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Bristol-Myers Squibb Reports Second Quarter Financial Results

- Increases Second Quarter Revenues 11% to \$5.7 Billion
- Posts Second Quarter GAAP EPS of \$0.23 and Non-GAAP EPS of \$1.01
- Achieves Significant Regulatory Milestones in Oncology
- Presents Important New Data on Immuno-Oncology Portfolio at ASCO
- Updates 2018 GAAP and Non-GAAP EPS Guidance

CATEGORY: [CORPORATE/FINANCIAL NEWS](#)

THURSDAY, JULY 26, 2018 6:59 AM EDT

NEW YORK--([BUSINESS WIRE](#))--[Bristol-Myers Squibb Company](#) (NYSE:BMJ) today reported results for the second quarter of 2018, which were highlighted by strong sales for [Eliquis](#) (apixaban) and [Opdivo](#) (nivolumab), and important regulatory progress in the company's Immuno-Oncology portfolio.

“We had a very good second quarter where we delivered strong performance for *Eliquis* and *Opdivo*, and achieved important regulatory and data milestones supporting our Immuno-Oncology portfolio,” said [Giovanni Caforio](#), M.D., chairman and chief executive officer, Bristol-Myers Squibb. “Looking forward, we are focused on robust commercial execution and the evolution of our diversified pipeline to deliver transformational medicines to the patients we serve.”

Second Quarter

\$ amounts in millions, except per share amounts

2018 2017 Change

Total Revenues	\$5,704	\$5,144	11%
GAAP Diluted EPS	0.23	0.56	(59)%
Non-GAAP Diluted EPS	1.01	0.74	36%

SECOND QUARTER FINANCIAL RESULTS

- Bristol-Myers Squibb posted second quarter 2018 revenues of \$5.7 billion, an increase of 11% compared with the same period a year ago. Revenues increased 9% when adjusted for foreign exchange impact.
- U.S. revenues increased 13% to \$3.2 billion in the quarter compared to the same period a year ago. International revenues increased 9%. When adjusted for foreign exchange impact, international revenues increased 4%.
- Gross margin as a percentage of revenue increased from 69.5% to 71.5% in the quarter primarily due to an impairment charge for a manufacturing site in the prior period.
- Marketing, selling and administrative expenses decreased 5% to \$1.1 billion in the quarter.
- Research and development expenses increased 45% to \$2.4 billion in the quarter, which includes a \$1.1 billion charge resulting from the Nektar collaboration in the second quarter of 2018.
- The effective tax rate was 26.1% in the quarter, compared to 28.8% in the second quarter last year. The effective tax rate includes a nondeductible equity investment loss in the second quarter of 2018.
- The company reported net earnings attributable to Bristol-Myers Squibb of \$373 million, or \$0.23 per share, in the second quarter compared to net earnings of \$916 million, or \$0.56 per share, for the same period in 2017.
- The company reported non-GAAP net earnings attributable to Bristol-Myers Squibb of \$1.6 billion, or \$1.01 per share, in the second quarter, compared to \$1.2 billion, or

\$0.74 per share, for the same period in 2017. An overview of specified items is provided under the “Use of Non-GAAP Financial Information” section.

- Cash, cash equivalents and marketable securities were \$8.2 billion, with a net cash position of \$805 million, as of June 30, 2018.

SECOND QUARTER PRODUCT AND PIPELINE UPDATE

Product Sales/Business Highlights

Global revenues for the second quarter of 2018, compared to the second quarter of 2017, were driven by:

- Eliquis, which grew by \$474 million or a 40% increase
- Opdivo, which grew by \$432 million or a 36% increase
- Orencia, which grew by 9%
- Sprycel, which grew by 6%
- Yervoy, which decreased by 2%

Opdivo

Regulatory

- In July, the company announced the U.S. Food and Drug Administration (FDA) approved *Opdivo* plus low-dose *Yervoy* (injections for intravenous use) for the treatment of adult and pediatric patients 12 years and older with microsatellite instability high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan.
- In June, the company announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended expanded approval of the current indications for *Opdivo* to include the adjuvant treatment of adult patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection. The CHMP recommendation will be

reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union.

- In June, the company announced the FDA accepted its supplemental Biologics License Application for *Opdivo* plus low-dose *Yervoy* for the treatment of first-line advanced non-small cell lung cancer (NSCLC) in patients with tumor mutational burden (TMB) ≥ 10 mutations per megabase (mut/Mb).
- In June, the China National Drug Administration approved *Opdivo* for the treatment of locally advanced or metastatic NSCLC after prior platinum-based chemotherapy in adult patients without EGFR or ALK genomic tumor aberrations.
- In May, the EMA validated a type II variation application for the *Opdivo* plus *Yervoy* combination for treatment in adult patients with first-line metastatic NSCLC who have TMB ≥ 10 mut/Mb.

