NEWS RELEASE

Merck Announces Third-Quarter 2019 Financial Results

10/29/2019

- Third-Quarter 2019 Worldwide Sales Were $12.4 Billion, an Increase of 15%; Sales Increased 16% Excluding Impact from Foreign Exchange; Growth Driven by Oncology and Human Health Vaccines
  - KEYTRUDA Sales Grew 62% to $3.1 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 64%
  - Human Health Vaccines Sales Grew 17% to $2.5 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 18%
- Third-Quarter 2019 GAAP EPS was $0.74, an Increase of 1%; Third-Quarter Non-GAAP EPS was $1.51, an Increase of 27%
- Company Narrows and Raises 2019 Full-Year Revenue Range to be Between $46.5 Billion and $47.0 Billion, Including a Negative Impact from Foreign Exchange of Approximately 2%
- Company Narrows and Reduces 2019 Full-Year GAAP EPS Range to be Between $3.75 and $3.80; Narrows and Raises 2019 Full-Year Non-GAAP EPS Range to be Between $5.12 and $5.17, Including a Negative Impact from Foreign Exchange of Approximately 1%

KENILWORTH, N.J.--(**BUSINESS WIRE**)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the third quarter of 2019.

“We achieved another quarter of strong revenue and earnings growth as we continue to realize the benefits of our sustained investment in research and development and our focus on commercial execution,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “We are confident that the investments we are making now will allow us to convert cutting-edge science into medicines and vaccines of great benefit to patients and value to shareholders.”

Financial Summary

$ in millions, except EPS amounts	Third Quarter			
	2019	2018	Change	Change Ex-Exchange
Sales	$12,397	$10,794	15%	16%
GAAP net income1	1,901	1,950	-3%	-3%
Non-GAAP net income that excludes certain items1,2*	3,873	3,178	22%	22%
GAAP EPS	0.74	0.73	1%	1%
Non-GAAP EPS that excludes certain items2*	1.51	1.19	27%	27%

*Refer to table on page 9

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) were $0.74 for the third quarter of 2019. Non-GAAP EPS of $1.51 for the third quarter of 2019 excludes a $982 million charge for the acquisition of Peloton Therapeutics, Inc. (Peloton), a $612 million pretax intangible asset impairment charge, other acquisition- and divestiture-related costs, restructuring costs and certain other items. Year-to-date results can be found in the attached tables.

Pipeline Highlights

Oncology

Merck continued to advance the development programs for KEYTRUDA (pembrolizumab), the company's anti-PD-1 therapy; Lynparza (olaparib), a PARP inhibitor being co-developed and co-commercialized with AstraZeneca; and Lenvima (lenvatinib mesylate), an orally available tyrosine kinase inhibitor being co-developed and co-commercialized with Eisai Co., Ltd. (Eisai).

KEYTRUDA

- Merck announced the following regulatory milestones for KEYTRUDA:
  - Approval in **China** as monotherapy for the first-line treatment of patients with locally advanced or

metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 based on overall survival results from the KEYNOTE-042 trial. KEYTRUDA is now the first anti-PD-1 therapy approved in China as both monotherapy and in combination with chemotherapy for the first-line treatment of NSCLC;
- Approval in **Europe** in combination with axitinib for the first-line treatment of advanced renal cell carcinoma (RCC) across all International Metastatic RCC Database Consortium (IMDC) risk groups based on overall survival results from the KEYNOTE-426 trial;
- Approval in the **United States** by the Food and Drug Administration (FDA) as monotherapy for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS] > 10) with disease progression after one or more prior lines of therapy based on the results from the KEYNOTE-181 and KEYNOTE-180 trials;
- Adoption of a **positive opinion** by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for two regimens of KEYTRUDA, as monotherapy or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy, for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC) in adults whose tumors express PD-L1 with a CPS ≥1 based on data from the KEYNOTE-048 trial; and
- Filing acceptance by the FDA for a supplemental Biologics License Application (sBLA) seeking use of KEYTRUDA for the treatment of patients with recurrent and/or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation. The FDA has set a PDUFA date of June 29, 2020.

