



NEWS RELEASE

Merck Announces Fourth-Quarter and Full-Year 2019 Financial Results

2/5/2020

- Fourth-Quarter 2019 Worldwide Sales Were \$11.9 Billion, an Increase of 8%; Excluding the Impact from Foreign Exchange, Sales Grew 9%
- Fourth-Quarter 2019 GAAP EPS Was \$0.92; Fourth-Quarter Non-GAAP EPS Was \$1.16
- Full-Year 2019 Worldwide Sales Were \$46.8 Billion, an Increase of 11%; Excluding the Impact from Foreign Exchange, Sales Grew 13%
 - KEYTRUDA 2019 Worldwide Sales Grew 55% to \$11.1 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 58%
 - Human Health Vaccines 2019 Worldwide Sales Grew 15% to \$8.4 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 17%
 - BRIDION 2019 Worldwide Sales Grew 23% to \$1.1 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 26%
 - Animal Health 2019 Worldwide Sales Grew 4% to \$4.4 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 9%
- Full-Year 2019 GAAP EPS Was \$3.81; Full-Year Non-GAAP EPS Was \$5.19
- 2020 Financial Outlook
 - Anticipates Full-Year 2020 Worldwide Sales to Be Between \$48.8 Billion and \$50.3 Billion, Including a Negative Impact from Foreign Exchange of Less Than 1%
 - Expects Full-Year 2020 GAAP EPS to Be Between \$4.57 and \$4.72; Expects Non-GAAP EPS to Be Between \$5.62 and \$5.77, Including a Negative Impact from Foreign Exchange of Approximately 1.5%
- In Conjunction with Fourth-Quarter Results, Merck Announces its Intention to Focus on Key Growth Pillars Through Spinoff of Women's Health, Trusted Legacy Brands and Biosimilar Products into NewCo

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

“As evidenced by our results and our 2020 guidance, Merck had an extraordinary year and is in a position of operational and financial strength,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “It is this position of strength, born of our focused execution, that gives us the confidence to spin off our Women’s Health, trusted Legacy Brands and Biosimilar products into a new company, which will position us to deliver even greater value to patients and shareholders.”

Financial Summary

\$ in millions, except EPS amounts	Fourth Quarter				Year Ended			
	2019	2018	Change	Change Ex-Exchange	Dec. 31, 2019	Dec. 31, 2018	Change	Change Ex-Exchange
Sales	\$11,868	\$10,998	8%	9%	\$46,840	\$42,294	11%	13%
GAAP net income ¹	2,357	1,827	29%	29%	9,843	6,220	58%	61%
Non-GAAP net income that excludes certain items ^{1,2*}	2,978	2,745	8%	8%	13,382	11,621	15%	16%
GAAP EPS	0.92	0.69	33%	32%	3.81	2.32	64%	67%
Non-GAAP EPS that excludes certain items ^{2*}	1.16	1.04	12%	12%	5.19	4.34	20%	21%

*Refer to table on page 10.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) was \$0.92 for the fourth quarter and \$3.81 for the full year of 2019. GAAP EPS for the full year of 2019 reflects a \$993 million charge for the acquisition of Peloton Therapeutics, Inc. (Peloton) and a \$612 million pretax intangible asset impairment charge related to SIVEXTRO (tedizolid phosphate). Non-GAAP EPS of \$1.16 for the fourth quarter and \$5.19 for the full year of 2019 excludes acquisition- and divestiture-related costs, restructuring costs and certain other items. Non-GAAP EPS for the full year of 2019 also excludes the charge for the acquisition of Peloton and the SIVEXTRO impairment charge.

Oncology Pipeline Highlights

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).

