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Bristol-Myers Squibb Reports First Quarter Financial Results

APR 27, 2017

- Increases First Quarter Revenues 12% to \$4.9 Billion
- Posts First Quarter GAAP EPS of \$0.94 and Non-GAAP EPS of \$0.84
- Achieves Key Regulatory Milestones For *Opdivo* in the U.S. and Europe
- Advances Immuno-Oncology Collaborations with Incyte and Exelixis to include Phase 3 Trials
- Increases 2017 GAAP and Non-GAAP EPS Guidance

NEW YORK--(BUSINESS WIRE)-- [Bristol-Myers Squibb Company](#) (NYSE:BMJ) today reported results for the first quarter of 2017, which were highlighted by strong sales for key products *Opdivo* and *Elquis*, regulatory approval for *Opdivo* in advanced bladder cancer in the U.S., positive opinions from the Committee for Medicinal Products for Human Use (CHMP) for advanced bladder and head and neck cancers in Europe, and strategic transactions in oncology that further strengthened the company's pipeline.

"During the first quarter we delivered strong sales and earnings growth, achieved important regulatory milestones for *Opdivo* in the U.S. and Europe and presented important new data across our Immuno-Oncology and fibrosis portfolios," said [Giovanni Caforio](#), M.D., chief executive officer, Bristol-Myers Squibb. "Building on this strong start to the year, we will continue to drive commercial performance in the short-term while advancing important opportunities to broaden our approach in Immuno-Oncology and progressing our early specialty portfolio."

First Quarter

\$ amounts in millions, except per share amounts

	<u>2017</u>	<u>2016</u>	<u>Change</u>
Total Revenues	\$4,929	\$4,391	12%
GAAP Diluted EPS	0.94	0.71	32%
Non-GAAP Diluted EPS	0.84	0.74	14%

FIRST QUARTER FINANCIAL RESULTS

- Bristol-Myers Squibb posted first quarter 2017 revenues of \$4.9 billion, an increase of 12% compared to the same period a year ago. Revenues increased 13% when adjusted for foreign exchange impact.
- U.S. revenues increased 8% to \$2.7 billion in the quarter compared to the same period a year ago. International revenues increased 18%. When adjusted for foreign exchange impact, international revenues increased 20%.

- Gross margin as a percentage of revenue decreased from 76.0% to 74.5% in the quarter primarily due to product mix.
- Marketing, selling and administrative expenses increased 1% to \$1.1 billion in the quarter.
- Research and development expenses increased 13% to \$1.3 billion in the quarter.
- The effective tax rate was 21.9% in the quarter, compared to 27.1% in the first quarter last year.
- The company reported net earnings attributable to Bristol-Myers Squibb of \$1.6 billion, or \$0.94 per share, in the first quarter compared to net earnings of \$1.2 billion, or \$0.71 per share, for the same period in 2016. The results for the first quarter of 2017 included Bristol-Myers Squibb's share of a patent-infringement litigation settlement related to Merck's PD-1 antibody Keytruda[®] that contributed \$0.18 per share.
- The company reported non-GAAP net earnings attributable to Bristol-Myers Squibb of \$1.4 billion, or \$0.84 per share, in the first quarter, compared to \$1.2 billion, or \$0.74 per share, for the same period in 2016. An overview of specified items is discussed under the "Use of Non-GAAP Financial Information" section.
- Cash, cash equivalents and marketable securities were \$8.8 billion, with a net cash position of \$360 million, as of March 31, 2017.

FIRST QUARTER PRODUCT AND PIPELINE UPDATE

Product Sales/Business Highlights

The increase in global revenues for the first quarter of 2017, compared to the first quarter of 2016, was driven by:

<u>Product</u>	<u>Growth %</u>
<i>Opdivo</i>	60%
<i>Eliquis</i>	50%
<i>Yervoy</i>	25%
<i>Sprycel</i>	14%
<i>Orencia</i>	13%

Opdivo

Regulatory

- In April, the company announced the CHMP recommended the approval of *Opdivo* for the treatment of patients with locally advanced unresectable or metastatic urothelial carcinoma (mUC) in adults after failure of prior platinum-containing chemotherapy. The CHMP recommendation will be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU).
- In April, the company announced the U.S. Food and Drug Administration (FDA) accepted a supplemental Biologics License Application seeking to extend the use of *Opdivo* to patients with mismatch repair deficient or microsatellite instability high metastatic colorectal cancer after prior fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy. The FDA granted the application priority review and the FDA action date is August 2, 2017.
- In April, the FDA approved an updated indication for *Opdivo* for the treatment of adult patients with Classical Hodgkin lymphoma that have relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or three or more lines of systemic therapy that includes autologous HSCT. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- In March, the company announced the CHMP recommended the approval of *Opdivo* as monotherapy for the treatment of squamous cell cancer of the head and neck in adults progressing on or after platinum-based therapy. The CHMP recommendation will be reviewed by the EC.
- In March, the company and its partner Ono Pharmaceutical Co. announced the approval of *Opdivo* as monotherapy for the treatment of recurrent or metastatic head and neck cancer in Japan.
- In February, the company announced the FDA provided accelerated approval for *Opdivo* for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Clinical