- Merck **presented** results from the pivotal neoadjuvant/adjuvant Phase 3 KEYNOTE-522 trial in patients with early-stage triple-negative breast cancer (TNBC), the first randomized trial of an anti-PD-1 therapy in this setting, at the 2019 European Society for Medical Oncology (ESMO) Congress. Interim results from the neoadjuvant phase showed the combination of KEYTRUDA plus chemotherapy resulted in a statistically significant increase in pathological complete response versus chemotherapy in patients with early-stage TNBC.
- Merck **presented** first-time results of a pooled analysis of three randomized KEYNOTE studies (KEYNOTE-189, KEYNOTE-407 and KEYNOTE-021 [Cohort G]) evaluating KEYTRUDA in combination with chemotherapy in advanced NSCLC in which the combination regimen demonstrated an improvement in overall survival among newly diagnosed patients whose tumors do not express PD-L1. The data were presented at the IASLC 2019 World Conference on Lung Cancer.

Lynparza

- Merck and AstraZeneca **presented** results from the Phase 3 PROfound trial in patients with metastatic castration-resistant prostate cancer (mCRPC) who have a mutation in their homologous recombination repair

(HRR) genes and whose disease has progressed on prior treatment with new hormonal agent treatments at the 2019 ESMO Congress. In this study, Lynparza improved radiographic progression-free survival versus standard of care in BRCA1/2 or ATM-mutated tumors as well as reduced the risk of disease progression or death in tumors with mutations in other genes associated with HRR.

- Merck and AstraZeneca also **presented** results from the Phase 3 PAOLA-1 trial at the 2019 ESMO Congress, in which Lynparza added to bevacizumab reduced the risk of disease progression or death (41%) in the first-line maintenance setting for patients with advanced ovarian cancer who had a complete or partial response to platinum-based chemotherapy and bevacizumab.
- Merck and AstraZeneca received filing submission acceptances from the FDA and EMA for the use of Lynparza in BRCAm pancreatic cancer based on results from the Phase 3 POLO trial. A decision by the FDA is expected in the fourth quarter of 2019 and from the EMA in the second half of 2020.

Lenvima

- Merck and Eisai **announced** accelerated FDA approval of the combination of KEYTRUDA and Lenvima for patients with certain types of endometrial carcinoma based on data from the KEYNOTE-146/Study 111, marking the first approval of the combination and the first time an anti-PD-1 therapy is approved in combination with a kinase inhibitor for advanced endometrial carcinoma in the United States. Approval was granted under the FDA's Real-Time Oncology Review pilot program as well as under a new FDA-initiated program in which the FDA partnered with the Australian and Canadian regulatory bodies to review the application, allowing for simultaneous decisions in all three countries.

Other Pipeline Highlights

- Merck **announced** FDA approval expanding the use of both PIFELTRO (doravirine), in combination with other antiretroviral agents, and DELSTRIGO (doravirine/lamivudine/tenofovir disoproxil fumarate) for the treatment of adult patients with HIV-1 infection who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure.
- Merck **announced** FDA acceptance of a New Drug Application (NDA) for DIFICID (fidaxomicin) for oral suspension and a supplemental NDA (sNDA) for use of DIFICID tablets and oral suspension for the treatment of Clostridium difficile infections in children aged six months or older. The FDA has set a PDUFA date of Jan. 24, 2020 for both applications.
- Merck **announced** the pivotal Phase 3 RESTORE-IMI 2 trial evaluating RECARBRIO (imipenem, cilastatin and relebactam) for use in adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) met its primary endpoint.
- Merck **announced** that the EMA's CHMP adopted a positive opinion recommending a conditional marketing authorization for the company's investigational V920 vaccine, brand name ERVEBO (rVSVΔG-ZEBOV-GP, live),

for protection against Ebola Virus Disease caused by Zaire Ebola virus, as well as **FDA acceptance** and priority review for its Biologics License Application (BLA) for V920. The FDA has set a PDUFA date of March 14, 2020.

Third-Quarter Revenue Performance

The following table reflects sales of the company's top pharmaceutical products, as well as sales of animal health products.