Clinical

- In June, at the 2018 American Society of Clinical Oncology, the company announced important new data and analysis from four studies evaluating *Opdivo* as monotherapy and in combination with *Yervoy*, chemotherapy or NKTR-214:
 - CheckMate -227: Results from a part of the Phase 3 trial evaluating *Opdivo* plus low-dose *Yervoy* and *Opdivo* plus chemotherapy versus chemotherapy in patients with first-line advanced NSCLC with PD-L1 expression $< 1\%$, across squamous and non-squamous tumor histologies (Part 1b). ([link](#))
 - CheckMate -238: Results from the Phase 3 trial evaluating *Opdivo* versus *Yervoy* in patients with stage IIIB/C or stage IV melanoma who are at high risk of recurrence following complete surgical resection. ([link](#))
 - CheckMate -214: Patient-reported outcomes from the Phase 3 trial evaluating *Opdivo* plus low-dose *Yervoy* versus sunitinib over a two-year follow-up period in intermediate- and poor-risk patients with advanced renal cell carcinoma. ([link](#))

- Results from the Phase 1/2 dose-escalation study with Nektar Therapeutics, evaluating the safety, efficacy and biomarker data of NKTR-214 in combination with *Opdivo* for patients enrolled in the Phase 1 dose-escalation stage of the study and for the first patients consecutively enrolled in select dose expansion cohorts in Phase 2. ([link](#))

Sprycel

Regulatory

- In July, the company announced the EC has expanded the indication for *Sprycel* to include the treatment of children and adolescents aged 1 year to 18 years with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, and to include a powder for oral suspension formulation.

Empliciti

Clinical

- In June, the company announced the Phase 2 study evaluating the addition of *Empliciti* to pomalidomide and low-dose dexamethasone in patients with relapsed/refractory multiple myeloma showed a statistically significant and clinically meaningful improvement in progression free survival for patients treated with EPd compared with pomalidomide and dexamethasone alone. ([link](#))

SECOND QUARTER BUSINESS DEVELOPMENT UPDATE

- In July, the company and Tsinghua University announced a collaboration to discover therapeutic agents against novel targets for autoimmune diseases and cancers. The collaboration brings together the respective scientific expertise and capabilities of both organizations with a focus on validating new targets and generating early drug candidates for clinical development.
- In April, the company and Nektar Therapeutics completed the agreement for the development and commercialization of NKTR-214 with *Opdivo* and *Opdivo* plus

Yervoy, originally announced in February 2018.

- In April, the company and Flatiron Health announced a three-year agreement to curate regulatory-grade real-world data for cancer research and real-world evidence generation.

2018 FINANCIAL GUIDANCE

Bristol-Myers Squibb is decreasing its 2018 GAAP EPS guidance range from \$2.70 - \$2.80 to \$2.68 - \$2.78 and increasing its non-GAAP EPS guidance range from \$3.35 - \$3.45 to \$3.55 - \$3.65. Both GAAP and non-GAAP guidance assume current exchange rates. Key revised 2018 GAAP and non-GAAP line-item guidance assumptions are:

- Worldwide revenues increasing in the mid- to high-single digits.

The financial guidance for 2018 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 2018 guidance also excludes other specified items as discussed under "Use of Non-GAAP Financial Information." Details reconciling adjusted non-GAAP amounts with the amounts reflecting specified items are provided in supplemental materials available on the company's website.

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 and equity investment 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 successfully execute 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](https://www.bms.com) or follow us on [LinkedIn](#), [Twitter](#), [YouTube](#) and [Facebook](#).

There will be a conference call on July 26, 2018 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 866-548-4713 or international 323-794-2093, confirmation code: 4235170. 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 July 26, 2018 through 1:30 p.m. EDT on August 9, 2018. 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: 4235170.

BRISTOL-MYERS SQUIBB COMPANY

PRODUCT REVENUE

FOR THE THREE MONTHS ENDED JUNE 30, 2018 AND 2017

(Unaudited, dollars in millions)

	Worldwide Revenues			U.S. Revenues		
			%			%
	2018	2017	Change	2018	2017	Change
<u>Three Months Ended June 30,</u>						
Prioritized Brands						
Opdivo	\$1,627	\$1,195	36%	\$1,024	\$ 768	33%
Eliquis	1,650	1,176	40%	979	703	39%
Orencia	711	650	9%	501	449	12%
Sprycel	535	506	6%	310	281	10%
Yervoy	315	322	(2)%	228	245	(7)%
Empliciti	64	55	16%	41	37	11%
Established Brands						
Baraclude	179	273	(34)%	9	12	(25)%
Sustiva Franchise	73	188	(61)%	8	161	(95)%