- In April, at the American Association for Cancer Research (AACR) Annual Meeting, the company announced new data and analysis from studies evaluating *Opdivo* and the *Opdivo* + *Yervoy* regimen:
 - First overall survival results from CheckMate -067, a Phase 3 trial of *Opdivo* and the *Opdivo* + *Yervoy* regimen versus *Yervoy* alone in patients with previously untreated advanced melanoma. More detail of the study results is included in the original press release ([link](#)).
 - The first report of five-year overall survival data from the Phase 1 dose-ranging study CA209-003 evaluating *Opdivo* in patients with previously treated advanced non-small cell lung cancer. More detail of the study results is included in the original press release ([link](#)).
- In April, the company announced CheckMate -143, a randomized Phase 3 clinical trial evaluating the efficacy and safety of *Opdivo* in patients with first recurrence of glioblastoma multiforme did not meet its primary endpoint of improved overall survival over bevacizumab monotherapy.

Sprycel

- In February, the company announced the European Patent Office (EPO) upheld a decision finding European Patent No. 1169038 (the '038 patent), the Composition of Matter patent covering dasatinib, the active ingredient in *Sprycel*, to be invalid. The decision does not impact patents outside of the EU or other *Sprycel*-related patents. Additionally in February, the EPO Board of Appeal reversed and remanded an invalidity decision on European Patent No. 1610780 and its claim to the use of dasatinib to treat chronic myeloid leukemia (CML), which the EPO's Opposition Division had revoked in October 2012. The company intends to take appropriate legal actions to protect *Sprycel*.

Eliquis

- In March, at the American College of Cardiology's (ACC) Annual Scientific Session, the company and its partner Pfizer Inc. announced findings from a real-world data analysis of the U.S. Medicare database comparing the risk of stroke or systemic embolism and rate of major bleeding among patients with non-valvular atrial fibrillation who were treated with direct oral anticoagulants *Eliquis*, dabigatran or rivaroxaban versus warfarin. More detail of the analysis is included in the original press release ([link](#)).

Fibrosis

- In April, at EASL: The International Liver Congress, the company announced data from a Phase 2 study of BMS-986036, an investigational pegylated analogue of human fibroblast growth factor 21 (FGF21), a key regulator of metabolism, in patients with biopsy-confirmed non-alcoholic steatohepatitis (NASH) (F1-F3). The study achieved its primary endpoint of significant reduction in liver fat versus placebo, and also showed improvement in markers of liver injury and fibrosis.