$ in millions	Third Quarter			
	2019	2018	Change	Change Ex-Exchange
Total Sales	$12,397	$10,794	15%	16%
Pharmaceutical	11,095	9,658	15%	16%
KEYTRUDA	3,070	1,889	62%	64%
GARDASIL / GARDASIL 9	1,320	1,048	26%	27%
JANUVIA / JANUMET	1,311	1,490	-12%	-11%
PROQUAD, M-M-R II and VARIVAX	623	525	19%	19%
BRIDION	284	217	31%	32%
ISENTRESS / ISENTRESS HD	250	275	-9%	-6%
NUVARING	241	234	3%	4%
PNEUMOVAX 23	237	214	11%	11%
SIMPONI	203	210	-3%	1%
IMPLANON / NEXPLANON	199	186	7%	8%
Animal Health	1,122	1,021	10%	12%
Livestock	726	660	10%	12%
Companion Animals	396	361	10%	12%
Other Revenues	180	115	59%	-18%

Pharmaceutical Revenue

Third-quarter pharmaceutical sales were $11.1 billion, an increase of 15% compared with the third quarter of 2018; excluding the unfavorable effect of foreign exchange, sales grew 16% in the third quarter. The increase was driven primarily by growth in oncology and vaccines, partially offset by the ongoing impacts of the loss of market exclusivity for several products as well as lower sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl). International pharmaceutical sales represented 54% of total sales in the quarter. Performance in international markets was led by China, which had pharmaceutical sales of $898 million representing growth of 84% compared with the third quarter of 2018, driven by vaccines, primarily GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] and GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), and oncology. Excluding the unfavorable effect of foreign exchange, pharmaceutical sales in China grew by 90%.

Growth in oncology was largely driven by a $1.2 billion increase in sales for KEYTRUDA to $3.1 billion, reflecting strong momentum from the NSCLC indications as well as continued uptake in other indications, including the recently launched RCC and adjuvant melanoma indications, along with growth from Lynparza and Lenvima.

Growth in vaccines reflects higher sales of GARDASIL and GARDASIL 9, vaccines to prevent certain cancers and other diseases caused by HPV, primarily due to higher demand in Asia Pacific, particularly in China. Also contributing to sales growth was higher demand in Europe, driven primarily by increased vaccination rates for both boys and girls, as well as higher pricing and demand in the United States, partially offset by public sector buying patterns.

In October 2019, the company borrowed doses of GARDASIL 9 from the U.S. Centers for Disease and Control and Prevention's (CDC) Pediatric Vaccine Stockpile, which will reduce GARDASIL 9 sales in the fourth quarter of 2019 by approximately $120 million. These doses will be allocated to support routine vaccination in the United States and will allow the company to manufacture doses for other parts of the world, including regions where some of the most vulnerable populations live.

Growth in pediatric vaccines was driven by VARIVAX (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox, and PROQUAD (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a combination vaccine to help protect against measles, mumps, rubella and varicella, reflecting higher demand and pricing in the United States and higher demand in Europe and Latin America.

Performance in hospital acute care reflects higher demand globally, particularly in the United States, for BRIDION (sugammadex) Injection 100 mg/mL, a medicine for the reversal of neuromuscular blockade induced by

rocuronium bromide or vecuronium bromide in adults undergoing surgery; and the ongoing launch of PREVYMIS (letermovir), a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant.

Pharmaceutical sales growth for the quarter was partially offset by the ongoing impacts from the loss of market exclusivity for INVANZ (ertapenem sodium), ZETIA (ezetimibe) and VYTORIN (ezetimibe/simvastatin), CUBICIN (daptomycin) and REMICADE (infliximab). In addition, the decline in sales of JANUVIA and JANUMET reflects continued pricing pressure in the United States, which more than offset higher demand globally.

Animal Health Revenue

Animal Health sales totaled $1.1 billion for the third quarter of 2019, an increase of 10% compared with the third quarter of 2018. Excluding the unfavorable effect from foreign exchange, Animal Health sales grew 12%. Growth in the third quarter was primarily driven by livestock, due to products acquired in the Antelliq acquisition, along with growth from companion animal products, driven largely by higher sales of the BRAVECTO (fluralaner) line of products for parasitic control.

Animal Health segment profits were $423 million in the third quarter of 2019, an increase of 4% compared with $409 million in the third quarter of 2018.3

Third-Quarter Expense, EPS and Related Information

The tables below present selected expense information.

