exchange; First-Quarter Global IMBRUVICA Net Revenues Were \$1.022 Billion, an Increase of 34.0 Percent; First-Quarter Global VENCLEXTA Net Revenues Were \$151 Million
- First-Quarter Global HCV Net Revenues Were \$815 Million, a Decrease of 9.1 Percent on an Operational Basis, Excluding a 2.2 Percent Unfavorable Impact From Foreign Exchange; U.S. HCV Net Revenues Were \$403 Million, an Increase of 17.3 Percent
- Obtains Regulatory Approval of SKYRIZI (risankizumab) for Moderate to Severe Plaque Psoriasis; Receives FDA Breakthrough Therapy Designation and Priority Review for VENCLEXTA in Front Line CLL
- Updates 2019 GAAP Diluted EPS Guidance Range to \$7.26 to \$7.36; Raises 2019 Adjusted Diluted EPS Guidance Range From \$8.65 to \$8.75 to \$8.73 to \$8.83, Representing Growth of 11.0 Percent at the Midpoint

NORTH CHICAGO, ILL., April 25, 2019 – AbbVie (NYSE:ABBV) announced financial results for the first quarter ended March 31, 2019.

“We are off to another excellent start, including first quarter sales and earnings above expectations,” said Richard A. Gonzalez, chairman and chief executive officer, AbbVie. “Additionally, we have made tremendous progress advancing our pipeline, including the recent approval of SKYRIZI, which has the potential to set a new standard of care in psoriasis and represents a significant long-term opportunity for AbbVie. We are extremely pleased with our strong performance and based on the continued business momentum, are increasing our full-year EPS guidance.”

First-Quarter Results

- Worldwide net revenues of \$7.828 billion decreased 1.3 percent on a reported basis and increased 0.4 percent operationally.

First-Quarter Results (continued)

- Global HUMIRA net revenues of \$4.446 billion decreased 5.6 percent on a reported basis, or 3.8 percent operationally. In the U.S., HUMIRA net revenues of \$3.215 billion grew 7.1 percent in the quarter. Internationally, HUMIRA net revenues of \$1.231 billion decreased 27.9 percent on a reported basis, or 23.0 percent operationally, due to biosimilar competition.
- Global net revenues from the hematologic oncology portfolio of \$1.173 billion increased 42.8 percent on a reported basis, or 43.2 percent operationally. Global IMBRUVICA net revenues were \$1.022 billion, with U.S. net revenues of \$829 million and international profit sharing of \$193 million. Global VENCLEXTA net revenues were \$151 million.
- Global HCV net revenues of \$815 million decreased 11.3 percent on a reported basis, or 9.1 percent operationally. In the U.S., HCV net revenues of \$403 million grew 17.3 percent in the quarter.
- On a GAAP basis, the gross margin ratio in the first quarter was 78.4 percent. The adjusted gross margin ratio was 83.3 percent.
- On a GAAP basis, selling, general and administrative expense was 21.5 percent of net revenues. The adjusted SG&A expense was 20.0 percent of net revenues.
- On a GAAP basis, research and development expense was 16.5 percent of net revenues. The adjusted R&D expense was 15.3 percent of net revenues, reflecting funding actions supporting all stages of our pipeline.
- On a GAAP basis, the operating margin in the first quarter was 38.5 percent. The adjusted operating margin was 48.1 percent.
- On a GAAP basis, net interest expense was \$325 million. On a GAAP basis, the tax rate in the quarter was 3.5 percent. The adjusted tax rate was 7.9 percent.
- Diluted EPS in the first quarter was \$1.65 on a GAAP basis. Adjusted diluted EPS, excluding specified items, was \$2.14, up 14.4 percent.

Recent Events

- AbbVie announced regulatory approvals for SKYRIZI for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The approvals from the U.S. Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare are based on results from four pivotal Phase 3 studies, ultIMMa-1, ultIMMa-2, IMMvent and IMMhance, evaluating more than 2,000 patients with moderate to severe plaque psoriasis. Additionally, the European Medicines Agency's Committee for Medicinal Products for Human Use adopted a positive opinion for SKYRIZI for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy. SKYRIZI is part of a collaboration between Boehringer Ingelheim and AbbVie, with AbbVie leading development and commercialization globally.