FIRST QUARTER BUSINESS DEVELOPMENT UPDATE

- In April, the company and Transgene announced a clinical research collaboration to evaluate the safety, tolerability and efficacy of Transgene's investigational therapeutic vaccine TG4010 in combination with *Opdivo* + standard chemotherapy (CT) as a first-line treatment for advanced non-squamous non-small cell lung cancer (NSCLC) in patients whose tumors have low or undetectable levels of PD-L1.
- In April, the company and Apexigen, Inc. announced a clinical trial collaboration to evaluate the safety, tolerability and preliminary efficacy of Apexigen's APX005M with *Opdivo* in patients with second-line metastatic NSCLC who have failed prior chemotherapy, and in metastatic melanoma patients who have failed prior Immuno-Oncology (I-O) therapy.
- In April, the company and Nordic Bioscience announced a collaboration to develop biomarker technology to potentially aid in the diagnosis and monitoring of fibrotic diseases including NASH.
- In April, the company announced it entered into two separate agreements to outlicense BMS-986168, an anti-eTau compound in development for Progressive Supranuclear Palsy, to Biogen, and BMS-986089, an anti-myostatin adnectin in development for Duchenne Muscular Dystrophy, to Roche. The company will receive upfront payments of \$300 million from Biogen and \$170 million from Roche, along with potential milestone payments and royalties from each company.
- In April, the company and Incyte Corporation announced an agreement to advance their clinical development program evaluating the combination of epacadostat, Incyte's investigational oral selective IDO1 enzyme inhibitor, with *Opdivo* into Phase 3 registrational studies in first-line NSCLC across the spectrum of PD-L1 expression and first-line head and neck cancer. Additionally, the companies are expanding the ECHO-204 Phase 1/2 study, established under a collaboration between the companies in 2014, to include anti-PD-1/PD-L1 relapsed/refractory melanoma cohorts.
- In March, the company and Foundation Medicine announced a collaboration to leverage Foundation Medicine's comprehensive genomic profiling and molecular information solutions to identify predictive biomarkers such as Tumor Mutational Burden and Microsatellite Instability in patients enrolled across clinical trials investigating Bristol-Myers Squibb's cancer immunotherapies.
- In March, the company, the Parker Institute for Cancer Immunotherapy and the Cancer Research Institute (CRI) announced a multi-year collaboration agreement to coordinate and rapidly initiate clinical I-O studies across the Parker Institute and CRI networks.
- In March, the company and CytomX Therapeutics, Inc. announced an expansion of their collaboration to discover novel therapies against multiple I-O targets using CytomX's proprietary Probody[®] Platform, expanding the number of targets from four to twelve.
- In March, the company announced an equity investment and plans for a research collaboration with GRAIL Inc. that grants the company early access to GRAIL's comprehensive clinical trial databases that may help improve understanding of tumor genomics. Additionally, Bristol-Myers Squibb will utilize GRAIL's analytics tools to inform research, advance diagnostics and improve patient outcomes.
- In February, the company and Exelixis, Inc. announced a clinical development collaboration to evaluate Cabometyx[®] (cabozantinib), Exelixis' small molecule inhibitor of receptor tyrosine kinases, with *Opdivo*, either alone or in combination with *Yervoy*. The agreement is expected to include a Phase 3 pivotal trial in first-line renal cell carcinoma, with additional trials planned in bladder cancer, hepatocellular carcinoma (HCC), and potentially other tumor types.

- In February, the company announced an expansion of the five-year old International Immuno-Oncology Network (II-ON) with the addition of Columbia University Medical Center and Peter MacCallum Cancer Centre (Peter Mac). II-ON is a global peer-to-peer collaboration between Bristol-Myers Squibb and academia that aims to advance I-O science and translational medicine to improve patient outcomes.

SHARE REPURCHASE

In February, the company executed accelerated share repurchase (ASR) agreements to repurchase, in aggregate, \$2 billion of the company's common stock. The ASR was funded through a combination of debt and cash and is part of the company's existing share repurchase authorization. Approximately 80 percent of the shares to be repurchased under the transaction were received by the company on February 28, 2017 and the company anticipates that all repurchases under the ASR will be completed by the end of the second quarter of 2017.

The decision reflects the company's strong financial position and its balanced approach to capital allocation, including a commitment to its dividend and a disciplined approach to business development.

2017 FINANCIAL GUIDANCE

Bristol-Myers Squibb is increasing its 2017 GAAP EPS guidance range from \$2.47- \$2.67 to \$2.72 - \$2.87 and is increasing its non-GAAP EPS guidance range from \$2.70 - \$2.90 to \$2.85 - \$3.00. Both GAAP and non-GAAP guidance assume current exchange rates. Key revised 2017 GAAP and non-GAAP line-item guidance assumptions are:

- Worldwide revenues increasing in the mid-single digits.
- Research and development expenses increasing in the high-teens digit range for GAAP and increasing in the low-double digits range for non-GAAP.
- An effective tax rate of approximately 22% for GAAP with non-GAAP remaining at approximately 21%.

The financial guidance excludes the impact of any potential future strategic acquisitions and divestitures and any specified items that have not yet been identified and quantified. The non-GAAP guidance also excludes other specified items as discussed under "Use of Non-GAAP Financial Information." Details reconciling GAAP amounts to non-GAAP amounts, with non-GAAP reflecting specified items are provided in supplemental materials attached to this press release and available on the company's website.

Keytruda[®] is a trademark of Merck & Co., Inc.

Probody[®] Platform is a trademark of CytomX Therapeutics, Inc.

Cabometyx[®] is a trademark of Exelixis, Inc.