$ in millions Third-Quarter 2019	GAAP	Acquisition- and Divestiture-Related Costs 4	Restructuring Costs	Certain Other Items	Non-GAAP 2
Cost of sales	$3,990	$941	$62	$–	$2,987
Selling, general and administrative	2,589	22	1	–	2,566
Research and development	3,204	6	1	982	2,215
Restructuring costs	232	–	232	–	–
Other (income) expense, net	35	6	–	–	29

Third-Quarter 2018					
Cost of sales	$3,619	$680	$2	$420	$2,517
Selling, general and administrative	2,443	2	–	–	2,441
Research and development	2,068	5	(4)	–	2,067
Restructuring costs	171	–	171	–	–
Other (income) expense, net	(172)	(10)	–	–	(162)

GAAP Expense, EPS and Related Information

Gross margin was 67.8% for the third quarter of 2019 compared to 66.5% for the third quarter of 2018. The increase in gross margin for the third quarter of 2019 reflects the favorable impacts of a charge in 2018 related to the termination of a collaboration agreement with Samsung Bioepis Co., Ltd. and product mix, partially offset by higher acquisition- and divestiture-related costs, including the impact of a 2019 intangible asset impairment charge, higher amortization of unfavorable manufacturing variances, higher amortization of intangible assets related to collaborations, higher restructuring costs, as well as manufacturing facilities startup costs.

Selling, general and administrative expenses were $2.6 billion in the third quarter of 2019, a 6% increase compared to the third quarter of 2018. The increase primarily reflects higher promotion and administrative costs primarily in support of strategic brands, and higher acquisition- and divestiture-related costs, partially offset by the favorable effects of foreign exchange.

Research and development (R&D) expenses were $3.2 billion in the third quarter of 2019, an increase of 55% compared with the third quarter of 2018. The increase was driven primarily by a $982 million charge recorded in the third quarter of 2019 for the acquisition of Peloton coupled with higher expenses related to clinical development and increased investment in discovery research and early drug development.

Other (income) expense, net, was $35 million of expense in the third quarter of 2019 compared to $172 million of income in the third quarter of 2018 primarily reflecting lower income from investments in equity securities and higher net interest expense.

The effective income tax rate of 18.7% for the third quarter of 2019 includes the unfavorable impact of the charge for the acquisition of Peloton for which no tax benefit was recognized and the favorable impact of product mix.

GAAP EPS was $0.74 for the third quarter of 2019 compared with $0.73 for the third quarter of 2018.

Non-GAAP Expense, EPS and Related Information

The non-GAAP gross margin was 75.9% for the third quarter of 2019 compared to 76.7% for the third quarter of 2018. The decrease in non-GAAP gross margin primarily reflects higher amortization of unfavorable manufacturing variances, higher amortization of intangible assets related to collaborations, as well as manufacturing facilities startup costs.

Non-GAAP selling, general and administrative expenses were $2.6 billion in the third quarter of 2019, a 5% increase compared to the third quarter of 2018. The increase reflects higher promotion and administrative costs primarily in support of strategic brands, partially offset by the favorable effects of foreign exchange.

Non-GAAP R&D expenses were $2.2 billion in the third quarter of 2019, a 7% increase compared to the third quarter of 2018. The increase primarily reflects higher expenses related to clinical development and increased investment in discovery research and early drug development.

Non-GAAP other (income) expense, net, was $29 million of expense in the third quarter of 2019 compared to $162 million of income in the third quarter of 2018 primarily reflecting lower income from investments in equity securities and higher net interest expense.

The non-GAAP effective income tax rate of 15.7% for the third quarter of 2019 reflects the favorable impact of product mix.

Non-GAAP EPS was $1.51 for the third quarter of 2019 compared with $1.19 for the third quarter of 2018.

A reconciliation of GAAP to non-GAAP net income and EPS is provided in the table that follows.

$ in millions, except EPS amounts	Third Quarter	
	2019	2018
EPS		
GAAP EPS	$0.74	$0.73
Difference5	0.77	0.46
Non-GAAP EPS that excludes items listed below2	$1.51	$1.19

Net Income		
GAAP net income1	$1,901	$1,950
Difference	1,972	1,228
Non-GAAP net income that excludes items listed below1,2	$3,873	$3,178
Decrease (Increase) in Net Income Due to Excluded Items:		
Acquisition- and divestiture-related costs4	$975	$677
Restructuring costs	296	169
Charge for the acquisition of Peloton	982	–
Charge related to the termination of a collaboration agreement with Samsung	–	420
Net decrease (increase) in income before taxes	2,253	1,266
Estimated income tax (benefit) expense	(281)	(38)
Decrease (increase) in net income	$1,972	$1,228

Financial Outlook

Merck narrowed and raised its full-year 2019 revenue range to be between $46.5 billion and $47.0 billion, including both the impact of the GARDASIL 9 stockpile borrowing noted above and a negative impact from foreign exchange of approximately 2% at mid-October exchange rates.