- Merck announced the following regulatory milestones for KEYTRUDA:
 - Approval in the **United States** by the Food and Drug Administration (FDA) as monotherapy for the treatment of certain patients with high-risk, non-muscle invasive bladder cancer (NMIBC) based on the KEYNOTE-057 trial;
 - Approval in **Japan** for three new first-line indications across advanced renal cell carcinoma (RCC) based on the KEYNOTE-426 trial and recurrent or distant metastatic head and neck cancer based on the KEYNOTE-048 trial;
 - Approval in **China** for first-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy based on the KEYNOTE-407 trial; and
 - Approval in **Europe** for two new regimens of KEYTRUDA, as monotherapy or in combination with 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 Combined Positive Score (CPS) >1 based on the KEYNOTE-048 trial.
- Merck **presented** results from an exploratory analysis of the pivotal Phase 3 KEYNOTE-042 trial that showed KEYTRUDA improved overall survival as monotherapy for the first-line treatment of metastatic NSCLC regardless of KRAS mutational status.
- Merck **announced** that the Phase 3 KEYNOTE-604 trial investigating KEYTRUDA in combination with chemotherapy significantly improved progression-free survival (PFS) compared to chemotherapy alone in the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC) but did not meet the other dual primary endpoint of overall survival.
- Merck and AstraZeneca announced the following regulatory milestones for Lynparza:
 - Approval in the **United States** by the FDA as first-line maintenance treatment of germline BRCA-mutated (BRCAm) metastatic pancreatic cancer in patients whose disease had not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen based on the Phase 3 POLO trial;
 - Approval in **China** as a first-line maintenance therapy in BRCAm advanced ovarian cancer following response to platinum-based chemotherapy based on the Phase 3 SOLO-1 trial;
 - **Filing acceptance** for priority review by the FDA for a supplemental New Drug Application (sNDA) seeking approval of Lynparza in combination with bevacizumab for the maintenance treatment of women with advanced ovarian cancer whose disease showed a complete or partial response to first-line

treatment with platinum-based chemotherapy and bevacizumab based on results from the Phase 3 PAOLA-1 trial. A Prescription Drug User Fee Act (PDUFA) date is set for the second quarter of 2020; and

- **Filing acceptance** for priority review by the FDA for a sNDA for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) and deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations, who have progressed following prior treatment with a new hormonal agent based on results from the Phase 3 PROfound trial. A PDUFA date is set for the second quarter of 2020.
- Merck and AstraZeneca **announced** filing acceptance for priority review by the FDA of a New Drug Application (NDA) for selumetinib, an oral MEK 1/2 inhibitor, for the treatment of certain pediatric patients with neurofibromatosis Type 1 (NF1) based on the results from the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP)-sponsored SPRINT Phase 2 Stratum 1 trial. A PDUFA date is set for the second quarter of 2020.

Other Pipeline Highlights

- Merck announced **conditional approval in Europe** as well as **U.S. approval** for ERVEBO (Ebola Zaire Vaccine, Live) for the prevention of disease caused by Zaire ebolavirus in individuals 18 years of age and older.
- Merck **announced** FDA approval of DIFICID (fidaxomicin) tablets and oral suspension for the treatment of Clostridioides difficile-associated diarrhea (CDAD) in children aged six months and older.
- Merck **announced** the adoption of a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for RECARBRIO (imipenem, cilastatin, and relebactam) for the treatment of infections due to aerobic gram-negative organisms in adults with limited treatment options.
- Merck **announced** filing acceptance for priority review by the FDA for a sNDA seeking approval of RECARBRIO to treat adult patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by certain susceptible Gram-negative microorganisms. The PDUFA date is June 4, 2020.
- Merck **announced** that the Phase 3 VICTORIA study evaluating vericiguat, a soluble guanylate cyclase (sGC) stimulator being jointly developed with Bayer AG, met its primary composite endpoint in reducing the risk of heart failure hospitalization or cardiovascular death in patients with worsening chronic heart failure with reduced ejection fraction (HFrEF) compared to placebo when given in combination with available heart failure therapies.

Business Development

- Merck **acquired** ArQule, Inc., diversifying its oncology portfolio with the expansion into targeted therapies that treat hematological malignancies with the addition of ARQ 531, a novel, oral Bruton's tyrosine kinase

(BTK) inhibitor currently in a Phase 2 development, among other candidates. The acquisition closed in January 2020.

- Merck **entered** into a strategic oncology collaboration with Taiho Pharmaceutical Co., Ltd., and Astex Pharmaceuticals focused on the development of small molecule inhibitors against several drug targets, including the KRAS oncogene, which are currently being investigated for the treatment of cancer.
- Merck Animal Health **acquired** Vaki, a leader in fish farming monitoring equipment and real-time video monitoring technology to advance fish health and welfare. The acquisition closed in December.