Use of Non-GAAP Financial Information

This press release contains non-GAAP financial measures, including non-GAAP earnings and related EPS information, that are adjusted to exclude certain costs, expenses, gains and losses and other specified items that are evaluated on an individual basis. These items are adjusted after considering their quantitative and qualitative aspects and typically have one or more of the following characteristics, such as being highly variable, difficult to project, unusual in nature, significant to the results of a particular period or not indicative of future operating results. Similar charges or gains were recognized in prior periods and will likely reoccur in future periods including restructuring costs, accelerated depreciation and impairment of property, plant and equipment and intangible assets, R&D charges in connection with the acquisition or licensing of third party intellectual property rights, divestiture gains or losses, upfront payments from out licensed assets, pension charges, legal and other contractual settlements and debt redemption gains or losses, among other items. Deferred and current income taxes attributed to these items are also adjusted for considering their individual impact to the overall tax expense, deductibility and jurisdictional tax rates. Non-GAAP information is intended to portray the results of our baseline performance, supplement or enhance management, analysts and investors overall understanding of our underlying financial performance and facilitate comparisons among current, past and future periods. For example, non-GAAP earnings and EPS information is an indication of our baseline performance before items that are considered by us to not be reflective of our ongoing results. In addition, this information is among the primary indicators we use as a basis

for evaluating performance, allocating resources, setting incentive compensation targets and planning and forecasting for future periods. This information is not intended to be considered in isolation or as a substitute for net earnings or diluted EPS prepared in accordance with GAAP.

Statement on Cautionary Factors

This press release contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans and projections regarding the company's financial position, results of operations, market position, product development and business strategy. These statements may be identified by the fact that they use words such as "anticipate", "estimates", "should", "expect", "guidance", "project", "intend", "plan", "believe" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. These factors include, among other things, effects of the continuing implementation of governmental laws and regulations related to Medicare, Medicaid, Medicaid managed care organizations and entities under the Public Health Service 340B program, pharmaceutical rebates and reimbursement, market factors, competitive product development and approvals, pricing controls and pressures (including changes in rules and practices of managed care groups and institutional and governmental purchasers), economic conditions such as interest rate and currency exchange rate fluctuations, judicial decisions, claims and concerns that may arise regarding the safety and efficacy of in-line products and product candidates, changes to wholesaler inventory levels, variability in data provided by third parties, changes in, and interpretation of, governmental regulations and legislation affecting domestic or foreign operations, including tax obligations, changes to business or tax planning strategies, difficulties and delays in product development, manufacturing or sales including any potential future recalls, patent positions and the ultimate outcome of any litigation matter. These factors also include the company's ability to execute successfully its strategic plans, including its business development strategy, the expiration of patents or data protection on certain products, including assumptions about the company's ability to retain patent exclusivity of certain products, and the impact and result of governmental investigations. There can be no guarantees with respect to pipeline products that future clinical studies will support the data described in this release, that the compounds will receive necessary regulatory approvals, or that they will prove to be commercially successful; nor are there guarantees that regulatory approvals will be sought, or sought within currently expected timeframes, or that contractual milestones will be achieved. For further details and a discussion of these and other risks and uncertainties, see the company's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission. The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Company and Conference Call Information

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at BMS.com or follow us on [LinkedIn](#), [Twitter](#), [YouTube](#) and [Facebook](#).

There will be a conference call on April 27, 2017 at 10:30 a.m. EDT during which company executives will review financial information and address inquiries from investors and analysts. Investors and the general public are invited to listen to a live webcast of the call at <http://investor.bms.com> or by calling the U.S. toll free 855-303-0072 or international 913-312-0976, confirmation code: 500711. Materials related to the call will be available at the same website prior to the conference call. A replay of the call will be available beginning at 1:30 p.m. EDT on April 27, 2017 through 1:30 p.m. EDT on May 11, 2017. The replay will also be available through <http://investor.bms.com> or by calling the U.S. toll free 888-203-1112 or international 719-457-0820, confirmation code: 6160500.

BRISTOL-MYERS SQUIBB COMPANY
PRODUCT REVENUE
FOR THE THREE MONTHS ENDED MARCH 31, 2017 AND 2016
(Unaudited, dollars in millions)

	Worldwide Revenues			U.S. Revenues		
	2017	2016	% Change	2017	2016	% Change
<u>Three Months</u>						
<u>Ended March 31,</u>						
Prioritized Brands						
Opdivo	\$ 1,127	\$ 704	60 %	\$ 761	\$ 594	28 %
Eliquis	1,101	734	50 %	699	468	49 %
Orencia	535	475	13 %	362	321	13 %
Sprycel	463	407	14 %	247	210	18 %
Yervoy	330	263	25 %	243	199	22 %
Empliciti	53	28	89 %	36	28	29 %
Established Brands						
Hepatitis C Franchise	162	427	(62)%	42	259	(84)%
Baraclude	282	291	(3)%	14	17	(18)%
Sustiva Franchise	184	273	(33)%	153	228	(33)%
Reyataz Franchise	193	221	(13)%	88	120	(27)%
Other Brands	499	568	(12)%	93	93	—
Total	\$4,929	\$4,391	12 %	\$2,738	\$2,537	8 %

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