Recent Events (continued)

- At the American Academy of Dermatology (AAD) Annual Meeting, AbbVie presented data from 19 abstracts, including 10 oral presentations and 9 poster presentations. Long-term data from multiple studies investigating SKYRIZI for the treatment of plaque psoriasis were presented, including the first integrated efficacy analyses highlighting response over time and across various subgroups. Additionally, AbbVie presented up to 40 months of SKYRIZI safety data indicating adverse events were low and similar to comparator groups and data showing that psoriasis patients achieved significantly higher PASI 90 response rates after switching to SKYRIZI versus those who remained on adalimumab. AbbVie also presented results from a Phase 2 upadacitinib atopic dermatitis study, as well as data from HUMIRA (adalimumab) in multiple psoriatic diseases.
- AbbVie announced that the FDA accepted for priority review its New Drug Application (NDA) for upadacitinib for the treatment of adult patients with moderate to severe rheumatoid arthritis. Upadacitinib is an investigational once-daily oral JAK1-selective inhibitor being studied for multiple immune-mediated diseases. The NDA is supported by data from the global upadacitinib SELECT Phase 3 rheumatoid arthritis program evaluating more than 4,000 patients with moderate to severe rheumatoid arthritis across five of six Phase 3 studies. AbbVie anticipates a regulatory decision in the third quarter of 2019.
- AbbVie announced that the FDA approved the use of IMBRUVICA (ibrutinib) in combination with obinutuzumab, for adult patients with previously untreated chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). This milestone marked the 10th FDA approval for IMBRUVICA in six different disease areas since 2013 and expands the use of IMBRUVICA, which can already be administered as a single agent or in combination with bendamustine and rituximab for adult CLL/SLL patients. The FDA approval is based on results from the Phase 3 iLLUMINATE study, which showed the combination of IMBRUVICA plus obinutuzumab significantly improved progression-free survival compared to chlorambucil plus obinutuzumab in previously untreated CLL/SLL patients who were 65 years or older, or less than 65 years old with coexisting conditions. The FDA also updated the IMBRUVICA label to include additional long-term efficacy follow-up data from the Phase 3 RESONATE and RESONATE-2 studies, supporting its use as a single agent in CLL/SLL. IMBRUVICA is jointly developed and commercialized with Janssen Biotech, Inc.
- AbbVie announced that the FDA granted a fifth Breakthrough Therapy Designation to VENCLEXTA (venetoclax), for use in combination with obinutuzumab as a fixed duration investigational combination, for untreated adult patients with CLL. The designation coincides with the completion of the supplemental New Drug Application (sNDA) submission to the FDA for approval in previously-untreated CLL patients. In addition, the sNDA was granted priority review by the FDA. The sNDA for the VENCLEXTA and obinutuzumab combination is based on data from the Phase 3 CLL14 trial and is being reviewed by the FDA under its Real-Time Oncology Review pilot program. Venetoclax is being developed by AbbVie and Roche and is jointly commercialized by AbbVie and Genentech, a member of the Roche Group, in the U.S. and by AbbVie outside of the U.S.
- AbbVie provided an update on the VENCLEXTA multiple myeloma program, announcing that the FDA placed a partial clinical hold on all clinical trials evaluating VENCLEXTA for the investigational treatment of multiple myeloma. The partial clinical hold followed a review of data from the ongoing Phase 3 BELLINI trial, a study in relapsed/refractory multiple myeloma, in which a higher proportion of deaths was observed in the VENCLEXTA arm compared to the control arm of the trial. This action does not impact any of the approved indications for VENCLEXTA, such as CLL or acute myeloid leukemia, and is limited to investigational clinical trials in multiple myeloma. Additional analyses are ongoing and data will be published in a peer-reviewed journal and/or presented at a future medical meeting.

Recent Events (continued)

- AbbVie announced a strategic partnership with Teneobio, a biotechnology company developing a new class of biologics for the treatments of cancer, autoimmunity and infectious diseases. Under the agreement, AbbVie and Teneobio will develop and commercialize TNB-383B, a B-cell maturation antigen (BCMA)-targeting immunotherapeutic for the potential treatment of multiple myeloma. TNB-383B is a bispecific antibody that simultaneously targets BCMA and CD3 and is designed to direct the body's own immune system to target and kill BCMA expressing tumor cells. The collaboration broadens AbbVie's oncology research platform to expand the development of potentially life-changing treatments for patients.
- AbbVie announced a strategic collaboration with Voyager Therapeutics, a clinical-stage gene therapy company focused on developing life-changing treatments for severe neurological diseases. The Voyager Therapeutics transaction expands collaborative efforts on vectorized antibodies to target pathological species of alpha-synuclein for the potential treatment of Parkinson's disease and other diseases characterized by the abnormal accumulation of misfolded alpha-synuclein protein. Voyager's vectorized antibody platform and approach aims to improve the delivery of sufficient quantities of antibodies across the blood-brain barrier by delivering the genes that encode for the production of therapeutic antibodies. The collaboration broadens AbbVie's neuroscience research platform to expand the development of potentially life-changing treatments for patients.