Reyataz Franchise	117	188	(38)%	54	87	(38)%
Hepatitis C Franchise	12	112	(89)%	(2)	30	**
Other Brands	421	479	(12)%	78	92	(15)%
Total	\$5,704	\$5,144	11%	\$3,230	\$2,865	13%

BRISTOL-MYERS SQUIBB COMPANY

PRODUCT REVENUE

FOR THE SIX MONTHS ENDED JUNE 30, 2018 AND 2017

(Unaudited, dollars in millions)

	Worldwide Revenues			U.S. Revenues		
			%			%
	2018	2017	Change	2018	2017	Change
<u>Six Months Ended June 30,</u>						
Prioritized Brands						
Opdivo	\$ 3,138	\$ 2,322	35%	\$1,962	\$1,529	28%
Eliquis	3,156	2,277	39%	1,864	1,402	33%
Orencia	1,304	1,185	10%	886	811	9%
Sprycel	973	969	—	524	528	(1)%
Yervoy	564	652	(13)%	390	488	(20)%
Empliciti	119	108	10%	78	73	7%
Established Brands						
Baraclude	404	555	(27)%	19	26	(27)%
Sustiva Franchise	157	372	(58)%	18	314	(94)%
Reyataz Franchise	241	381	(37)%	105	175	(40)%
Hepatitis C Franchise	15	274	(95)%	3	72	(96)%

Other Brands	826	978	(16)%	159	185	(14)%
Total	\$10,897	\$10,073	8%	\$6,008	\$5,603	7%

BRISTOL-MYERS SQUIBB COMPANY
CONSOLIDATED STATEMENTS OF EARNINGS
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2018 AND 2017
(Unaudited, dollars and shares in millions except per share data)

	Three Months			
	Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Net product sales	\$ 5,461	\$ 4,770	\$10,433	\$ 9,350
Alliance and other revenues	243	374	464	723
Total Revenues	<u>5,704</u>	<u>5,144</u>	<u>10,897</u>	<u>10,073</u>
Cost of products sold	1,625	1,569	3,209	2,834
Marketing, selling and administrative	1,131	1,187	2,111	2,272
Research and development	2,435	1,679	3,685	2,982
Other income (net)	(4)	(586)	(404)	(1,265)
Total Expenses	<u>5,187</u>	<u>3,849</u>	<u>8,601</u>	<u>6,823</u>
Earnings Before Income Taxes	517	1,295	2,296	3,250
Provision for Income Taxes	<u>135</u>	<u>373</u>	<u>419</u>	<u>802</u>
Net Earnings	382	922	1,877	2,448
Net Earnings/(Loss) Attributable to	9	6	18	(42)

Noncontrolling Interest

Net Earnings Attributable to BMS	\$ 373	\$ 916	\$ 1,859	\$ 2,490
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Average Common Shares Outstanding:

Basic	1,633	1,644	1,633	1,653
Diluted	1,636	1,650	1,638	1,660

Earnings per Common Share

Basic	\$ 0.23	\$ 0.56	\$ 1.14	\$ 1.51
Diluted	0.23	0.56	1.13	1.50

Other income (net)

Interest expense	\$ 45	\$ 52	\$ 91	\$ 97
Investment income	(38)	(29)	(74)	(55)
Loss/(gain) on equity investments	356	(5)	341	(12)
Provision for restructuring	37	15	57	179
Litigation and other settlements	(1)	(5)	(1)	(489)
Equity in net income of affiliates	(27)	(20)	(51)	(38)
Divestiture gains	(25)	—	(70)	(127)
Royalties and licensing income	(353)	(685)	(720)	(884)
Transition and other service fees	(1)	(13)	(5)	(20)
Pension and postretirement	(19)	(11)	(30)	(10)
Intangible asset impairment	—	—	64	—
Loss on debt redemption	—	109	—	109
Other	22	6	(6)	(15)
Other income (net)	\$ (4)	\$ (586)	\$ (404)	\$ (1,265)

BRISTOL-MYERS SQUIBB COMPANY

SPECIFIED ITEMS

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2018 AND 2017

(Unaudited, dollars in millions)

	Three Months		Six Months	
	Ended		Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Impairment charges	\$ —	\$127	\$ 10	\$127
Accelerated depreciation and other shutdown costs	14	3	17	3
Cost of products sold	14	130	27	130
Marketing, selling and administrative	—	—	1	—
License and asset acquisition charges	1,075	393	1,135	443
IPRD impairments	—	—	—	75
Site exit costs and other	19	96	39	168
Research and development	1,094	489	1,174	686
Loss/(gain) on equity investments	356	—	341	—
Provision for restructuring	37	15	57	179
Litigation and other settlements	—	—	—	(481)
Divestiture gains	(25)	—	(68)	(100)
Royalties and licensing income	(25)	(497)	(75)	(497)
Pension and postretirement	37	36	68	69
Intangible asset impairment	—	—	64	—
Loss on debt redemption	—	109	—	109
Other income (net)	380	(337)	387	(721)