Merck reduced its expected full-year GAAP effective tax rate to approximately 16.5% and its expected full-year non-GAAP effective tax rate to approximately 17.5%. These reductions are primarily attributable to favorable product mix.

Merck narrowed and reduced its full-year 2019 GAAP EPS range to be between $3.75 and $3.80. The change in the GAAP EPS range primarily reflects the impact of the intangible asset impairment charge noted above. Merck narrowed and raised its full-year 2019 non-GAAP EPS range to be between $5.12 and $5.17, including a negative impact from foreign exchange of approximately 1% at mid-October exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs, a net benefit from the settlement of certain federal income tax matters, the charge for the acquisition of Peloton and certain other items.

The following table summarizes the company’s full-year 2019 financial guidance.

	GAAP	Non-GAAP [2]
Revenue	$46.5 to $47.0 billion	$46.5 to $47.0 billion*
Operating expenses	Higher than 2018 by a low-single digit rate	Higher than 2018 by a mid-single digit rate
Effective tax rate	Approximately 16.5%	Approximately 17.5%
EPS**	$3.75 to $3.80	$5.12 to $5.17

*The company does not have any non-GAAP adjustments to revenue.

**EPS guidance for 2019 assumes a share count (assuming dilution) of approximately 2.6 billion shares.

A reconciliation of anticipated 2019 GAAP EPS to non-GAAP EPS and the items excluded from non-GAAP EPS are provided in the table below.

$ in millions, except EPS amounts	Full-Year 2019
GAAP EPS	$3.75 to $3.80
Difference[5]	1.37
Non-GAAP EPS that excludes items listed below[2]	$5.12 to $5.17
Acquisition- and divestiture-related costs[4]	$2,700
Restructuring costs	750
Charge for the acquisition of Peloton	982
Net decrease (increase) in income before taxes	4,432
Income tax (benefit) expense[6]	(900)
Decrease (increase) in net income	$3,532

The expected full-year GAAP effective tax rate of 16.5% reflects a net favorable impact of approximately one percentage point from the above items.

Earnings Conference Call

Investors, journalists and the general public may access a live audio webcast of the call today at 8:00 a.m. EDT on Merck's website at **http://investors.merck.com/events-and-presentations/default.aspx**. Institutional investors and analysts can participate in the call by dialing (706) 758-9927 or (877) 381-5782 and using ID code number 5635157. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 5635157. Journalists who wish to ask questions are requested to contact a member of Merck's Media Relations team at the conclusion of the call.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical

industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2018 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

1Net income attributable to Merck & Co., Inc.

2Merck is providing certain 2019 and 2018 non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of the company's results and permits investors to understand how management assesses performance. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the company along with other metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP. For a description of the items, see Table 2a attached to this release.

3Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting, Merck does not allocate general and administrative expenses not directly incurred by the segment, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits.

4Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories recognized as a result of acquisitions, intangible asset impairment charges, and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also includes integration, transaction and certain other costs related to business acquisitions and divestitures.

5Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the period.

6Includes the estimated tax impact on the reconciling items. In addition, includes a $360 million net tax benefit related to the settlement of certain federal income tax matters and a $67 million tax charge related to the finalization of treasury regulations for the Tax Cuts and Jobs Act of 2017.

MERCK & CO., INC.
CONSOLIDATED STATEMENT OF INCOME - GAAP
(AMOUNTS IN MILLIONS, EXCEPT PER SHARE FIGURES)
(UNAUDITED)
Table 1