Fourth-Quarter and Full-Year Revenue Performance

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

\$ in millions	Fourth Quarter				Year Ended			
	2019	2018	Change	Change Ex Exchange	Dec. 31, 2019	Dec. 31, 2018	Change	Change Ex Exchange
Total Sales	\$11,868	\$10,998	8%	9%	\$46,840	\$42,294	11%	13%
Pharmaceutical	10,533	9,830	7%	8%	41,751	37,689	11%	14%
KEYTRUDA	3,111	2,151	45%	46%	11,084	7,171	55%	58%
JANUVIA / JANUMET	1,418	1,465	-3%	-2%	5,524	5,914	-7%	-4%
GARDASIL / GARDASIL 9	693	835	-17%	-16%	3,737	3,151	19%	21%
PROQUAD, M-M-R II and VARIVAX	481	455	6%	7%	2,275	1,798	27%	28%
PNEUMOVAX 23	334	322	4%	4%	926	907	2%	3%
BRIDION	313	256	22%	24%	1,131	917	23%	26%
ROTATEQ	227	188	21%	21%	791	728	9%	10%
ISENTRESS / ISENTRESS HD	223	280	-20%	-18%	975	1,140	-15%	-10%
IMPLANON / NEXPLANON	206	169	22%	23%	787	703	12%	14%
SIMPONI	205	220	-7%	-3%	830	893	-7%	-2%
Animal Health	1,122	1,036	8%	10%	4,393	4,212	4%	9%
Livestock	777	684	14%	16%	2,784	2,630	6%	11%
Companion Animals	345	352	-2%	0%	1,609	1,582	2%	5%

Other Revenues	213	132	61%	30%	696	393	77%	-26%
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Pharmaceutical Revenue

Fourth-quarter pharmaceutical sales increased 7% to \$10.5 billion, excluding the unfavorable effect from foreign exchange, sales grew 8%. The increase was driven primarily by growth in oncology, partially offset by the ongoing impacts of the loss of market exclusivity for several products. Additionally, fourth quarter 2019 sales were reduced by \$120 million due to a previously disclosed borrowing of doses of GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) from the U.S. Centers for Disease Control and Prevention's (CDC) Pediatric Vaccine Stockpile. Sales in the fourth quarter of 2018 were increased by \$125 million due to the replenishment of previously borrowed doses of GARDASIL 9.

Growth in oncology was largely driven by sales of KEYTRUDA, which were \$3.1 billion for the quarter, reflecting strong momentum from the NSCLC indications as well as continued uptake in other indications, including the recently launched RCC and adjuvant melanoma indications. Additionally, oncology sales reflect alliance revenue of \$132 million related to Lynparza and \$124 million related to Lenvima, representing Merck's share of profits, which are product sales net of cost of sales and commercialization costs.

Performance in vaccines for the fourth quarter reflects the negative impact of borrowing doses of GARDASIL 9 from the CDC Pediatric Vaccine Stockpile as discussed above, partially offset by higher demand in Europe and China, as well as higher demand and pricing in the United States. Excluding the borrowing-related activity in both periods, GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] and GARDASIL 9 sales grew 15% in the quarter, including a 1% negative impact from foreign exchange.

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 PREVMIS (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, including for NOXAFIL (posaconazole), EMEND (aprepitant), ZETIA (ezetimibe) and VYTORIN (ezetimibe/simvastatin), CUBICIN (daptomycin) and REMICADE (infliximab). A generic entrant of NUVARING (etonogestrel/ethinyl estradiol vaginal ring) in the U.S. also negatively affected sales for the quarter and will continue to negatively affect sales in the future. In addition, the decline in sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl) reflects continued pricing pressure in the United States, which more than

offset higher demand globally.

Full-year 2019 pharmaceutical sales increased 11% to \$41.8 billion; excluding the unfavorable effect from foreign exchange, sales grew 14%, primarily reflecting growth in oncology and vaccines, partially offset by the ongoing effects from the loss of market exclusivity for several products and continued pricing pressure in diabetes.

Animal Health Revenue

Animal Health sales totaled \$1.1 billion for the fourth quarter of 2019, an increase of 8% compared with the fourth quarter of 2018; excluding the unfavorable effect from foreign exchange, Animal Health sales grew 10%. Growth for the quarter was mainly driven by livestock products due to the Antelliq acquisition.

Worldwide sales for the full year of 2019 were \$4.4 billion, an increase of 4%; excluding the unfavorable effect from foreign exchange, sales grew 9%. Full-year sales growth was mainly driven by livestock products due to the Antelliq acquisition, along with higher sales of companion animal products, primarily the BRAVECTO (fluralaner) line of products for parasitic control.