Increase to pretax income	1,488	282	1,589	95
Income taxes on specified items	(218)	20	(226)	92
Income taxes attributed to U.S. tax reform	3	—	(29)	—
Income taxes	<u>(215)</u>	<u>20</u>	<u>(255)</u>	<u>92</u>
Increase to net earnings	1,273	302	1,334	187
Noncontrolling interest	<u>—</u>	<u>—</u>	<u>—</u>	<u>(59)</u>
Increase to net earnings used for diluted Non-GAAP EPS calculation	<u>\$ 1,273</u>	<u>\$ 302</u>	<u>\$ 1,334</u>	<u>\$ 128</u>

BRISTOL-MYERS SQUIBB COMPANY

RECONCILIATION OF CERTAIN GAAP LINE ITEMS TO CERTAIN NON-GAAP LINE
ITEMS

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2018 AND 2017

(Unaudited, dollars in millions)

	Three Months Ended June 30, 2018			Six Months Ended June 30, 2018		
	GAAP	Specified Items ^(a)	Non- GAAP	GAAP	Specified Items ^(a)	Non- GAAP
Gross Profit	\$4,079	\$ 14	\$4,093	\$7,688	\$ 27	\$7,715
Marketing, selling and administrative	1,131	—	1,131	2,111	(1)	2,110
Research and development	2,435	(1,094)	1,341	3,685	(1,174)	2,511
Other income (net)	(4)	(380)	(384)	(404)	(387)	(791)

Earnings Before Income Taxes	517	1,488	2,005	2,296	1,589	3,885
Provision for Income Taxes	135	(215)	350	419	(255)	674
Noncontrolling interest	9	—	9	18	—	18
Net Earnings Attributable to BMS used for Diluted EPS Calculation	\$ 373	\$1,273	\$1,646	\$1,859	\$1,334	\$3,193
Average Common Shares Outstanding - Diluted	1,636	1,636	1,636	1,638	1,638	1,638
Diluted Earnings Per Share	\$ 0.23	\$ 0.78	\$ 1.01	\$ 1.13	\$ 0.82	\$ 1.95
Effective Tax Rate	26.1%	(8.6)%	17.5%	18.2%	(0.9)%	17.3%
	Three Months Ended June 30, 2017			Six Months Ended June 30, 2017		
	GAAP	Specified Items ^(a)	Non-GAAP	GAAP	Specified Items ^(a)	Non-GAAP
Gross Profit	\$3,575	\$ 130	\$3,705	\$7,239	\$ 130	\$7,369
Marketing, selling and administrative	1,187	—	1,187	2,272	—	2,272
Research and development	1,679	(489)	1,190	2,982	(686)	2,296
Other income (net)	(586)	337	(249)	(1,265)	721	(544)
Earnings Before Income Taxes						
Taxes	1,295	282	1,577	3,250	95	3,345
Provision for Income Taxes	373	20	353	802	92	710
Noncontrolling interest	6	—	6	(42)	(59)	17
Net Earnings Attributable	\$ 916	\$ 302	\$1,218	\$2,490	\$ 128	\$2,618

to BMS used for Diluted EPS

Calculation

Average Common Shares

Outstanding - Diluted	1,650	1,650	1,650	1,660	1,660	1,660
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Diluted Earnings Per Share	\$ 0.56	\$ 0.18	\$ 0.74	\$ 1.50	\$ 0.08	\$ 1.58
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Effective Tax Rate	28.8%	(6.4)%	22.4%	24.7%	(3.5)%	21.2%
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(a) Refer to the Specified Items schedule for further details. Effective tax rate on the Specified Items represents the difference between the GAAP and Non-GAAP effective tax rate.

BRISTOL-MYERS SQUIBB COMPANY

NET CASH/(DEBT) CALCULATION

AS OF JUNE 30, 2018 AND MARCH 31, 2018

(Unaudited, dollars in millions)

	June 30, 2018	March 31, 2018
Cash and cash equivalents	\$ 4,999	\$ 5,342
Marketable securities - current	1,076	1,428
Marketable securities - non-current	2,117	2,252
Cash, cash equivalents and marketable securities	8,192	9,022
Short-term debt obligations	(1,716)	(1,925)
Long-term debt	(5,671)	(5,775)
Net cash position	\$ 805	\$ 1,322