	GAAP 3Q19	3Q18	% Change	GAAP Sep YTD 2019	Sep YTD 2018	% Change
Sales	$12,397	$10,794	15%	$34,972	$31,296	12%
Costs, Expenses and Other						
Cost of sales (1)	3,990	3,619	10%	10,443	10,220	2%
Selling, general and administrative (1)	2,589	2,443	6%	7,726	7,459	4%
Research and development (1)(2)	3,204	2,068	55%	7,324	7,538	-3%
Restructuring costs (3)	232	171	36%	444	494	-10%
Other (income) expense, net (1)	35	(172)	*	362	(512)	*
Income Before Taxes	2,347	2,665	-12%	8,673	6,097	42%
Taxes on Income (1)	440	707		1,259	1,682	
Net Income	1,907	1,958	-3%	7,414	4,415	68%
Less: Net Income (Loss) Attributable to Noncontrolling Interests (1)	6	8		(73)	22	
Net Income Attributable to Merck & Co., Inc.	$1,901	$1,950	-3%	$7,487	$4,393	70%
Earnings per Common Share Assuming Dilution	$0.74	$0.73	1%	$2.89	$1.63	77%
Average Shares Outstanding Assuming Dilution	2,572	2,678		2,587	2,694	
Tax Rate (4)	18.7%	26.5%		14.5%	27.6%	

* 100% or greater

(1) Amounts include the impact of acquisition and divestiture-related costs, restructuring costs and certain other items. See accompanying tables for details.

(2) Research and development expenses for the third quarter and first nine months of 2019 include a $982 million charge for the acquisition of Peloton Therapeutics (Peloton). Research and development expenses in the first nine months of 2018 include a $344 million charge for the acquisition of Viralytics Limited. Research and development expenses in the first nine months of 2018 also include a $1.4 billion charge related to the formation of a collaboration with Eisai Co., Ltd. (Eisai).

(3) Represents separation and other related costs associated with restructuring activities under the company's formal restructuring programs.

(4) The effective income tax rates for the third quarter and the first nine months of 2019 include the unfavorable impact of a charge for the acquisition of Peloton for which no tax benefit was recognized and the favorable impact of product mix. The effective income tax rate for the first nine months of 2019 reflects a net tax benefit of $360 million related to the settlement of certain federal income tax matters. The effective income tax rates for the third quarter and first nine months of 2018 include the unfavorable impact of a charge related to the termination of a collaboration agreement with Samsung for which no tax benefit was recognized. The effective income tax rate for the first nine months of 2018 reflects the unfavorable impact of a charge related to the formation of a collaboration with Eisai for which no tax benefit was recognized.

MERCK & CO., INC.
GAAP TO NON-GAAP RECONCILIATION
THIRD QUARTER 2019
(AMOUNTS IN MILLIONS, EXCEPT PER SHARE FIGURES)
(UNAUDITED)
Table 2a

	GAAP	Acquisition and Divestiture-Related Costs (1)	Restructuring Costs (2)	Certain Other Items (4)	Adjustment Subtotal	Non-GAAP
Cost of sales	$3,990	941	62		1,003	$ 2,987
Selling, general and administrative	2,589	22	1		23	2,566
Research and development	3,204	6	1	982	989	2,215
Restructuring costs	232		232		232	-
Other (income) expense, net	35	6			6	29
Income Before Taxes	2,347	(975)	(296)	(982)	(2,253)	4,600
Income Tax Provision (Benefit)	440	(231) (3)	(50) (3)	-	(281)	721
Net Income	1,907	(744)	(246)	(982)	(1,972)	3,879
Net Income Attributable to Merck & Co., Inc.	1,901	(744)	(246)	(982)	(1,972)	3,873
Earnings per Common Share Assuming Dilution	$0.74	(0.29)	(0.10)	(0.38)	(0.77)	$ 1.51
Tax Rate	18.7 %					15.7 %

Only the line items that are affected by non-GAAP adjustments are shown.

Merck is providing certain non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of the company's results as it permits investors to understand how management assesses performance. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the company along with other metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP.

(1) Amount included in cost of sales primarily reflects $320 million of expenses for the amortization of intangible assets recognized as a result of business acquisitions, as well as $612 million of intangible asset impairment charges related to SIVEXTRO. Amount included in selling, general and administrative expenses primarily reflects integration, transaction and certain other costs related to business acquisitions and divestitures.

(2) Amounts primarily include employee separation costs and accelerated depreciation associated with facilities to be closed or divested related to activities under the company's formal restructuring programs.

(3) Represents the estimated tax impact on the reconciling items based on applying the statutory rate of the originating territory of the non-GAAP adjustments.

(4) Amount included in research and development represents the charge related to the acquisition of Peloton Therapeutics.