Animal Health segment profits were \$366 million in the fourth quarter of 2019, a decrease of 5% compared with \$387 million in the fourth quarter of 2018, primarily driven by unfavorable product mix and higher investments in selling and product development, partially offset by higher sales. Segment profits were \$1.6 billion for the full year of 2019, a decrease of 3% compared with \$1.7 billion in 2018, primarily driven by the unfavorable effects of foreign exchange.³

Fourth-Quarter and Full-Year Expense, EPS and Related Information

The tables below present selected expense information.

\$ in millions	Acquisition- and Divestiture-Related Costs ⁴		Restructuring Costs	Certain Other Items	Non-GAAP ²
	GAAP				
Fourth-Quarter 2019					
Cost of sales	\$3,669	\$325	\$90	\$-	\$3,254
Selling, general and administrative	2,888	44	1	-	2,843
Research and development	2,548	166	-	11	2,371
Restructuring costs	194	-	194	-	-

Other (income) expense, net	(223)	(37)	-	7	(193)
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Fourth-Quarter 2018

Cost of sales	\$3,289	\$525	\$10	\$3	\$2,751
Selling, general and administrative	2,643	6	1	-	2,636
Research and development	2,214	91	1	-	2,122
Restructuring costs	138	-	138	-	-
Other (income) expense, net	110	179	-	(3)	(66)

\$ in millions	Acquisition- and Divestiture-Related Costs 4		Restructuring Costs	Certain Other Items	
	GAAP				Non-GAAP 2
Year Ended Dec. 31, 2019					
Cost of sales	\$14,112	\$2,126	\$251	\$-	\$11,735
Selling, general and administrative	10,615	126	34	-	10,455
Research and development	9,872	145	4	993	8,730
Restructuring costs	638	-	638	-	-
Other (income) expense, net	139	284	-	55	(200)

Year Ended Dec. 31, 2018

Cost of sales	\$13,509	\$2,672	\$21	\$423	\$10,393
Selling, general and administrative	10,102	32	3	-	10,067
Research and development	9,752	98	2	1,744	7,908
Restructuring costs	632	-	632	-	-
Other (income) expense, net	(402)	264	-	(57)	(609)

GAAP Expense, EPS and Related Information

Gross margin was 69.1% for the fourth quarter of 2019 compared to 70.1% for the fourth quarter of 2018. The decrease reflects unfavorable manufacturing variances, inventory write-offs, higher amortization of intangible assets related to collaborations, the unfavorable effects of pricing pressure and restructuring costs, partially offset by favorable product mix and lower acquisition- and divestiture-related costs.

Gross margin was 69.9% for the full year of 2019 compared to 68.1% for the full year of 2018. The increase in gross margin for the full year of 2019 reflects a charge in 2018 related to the termination of a collaboration agreement with Samsung Bioepis Co., Ltd., favorable product mix and lower acquisition- and divestiture-related costs, partially offset by unfavorable manufacturing variances, inventory write-offs, the unfavorable effects of pricing pressure, higher amortization of intangible assets related to collaborations and higher restructuring costs.

Selling, general and administrative expenses were \$2.9 billion in the fourth quarter of 2019, an increase of 9% compared to the fourth quarter of 2018. Full-year 2019 selling, general and administrative expenses were \$10.6 billion, an increase of 5% compared to the full year of 2018. The increase in both periods reflects higher administrative costs, acquisition- and divestiture-related costs, and promotion costs primarily in support of strategic brands, partially offset by the favorable effects of foreign exchange.

Research and development (R&D) expenses were \$2.5 billion in the fourth quarter of 2019, an increase of 15% compared with the fourth quarter of 2018. R&D expenses were \$9.9 billion for the full year of 2019, a 1% increase compared to the full year of 2018. The increase in both periods primarily reflects higher expenses related to clinical development and increased investment in discovery research and early drug development. In addition, the increase for the full year of 2019 was driven by a \$993 million charge for the acquisition of Peloton. The increase in R&D expenses for the full year of 2019 was partially offset by charges in 2018 including \$1.4 billion related to the formation of an oncology collaboration with Eisai and \$344 million related to the Viralytics Limited acquisition.