Full-Year 2019 Outlook

AbbVie is raising its GAAP diluted EPS guidance for the full-year 2019 to \$7.26 to \$7.36. The company's 2019 GAAP guidance does not reflect a non-cash charge for contingent consideration related to the approval of SKYRIZI, which is planned to be communicated on the second-quarter earnings call. AbbVie is raising its previously announced adjusted EPS guidance range for the full-year 2019 from \$8.65 to \$8.75 to \$8.73 to \$8.83, representing growth of 11.0 percent at the mid-point. The company's 2019 adjusted diluted EPS guidance excludes \$1.47 per share of intangible asset amortization expense, non-cash charges for contingent consideration adjustments and other specified items.

About AbbVie

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.com. Follow [@abbvie](https://twitter.com/abbvie) on Twitter, [Facebook](https://www.facebook.com/abbvie) or [LinkedIn](https://www.linkedin.com/company/abbvie).

Conference Call

AbbVie will host an investor conference call today at 8:00 a.m. Central time to discuss our first-quarter performance. The call will be webcast through AbbVie's Investor Relations website at investors.abbvie.com. An archived edition of the call will be available after 11:00 a.m. Central time.

Non-GAAP Financial Results

Financial results for 2019 and 2018 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 2019 financial guidance is also being provided on both a reported and a non-GAAP basis.

Forward-Looking Statements

Some statements in this news release are, or may be considered, 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," of AbbVie's 2018 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission (SEC). 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.

Media:

Adelle Infante
(847) 938-8745

Investors:

Liz Shea
(847) 935-2211

Todd Bosse
(847) 936-1182

Jeffrey Byrne
(847) 938-2923

AbbVie Inc.
Key Product Revenues
Quarter Ended March 31, 2019
(Unaudited)

	Net Revenues (in millions)			% Change vs. 1Q18				
				International		Total		
	U.S.	Int'l.	Total	U.S.	Operational	Reported	Operational	Reported
ADJUSTED NET REVENUES^a	\$5,270	\$2,558	\$7,828	10.0%	(14.2)%	(18.6)%	0.4%	(1.3)%
Immunology	3,215	1,231	4,446	7.1	(23.0)	(27.9)	(3.8)	(5.6)
Humira	3,215	1,231	4,446	7.1	(23.0)	(27.9)	(3.8)	(5.6)
Hematologic Oncology	934	239	1,173	40.4	55.0	53.0	43.2	42.8
Imbruvicab	829	193	1,022	32.8	39.6	39.6	34.0	34.0
Venclexta	105	46	151	>100.0	>100.0	>100.0	>100.0	>100.0
HCV	403	412	815	17.3	(24.9)	(28.4)	(9.1)	(11.3)
Mavyret	403	387	790	18.3	(20.4)	(23.8)	(4.9)	(6.9)
Viekira	—	25	25	(100.0)	(58.5)	(62.9)	(60.4)	(64.7)
Other Key Products	726	554	1,280	(2.5)	(2.5)	(7.5)	(2.5)	(4.7)
Creon	227	—	227	8.6	n/a	n/a	8.6	8.6
Lupron	191	38	229	7.4	(1.4)	(9.0)	5.7	4.2
Synthroid	182	—	182	0.3	n/a	n/a	0.3	0.3
Synagis	—	287	287	n/a	(7.0)	(10.8)	(7.0)	(10.8)
Duodopa	22	89	111	28.5	11.6	4.2	14.4	8.3
Sevoflurane	17	75	92	(0.6)	(10.1)	(16.2)	(8.5)	(13.6)
Kaletra	13	65	78	3.4	12.6	7.7	10.9	6.9
AndroGel	74	—	74	(42.9)	n/a	n/a	(42.9)	(42.9)

Note: "Operational" comparisons are presented at constant currency rates and reflect comparative local currency net revenues at the prior year's foreign exchange rates.

n/a = not applicable

a Adjusted net revenues exclude specified items. Refer to the Reconciliation of GAAP Reported to Non-GAAP Adjusted Information for further details. Percentage change is calculated using adjusted net revenues.

b Reflects profit sharing for Imbruvica international revenues.