MERCK & CO., INC.
GAAP TO NON-GAAP RECONCILIATION
NINE MONTHS ENDED SEPTEMBER 30, 2019
(AMOUNTS IN MILLIONS, EXCEPT PER SHARE FIGURES)
(UNAUDITED)
Table 2b

	GAAP	Acquisition and Divestiture-Related Costs (1)	Restructuring Costs (2)	Certain Other Items (4)	Adjustment Subtotal	Non-GAAP
Cost of sales	$10,443	1,801	161		1,962	$8,481
Selling, general and administrative	7,726	82	33		115	7,611
Research and development	7,324	(21)	4	982	965	6,359
Restructuring costs	444		444		444	-
Other (income) expense, net	362	321		48	369	(7)
Income Before Taxes	8,673	(2,183)	(642)	(1,030)	(3,855)	12,528
Income Tax Provision (Benefit)	1,259	(438) (3)	(106) (3)	(304) (5)	(848)	2,107
Net Income	7,414	(1,745)	(536)	(726)	(3,007)	10,421
Less: Net (Loss) Income Attributable to Noncontrolling Interests	(73)	(89)			(89)	16
Net Income Attributable to Merck & Co., Inc.	7,487	(1,656)	(536)	(726)	(2,918)	10,405
Earnings per Common Share Assuming Dilution	$2.89	(0.64)	(0.21)	(0.28)	(1.13)	$4.02
Tax Rate	14.5 %					16.8 %

Only the line items that are affected by non-GAAP adjustments are shown.

Merck is providing certain non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of the company's results as it permits investors to understand how management assesses performance. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the company along with other metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP.

(1) Amount included in cost of sales primarily reflects $1.1 billion of expenses for the amortization of intangible assets recognized as a result of business acquisitions, as well as $693 million of intangible asset impairment charges, including $612 million related to SIVEXTRO. Amount included in selling, general and administrative expenses primarily reflects integration, transaction and certain other costs related to business acquisitions and divestitures, including costs related to the acquisition of Antelliq Corporation. Amount included in research and development expenses primarily reflects a reduction in expenses related to a decrease in the estimated fair value measurement of liabilities for contingent consideration. Amount included in other (income) expense, net primarily reflects goodwill and intangible asset impairment charges related to certain businesses in the Healthcare Services segment and expenses related to an increase in the estimated fair value measurement of liabilities for contingent consideration, partially offset by royalty income related to the termination of the Sanofi-Pasteur MSD joint venture.

(2) Amounts primarily include employee separation costs and accelerated depreciation associated with facilities to be closed or divested related to activities under the company's formal restructuring programs.

(3) Represents the estimated tax impact on the reconciling items based on applying the statutory rate of the originating territory of the non-GAAP adjustments.

(4) Amount included in research and development represents the charge related to the acquisition of Peloton Therapeutics.

(5) Primarily reflects a $360 million net tax benefit related to the settlement of certain federal income tax matters and a $67 million tax charge related to the finalization of treasury regulations associated with the 2017 enactment of U.S. tax legislation.

MERCK & CO., INC.
FRANCHISE / KEY PRODUCT SALES
(AMOUNTS IN MILLIONS)
(UNAUDITED)
Table 3

	2019				2018						3Q		Sep YTD	
	1Q	2Q	3Q	Sep YTD	1Q	2Q	3Q	Sep YTD	4Q	Full Year	Nom %	Ex-Exch %	Nom %	Ex-Exch %
TOTAL SALES (1)	$10,816	$11,760	$12,397	$34,972	$10,037	$10,465	$10,794	$31,296	$10,998	$42,294	15	16	12	14
PHARMACEUTICAL	9,663	10,460	11,095	31,218	8,919	9,282	9,658	27,859	9,830	37,689	15	16	12	15
Oncology														
Keytruda	2,269	2,634	3,070	7,973	1,464	1,667	1,889	5,020	2,151	7,171	62	64	59	63
Emend	117	121	98	336	125	148	123	396	126	522	-20	-19	-15	-13
Alliance Revenue – Lynparza (2)	79	111	123	313	33	44	49	125	62	187	154	157	151	156
Alliance Revenue – Lenvima (2)	74	97	109	280		35	43	78	71	149	154	156	*	*
Vaccines (3)														
Gardasil / Gardasil 9	838	886	1,320	3,044	660	608	1,048	2,317	835	3,151	26	27	31	34
ProQuad / M-M-R II / Varivax	496	675	623	1,794	392	426	525	1,343	455	1,798	19	19	34	36
Pneumovax 23	185	170	237	592	179	193	214	586	322	907	11	11	1	2
RotaTeq	211	172	180	564	193	156	191	540	188	728	-5	-5	4	6
Vaqta	47	58	62	167	37	65	66	167	72	239	-6	-3	0	3
Hospital Acute Care														
Bridion	255	278	284	817	204	240	217	661	256	917	31	32	24	27