Other (income) expense, net, was \$223 million of income in the fourth quarter of 2019 compared to \$110 million of expense in the fourth quarter of 2018 primarily reflecting income from investments in equity securities in 2019 compared with losses in 2018. In addition, the fourth quarter of 2018 included goodwill impairment charges. Other (income) expense, net, was \$139 million of expense for the full year of 2019 compared to \$402 million of income for the full year of 2018 driven by lower income from investments in equity securities and higher net interest expense.

The effective income tax rates were 15.3% for the fourth quarter and 14.7% for full year of 2019. The effective income tax rate for the full year of 2019 reflects a net tax benefit of \$364 million related to the settlement of certain federal income tax matters, partially offset by the unfavorable impact of the charge for the acquisition of Peloton for which no tax benefit was recognized.

GAAP EPS was \$0.92 for the fourth quarter of 2019 compared with \$0.69 for the fourth quarter of 2018. GAAP EPS was \$3.81 for the full year of 2019 compared with \$2.32 for the full year of 2018.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 72.6% for the fourth quarter of 2019 compared to 75.0% for the fourth quarter of

2018. Non-GAAP gross margin was 74.9% for the full year of 2019 compared to 75.4% for the full year of 2018. The decrease in both periods reflects unfavorable manufacturing variances, inventory write-offs, the unfavorable effects of pricing pressure and higher amortization of intangible assets related to collaborations, partially offset by favorable product mix.

Non-GAAP selling, general and administrative expenses were \$2.8 billion in the fourth quarter of 2019, an increase of 8% compared to the fourth quarter of 2018. Full-year 2019 non-GAAP selling, general and administrative expenses were \$10.5 billion, an increase of 4% compared to the full year of 2018. The increase in both periods primarily reflects higher administrative costs and higher promotion costs primarily in support of strategic brands, partially offset by the favorable effects of foreign exchange.

Non-GAAP R&D expenses were \$2.4 billion in the fourth quarter of 2019, a 12% increase compared to the fourth quarter of 2018. Non-GAAP R&D expenses were \$8.7 billion for the full year of 2019, a 10% increase compared to the full year of 2018. The increases in both periods primarily reflect higher expenses related to clinical development and increased investment in discovery research and early drug development.

Non-GAAP other (income) expense, net, was \$193 million of income in the fourth quarter of 2019 compared to \$66 million of income in the fourth quarter of 2018, primarily reflecting income from investments in equity securities in 2019 compared with losses in 2018, partially offset by higher net interest expense. Non-GAAP other (income) expense, net, for the full year of 2019 was \$200 million of income compared to \$609 million of income for the full year of 2018, primarily driven by lower income from investments in equity securities and higher net interest expense.

The non-GAAP effective income tax rates were 16.9% for the fourth quarter of 2019 and 16.8% for the full year of 2019.

Non-GAAP EPS was \$1.16 for the fourth quarter of 2019 compared with \$1.04 for the fourth quarter of 2018. Non-GAAP EPS was \$5.19 for the full year of 2019 compared with \$4.34 for the full year 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

Fourth Quarter		Year Ended	
2019	2018	Dec. 31, 2019	Dec. 31, 2018

EPS

GAAP EPS	\$0.92	\$0.69	\$3.81	\$2.32
Difference ⁵	0.24	0.35	1.38	2.02
Non-GAAP EPS that excludes items listed below ²	\$1.16	\$1.04	\$5.19	\$4.34
Net Income				
GAAP net income ¹	\$2,357	\$1,827	\$9,843	\$6,220
Difference	621	918	3,539	5,401
Non-GAAP net income that excludes items listed below ^{1,2}	\$2,978	\$2,745	\$13,382	\$11,621
Decrease (Increase) in Net Income Due to Excluded Items:				
Acquisition- and divestiture-related costs ⁴	\$498	\$801	\$2,681	\$3,066
Restructuring costs	285	150	927	658
Charge for the acquisition of Peloton	11	–	993	–
Charge related to termination of a collaboration agreement with Samsung	–	3	–	423
Charge related to formation of a collaboration with Eisai	–	–	–	1,400
Charge for the acquisition of Viralytics	–	–	–	344
Other	7	(3)	55	(57)
Net decrease (increase) in income before taxes	801	951	4,656	5,834
Income tax (benefit) expense ⁶	(180)	25	(1,028)	(375)
Acquisition- and divestiture-related costs attributable to non-controlling interests	–	(58)	(89)	(58)
Decrease (increase) in net income	\$621	\$918	\$3,539	\$5,401

Financial Outlook

At mid-January 2020 exchange rates, Merck anticipates full-year 2020 revenue to be between \$48.8 billion and \$50.3 billion, including a negative impact from foreign exchange of less than 1%.