AbbVie Inc.
Consolidated Statements of Earnings
Quarter Ended March 31, 2019 and 2018
(Unaudited) (In millions, except per share data)

	First Quarter Ended March 31	
	2019	2018
Net revenues	\$ 7,828	\$ 7,934
Cost of products sold	1,694	1,927
Selling, general and administrative	1,680	1,791
Research and development	1,289	1,244
Acquired in-process research and development	155	69
Total operating costs and expenses	4,818	5,031
Operating earnings	3,010	2,903
Interest expense, net	325	251
Net foreign exchange loss	6	8
Other (income) expense, net	135	(153)
Earnings before income tax expense	2,544	2,797
Income tax expense	88	14
Net earnings	\$ 2,456	\$ 2,783
Diluted earnings per share	\$ 1.65	\$ 1.74
Adjusted diluted earnings per share ^a	\$ 2.14	\$ 1.87
Weighted-average diluted shares outstanding	1,483	1,596

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, 2019
(Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

	1Q19		
	Earnings		Diluted
	Pre-tax	After-tax	EPS
As reported (GAAP)	\$ 2,544	\$ 2,456	\$ 1.65
Adjusted for specified items:			
Intangible asset amortization	385	318	0.21
Milestones and other R&D expenses	40	40	0.03
Acquired IPR&D	155	155	0.10
Change in fair value of contingent consideration	169	171	0.12
Restructuring	163	133	0.09
Litigation reserves	10	8	—
Tax audit settlement	—	(89)	(0.06)
As adjusted (non-GAAP)	\$ 3,466	\$ 3,192	\$ 2.14

Milestones and other R&D expenses are associated with milestone payments for previously announced collaborations. Acquired IPR&D primarily reflects upfront payments related to R&D collaborations and licensing arrangements with third parties. Restructuring is primarily associated with streamlining global operations.

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

	1Q19				
	Cost of products sold	SG&A	R&D	Acquired IPR&D	Other (income) expense, net
As reported (GAAP)	\$ 1,694	\$ 1,680	\$ 1,289	\$ 155	\$ 135
Adjusted for specified items:					
Intangible asset amortization	(385)	—	—	—	—
Milestones and other R&D expenses	—	—	(40)	—	—
Acquired IPR&D	—	—	—	(155)	—
Change in fair value of contingent consideration	—	—	—	—	(169)
Restructuring	(6)	(107)	(50)	—	—
Litigation reserves	—	(10)	—	—	—
As adjusted (non-GAAP)	\$ 1,303	\$ 1,563	\$ 1,199	\$ —	\$ (34)

3. The adjusted tax rate for the first quarter of 2019 was 7.9 percent, as detailed below:

	1Q19		
	Pre-tax earnings	Income taxes	Tax rate
As reported (GAAP)	\$ 2,544	\$ 88	3.5%
Specified items	922	186	20.2%
As adjusted (non-GAAP)	\$ 3,466	\$ 274	7.9%

AbbVie Inc.
Reconciliation of GAAP Reported to Non-GAAP Adjusted Information
Quarter Ended March 31, 2018
(Unaudited) (In millions, except per share data)

1. Specified items impacted results as follows:

	1Q18		
	Earnings		Diluted
	Pre-tax	After-tax	EPS
As reported (GAAP)	\$ 2,797	\$ 2,783	\$ 1.74
Adjusted for specified items:			
Intangible asset amortization	330	272	0.17
Milestones and other R&D expenses	32	32	0.02
Acquired IPR&D	69	69	0.04
Change in fair value of contingent consideration	(148)	(148)	(0.09)
Litigation reserves	118	100	0.06
Impacts of U.S. tax reform	—	(155)	(0.10)
Other	51	47	0.03
As adjusted (non-GAAP)	\$ 3,249	\$ 3,000	\$ 1.87

Milestones and other R&D expenses are associated with milestone payments for previously announced collaborations. Acquired IPR&D primarily reflects upfront payments related to R&D collaborations and licensing arrangements with third parties. Impacts of U.S. tax reform reflects a net tax benefit related to the timing of the new legislation's phase in on certain subsidiaries. Other primarily includes restructuring charges associated with streamlining global operations.

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

	1Q18				
	Cost of products sold	SG&A	R&D	Acquired IPR&D	Other (income) expense, net
As reported (GAAP)	\$ 1,927	\$ 1,791	\$ 1,244	\$ 69	\$ (153)
Adjusted for specified items:					
Intangible asset amortization	(330)	—	—	—	—
Milestones and other R&D expenses	—	—	(32)	—	—
Acquired IPR&D	—	—	—	(69)	—
Change in fair value of contingent consideration	—	—	—	—	148
Litigation reserves	—	(118)	—	—	—
Other	(25)	(3)	(23)	—	—
As adjusted (non-GAAP)	\$ 1,572	\$ 1,670	\$ 1,189	\$ —	\$ (5)

3. The adjusted tax rate for the first quarter of 2018 was 7.6 percent, as detailed below:

	1Q18		
	Pre-tax earnings	Income taxes	Tax rate
As reported (GAAP)	\$ 2,797	\$ 14	0.5%
Specified items	452	235	51.8%
As adjusted (non-GAAP)	\$ 3,249	\$ 249	7.6%