Noxafil	190	193	177	560	176	188	188	551	191	742	-6	-4	1	5
Cubicin	88	67	52	207	98	94	95	287	80	367	-45	-44	-28	-25
Primaxin	59	71	77	207	72	68	72	212	53	265	7	10	-2	2
Invanz	72	78	57	206	151	149	137	437	59	496	-58	-57	-53	-50
Cancidas	61	67	62	191	91	87	79	257	69	326	-21	-19	-26	-22
Immunology														
Simponi	208	214	203	625	231	233	210	673	220	893	-3	1	-7	-1
Remicade	123	98	101	322	167	157	135	459	123	582	-25	-23	-30	-25
Neuroscience														
Belsomra	67	76	80	223	54	71	66	191	69	260	22	19	17	17
Virology														
Isentress / Isentress HD	255	247	250	752	281	305	275	860	280	1,140	-9	-6	-13	-7
Zepatier	114	108	83	304	131	113	104	347	108	455	-20	-18	-12	-9
Cardiovascular														
Zetia	140	156	147	443	305	226	165	696	162	857	-11	-12	-36	-35
Vytorin	97	76	57	231	167	155	92	414	83	497	-38	-36	-44	-41
Atozet	94	92	97	283	73	101	84	258	89	347	15	19	9	16
Adempas	90	104	107	302	68	75	94	238	91	329	14	15	27	30
Diabetes (4)														
Januvia	824	908	807	2,539	880	949	927	2,756	930	3,686	-13	-12	-8	-6
Janumet	530	533	503	1,567	544	585	563	1,693	535	2,228	-11	-9	-7	-4
Women's Health														
NuvaRing	219	240	241	700	216	236	234	686	216	902	3	4	2	3
Implanon / Nexplanon	199	183	199	581	174	174	186	535	169	703	7	8	9	10
Diversified Brands														
Singulair	191	160	152	503	175	185	161	521	187	708	-6	-5	-3	0
Cozaar / Hyzaar	103	109	116	329	120	125	103	348	105	453	13	16	-6	-1
Nasonex	96	72	58	226	122	81	71	274	102	376	-17	-17	-17	-14

Arcoxia	75	75	72	221	83	84	83	249	86	335	-13	-11	-11	-6
Follistim AQ	57	63	62	182	67	70	60	198	70	268	2	4	-8	-5
Other Pharmaceutical (5)	1,140	1,268	1,229	3,634	1,186	1,189	1,109	3,486	1,215	4,705	11	12	4	8
ANIMAL HEALTH	1,025	1,124	1,122	3,271	1,065	1,090	1,021	3,176	1,036	4,212	10	12	3	8
Livestock	611	671	726	2,007	652	633	660	1,946	684	2,630	10	12	3	9
Companion Animals	414	453	396	1,264	413	457	361	1,230	352	1,582	10	12	3	7
Other Revenues (6)	128	176	180	483	53	93	115	261	132	393	59	-18	86	-54

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* 200% or greater

Sum of quarterly amounts may not equal year-to-date amounts due to rounding.

(1) Only select products are shown.

(2) Alliance Revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.

(3) Total Vaccines sales were $1,887 million, $2,037 million and $2,517 million in the first, second and third quarters of 2019, respectively, and $1,561 million, $1,533 million, $2,159 million and $2,008 million for the first, second, third and fourth quarters of 2018, respectively.

(4) Total Diabetes sales were $1,402 million, $1,480 million and $1,360 million in the first, second and third quarters of 2019, respectively, and $1,433 million, $1,571 million, $1,506 million and $1,485 million for the first, second, third and fourth quarters of 2018, respectively.

(5) Includes Pharmaceutical products not individually shown above.

(6) Other Revenues are comprised primarily of Healthcare Services segment revenues, third-party manufacturing sales and miscellaneous corporate revenues, including revenue hedging activities.

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