Merck expects full-year 2020 GAAP EPS to be between \$4.57 and \$4.72. Merck expects full-year 2020 non-GAAP EPS to be between \$5.62 and \$5.77, including an approximately 1.5% negative impact from foreign exchange. The non-GAAP range excludes acquisition- and divestiture-related costs and costs related to restructuring programs.

The following table summarizes the company's full-year 2020 financial guidance.

	GAAP	Non-GAAP 2
Revenue	\$48.8 to \$50.3 billion	\$48.8 to \$50.3 billion*
Operating expenses	Slightly lower than 2019	Higher than 2019 by a low-single-digit rate
Effective tax rate	17% to 18%	17.5% to 18.5%
EPS**	\$4.57 to \$4.72	\$5.62 to \$5.77

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

**EPS guidance for 2020 assumes a share count (assuming dilution) of approximately 2.54 billion shares.

A reconciliation of anticipated 2020 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 2020
GAAP EPS	\$4.57 to \$4.72
Difference ⁵	1.05
Non-GAAP EPS that excludes items listed below ²	\$5.62 to \$5.77
Acquisition- and divestiture-related costs	\$2,500
Restructuring costs	800
Net decrease (increase) in income before taxes	3,300
Estimated income tax (benefit) expense	(640)
Decrease (increase) in net income	\$2,660

Earnings Conference Call

Investors, journalists and the general public may access a live audio webcast of the call today at 8:00 a.m. EST on Merck's website at <https://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 8583879. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 8583879. 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 125 years, Merck, 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 in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. 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. Examples of forward-looking statements include statements with respect to the company's plans to spin-off certain of its businesses into an independent company, the timing and structure of such spin-off, the characteristics of the business to be separated, the expected benefits of the spin-off to the company and the expected effect on the company's dividends. 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 whether the proposed spin-off will be completed on the proposed timetable or at all. 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, uncertainties as to the timing of the proposed spin-off; uncertainties as to the status of any required regulatory approvals; the possibility that various conditions to the consummation of the spin-off may not be satisfied; the effects of disruption from the transactions contemplated in connection with the spin-off; 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 Tables 2a and 2b 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. Amounts for full-year 2019 include a \$364 million net tax benefit related to the settlement of certain federal income tax matters, an \$86 million tax benefit related to the reversal of tax reserves established in conjunction with the divestiture of Merck's Consumer Care business in 2014 as a result of the lapse in the statute of limitations, and a \$117 million tax charge related to the finalization of treasury regulations associated with the 2017 enactment of U.S. tax legislation. Amounts for fourth-quarter and full-year 2018 include adjustments to the provisional amounts recorded in 2017 related to the enactment of the U.S. tax legislation.

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

(UNAUDITED)
Table 1

	GAAP		% Change	GAAP		% Change
	4Q19	4Q18		Full Year 2019	Full Year 2018	
Sales	\$11,868	\$10,998	8%	\$46,840	\$42,294	11%
Costs, Expenses and Other						
Cost of sales (1)	3,669	3,289	12%	14,112	13,509	4%
Selling, general and administrative (1)	2,888	2,643	9%	10,615	10,102	5%
Research and development (1)(2)	2,548	2,214	15%	9,872	9,752	1%
Restructuring costs (3)	194	138	41%	638	632	1%
Other (income) expense, net (1)	(223)	110	*	139	(402)	*
Income Before Taxes	2,792	2,604	7%	11,464	8,701	32%
Taxes on Income (1)	428	826		1,687	2,508	
Net Income	2,364	1,778	33%	9,777	6,193	58%
Less: Net Income (Loss) Attributable to Noncontrolling Interests (1)	7	(49)		(66)	(27)	
Net Income Attributable to Merck & Co., Inc.	\$2,357	\$1,827	29%	\$9,843	\$6,220	58%
Earnings per Common Share Assuming Dilution	\$0.92	\$0.69	33%	\$3.81	\$2.32	64%
Average Shares Outstanding Assuming Dilution	2,559	2,634		2,580	2,679	
Tax Rate (4)	15.3 %	31.7 %		14.7 %	28.8 %	

* 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 full year of 2019 include a \$993 million charge for the acquisition of Peloton Therapeutics (Peloton). Research and development expenses for the full year of 2018 include a \$1.4 billion charge related to the formation of a collaboration with Eisai Co., Ltd. (Eisai), as well as a \$344 million charge for the acquisition of Viralytics Limited.

(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 fourth quarter and the full year 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 full year of 2019 also reflects a net tax benefit of \$364 million related to the settlement of certain federal income tax matters.

The effective income tax rates for the fourth quarter and full year of 2018 include the unfavorable impact of adjustments to the provisional amounts recorded in the prior year associated with the enactment of U.S. tax legislation, including \$124 million related to the transition tax. The effective income tax rate for the full year of 2018 also includes the unfavorable impacts of a charge related to the formation of a collaboration with Eisai and a charge related to the termination of a collaboration agreement with Samsung for which no tax benefits were recognized.

MERCK & CO., INC.
GAAP TO NON-GAAP RECONCILIATION
FOURTH 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	Adjustment Subtotal	Non- GAAP
Cost of sales	\$3,669	325	90		415	\$3,254
Selling, general and administrative	2,888	44	1		45	2,843
Research and development	2,548	166		11	177	2,371
Restructuring costs	194		194		194	-
Other (income) expense, net	(223)	(37)		7	(30)	(193)
Income Before Taxes	2,792	(498)	(285)	(18)	(801)	3,593
Income Tax Provision (Benefit)	428	(55)	(3)(49)	(3)(76)	(4)(180)	608
Net Income	2,364	(443)	(236)	58	(621)	2,985
Net Income Attributable to Merck & Co., Inc.	2,357	(443)	(236)	58	(621)	2,978
Earnings per Common Share Assuming Dilution	\$0.92	(0.17)	(0.09)	0.02	(0.24)	\$1.16
Tax Rate	15.3 %					16.9 %

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 \$306 million of expenses for the amortization of intangible assets recognized as a result of business acquisitions, as well as \$12 million of intangible asset impairment charges. Amount included in selling, general and administrative expenses primarily reflects integration, transaction and certain other costs related to business acquisitions and divestitures. Amount included in research and development expenses primarily reflects \$164 million of in-process research and development (IPR&D) impairment charges.

(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) Primarily reflects an \$86 million tax benefit related to the reversal of tax reserves established in conjunction with the divestiture of Merck's Consumer Care business in 2014 as a result of the lapse in the statute of limitations.

MERCK & CO., INC.
GAAP TO NON-GAAP RECONCILIATION
FULL YEAR 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	\$14,112	2,126	251		2,377	\$11,735
Selling, general and administrative	10,615	126	34		160	10,455
Research and development	9,872	145	4	993	1,142	8,730
Restructuring costs	638		638		638	-
Other (income) expense, net	139	284		55	339	(200)
Income Before Taxes	11,464	(2,681)	(927)	(1,048)	(4,656)	16,120
Income Tax Provision (Benefit)	1,687	(493)	(3)(155)	(3)(380)	(5)(1,028)	2,715
Net Income	9,777	(2,188)	(772)	(668)	(3,628)	13,405
Less: Net (Loss) Income Attributable to Noncontrolling Interests	(66)	(89)			(89)	23
Net Income Attributable to Merck & Co., Inc.	9,843	(2,099)	(772)	(668)	(3,539)	13,382
Earnings per Common Share Assuming Dilution	\$3.81	(0.82)	(0.30)	(0.26)	(1.38)	\$5.19
Tax Rate	14.7 %					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 \$1.4 billion of expenses for the amortization of intangible assets recognized as a result of business acquisitions, as well as \$705 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 Antelq Corporation. Amounts included in research and development expenses primarily reflect \$172 million of in-process research and development (IPR&D) impairment charges, partially offset by 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.

(5) Primarily reflects a \$364 million net tax benefit related to the settlement of certain federal income tax matters, an \$86 million tax benefit related to the reversal of tax reserves established in conjunction with the divestiture of Merck's Consumer Care business in 2014 as a result of the lapse in the statute of limitations, and a \$117 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					4Q		Full Year	
	1Q	2Q	3Q	4Q	Full Year	1Q	2Q	3Q	4Q	Full Year	Nom %	Ex-Exch %	Nom %	Ex-Exch %
TOTAL SALES (1)	\$10,816	\$11,760	\$12,397	\$11,868	\$46,840	\$10,037	\$10,465	\$10,794	\$10,998	\$42,294	8	9	11	13
PHARMACEUTICAL	9,663	10,460	11,095	10,533	41,751	8,919	9,282	9,658	9,830	37,689	7	8	11	14
Oncology														
Keytruda	2,269	2,634	3,070	3,111	11,084	1,464	1,667	1,889	2,151	7,171	45	46	55	58
Alliance Revenue – Lynparza (2)	79	111	123	132	444	33	44	49	62	187	111	112	137	141
Alliance Revenue – Lenvima (2)	74	97	109	124	404		35	43	71	149	74	73	171	173
Emend	117	121	98	53	388	125	148	123	126	522	-58	-58	-26	-24
Vaccines (3)														
Gardasil / Gardasil 9	838	886	1,320	693	3,737	660	608	1,048	835	3,151	-17	-16	19	21
ProQuad / M-M-R II / Varivax	496	675	623	481	2,275	392	426	525	455	1,798	6	7	27	28
Pneumovax 23	185	170	237	334	926	179	193	214	322	907	4	4	2	3
RotaTeq	211	172	180	227	791	193	156	191	188	728	21	21	9	10
Vaqta	47	58	62	71	238	37	65	66	72	239	-2	-1	0	2
Hospital Acute Care														
Bridion	255	278	284	313	1,131	204	240	217	256	917	22	24	23	26
Noxafil	190	193	177	103	662	176	188	188	191	742	-46	-44	-11	-7
Primaxin	59	71	77	67	273	72	68	72	53	265	25	27	3	7
Invanz	72	78	57	57	263	151	149	137	59	496	-5	-2	-47	-44

Cubicin	88	67	52	50	257	98	94	95	80	367	-38	-37	-30	-28
Cancidas	61	67	62	58	249	91	87	79	69	326	-17	-15	-24	-20
Immunology														
Simponi	208	214	203	205	830	231	233	210	220	893	-7	-3	-7	-2
Remicade	123	98	101	89	411	167	157	135	123	582	-27	-25	-29	-25
Neuroscience														
Belsomra	67	76	80	83	306	54	71	66	69	260	19	16	18	17
Virology														
Isentress / Isentress HD	255	247	250	223	975	281	305	275	280	1,140	-20	-18	-15	-10
Zepatier	114	108	83	66	370	131	113	104	108	455	-38	-38	-19	-16
Cardiovascular														
Zetia	140	156	147	146	590	305	226	165	162	857	-9	-11	-31	-30
Vytorin	97	76	57	54	285	167	155	92	83	497	-35	-33	-43	-40
Atozet	94	92	97	108	391	73	101	84	89	347	22	26	13	18
Adempas	90	104	107	117	419	68	75	94	91	329	28	29	27	30
Diabetes (4)														
Januvia	824	908	807	943	3,482	880	949	927	930	3,686	1	2	-6	-4
Janumet	530	533	503	475	2,041	544	585	563	535	2,228	-11	-9	-8	-5
Women's Health														
NuvaRing	219	240	241	179	879	216	236	234	216	902	-17	-17	-3	-2
Implanon / Nexplanon	199	183	199	206	787	174	174	186	169	703	22	23	12	14
Diversified Brands														
Singulair	191	160	152	195	698	175	185	161	187	708	4	5	-1	1
Cozaar / Hyzaar	103	109	116	113	442	120	125	103	105	453	8	9	-3	2
Nasonex	96	72	58	67	293	122	81	71	102	376	-34	-34	-22	-19
Arcoxia	75	75	72	67	288	83	84	83	86	335	-23	-22	-14	-10
Follistim AQ	57	63	62	58	241	67	70	60	70	268	-16	-15	-10	-7
Other Pharmaceutical (5)	1,140	1,268	1,229	1,265	4,901	1,186	1,189	1,109	1,215	4,705	4	6	4	7
ANIMAL HEALTH	1,025	1,124	1,122	1,122	4,393	1,065	1,090	1,021	1,036	4,212	8	10	4	9
Livestock	611	671	726	777	2,784	652	633	660	684	2,630	14	16	6	11
Companion Animals	414	453	396	345	1,609	413	457	361	352	1,582	-2	0	2	5
Other Revenues (6)	128	176	180	213	696	53	93	115	132	393	61	30	77	-26



* 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, \$2,517 million and \$1,928 million in the first, second, third and fourth 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, \$1,360 million and \$1,472 million in the first, second, third and fourth 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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