



NEWS RELEASE

Merck Announces Second-Quarter 2020 Financial Results

7/31/2020

- Second-Quarter 2020 Worldwide Sales Were \$10.9 Billion, a Decrease of 8%, Reflecting the Negative Impact of COVID-19; Excluding the Impact from Foreign Exchange, Sales Declined 5%
 - KEYTRUDA Sales Grew 29% to \$3.4 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 31%
- Second-Quarter 2020 GAAP EPS Was \$1.18; Second-Quarter Non-GAAP EPS Was \$1.37
- Secured Multiple Regulatory Approvals and Progressed Pipeline
 - Revealed Initial Investigational Phase 3 Results for V114
 - First Data Presentation with Investigational, Novel HIF-2 α Inhibitor MK-6482
- Company Accelerates Three COVID-19-Related Vaccine and Antiviral Research Programs
- Company Narrows and Raises 2020 Full-Year Revenue Range to be Between \$47.2 Billion and \$48.7 Billion, Including a Negative Impact from Foreign Exchange of Approximately 2%
- Company Narrows and Raises 2020 Full-Year GAAP EPS Range to be Between \$4.58 and \$4.73; Narrows and Raises 2020 Full-Year Non-GAAP EPS Range to be Between \$5.63 and \$5.78, Including a Negative Impact from Foreign Exchange of Approximately 3%

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the second quarter of 2020.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20200731005100/en/>

“Despite the impact COVID-19 had on patient access to health care providers, Merck continued to execute well with business momentum improving through the quarter. We remain confident that Merck will drive strong long-term growth based on underlying demand for our unique portfolio of innovative medicines, vaccines and animal health products. Our financial strength underpins our capital allocation priorities, including business development and the breakthrough research and development that creates value for society and our shareholders,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “In response to the SARS-CoV-2 pandemic, Merck is moving with urgency on three critical priorities: protecting the health and safety of our employees and their families, sustaining the supply of our medicines and vaccines to our patients and customers, and mobilizing our unique scientific expertise and experience to develop vaccines and antivirals that we believe may help save many lives.”

Financial Summary

	Second Quarter			
	2020	2019	Change	Change Ex-Exchange
\$ in millions, except EPS amounts				
Sales	\$10,872	\$11,760	-8%	-5%
GAAP net income ¹	3,002	2,670	12%	17%
Non-GAAP net income that excludes certain items ^{1,2*}	3,484	3,356	4%	7%
GAAP EPS	1.18	1.03	15%	19%
Non-GAAP EPS that excludes certain items ^{2*}	1.37	1.30	6%	9%

*Refer to table on page 11.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) was \$1.18 for the second quarter of 2020. Non-GAAP EPS of \$1.37 for the second quarter of 2020 excludes acquisition- and divestiture-related costs and restructuring costs. Year-to-date results can be found in the attached tables.

COVID-19 Research Highlights

Building on the company’s experience with antivirals and vaccines, Merck is accelerating two COVID-19 vaccine development efforts and a novel antiviral candidate, specifically,

- **Merck in collaboration with IAVI** is developing V590, a SARS-CoV-2 vaccine candidate that uses a recombinant vesicular stomatitis virus (rVSV) platform, the same platform that was used for Merck’s approved Ebola Zaire virus vaccine. V590 is currently in preclinical development and clinical studies are planned to start this year.
- **Merck has acquired Themis** to accelerate the development of V591, a SARS-CoV-2 vaccine candidate that uses a measles virus vector platform based on a vector originally developed by scientists at the Institut Pasteur, a world-leading European vaccine research institute, and licensed exclusively to Themis. V591 is currently in preclinical development and clinical studies are planned to start in the third quarter. The

acquisition closed in June.

- **Merck in collaboration with Ridgeback Bio** is developing MK-4482 (formerly known as EIDD-2801), an orally available antiviral candidate for the treatment of COVID-19. In preclinical studies, MK-4482 demonstrated antiviral properties against SARS-CoV-2, the virus that causes COVID-19, as well as the coronaviruses responsible for MERS and SARS. The candidate is currently being evaluated in Phase 2 clinical trials.
- As previously **announced**, Merck also is collaborating with the Institute for Systems Biology to investigate and define the molecular mechanisms of SARS-CoV-2 infection and COVID-19 and to identify targets for medicines and vaccines, as well as participating in the National Institutes of Health (NIH)-led Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) consortium.

“We are conscious of our abiding responsibility to help advance vaccine and antiviral efforts as part of the global response to SARS-CoV-2 and to ensure broad, equitable and affordable global access to any medicines and vaccines we bring forward,” Frazier said. “This pandemic underscores the essential role of Merck and the biopharmaceutical industry in addressing the world’s greatest health challenges and underscores the importance of a health care ecosystem that incentivizes risk-taking and innovation. Ultimately, scientific and medical knowledge will help overcome this ongoing global pandemic – and that is why we must continue to trust and invest in breakthrough science.”

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), in addition to other notable developments as follows:

- Merck announced the following regulatory milestones for KEYTRUDA:
 - **U.S. approval** as monotherapy for the first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer based on the Phase 3 results of the KEYNOTE-177 trial. Approval granted less than one month following submission of regulatory application;
 - **U.S. approval** as monotherapy for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation based on data from the Phase 2 KEYNOTE-629 trial;
 - **U.S. approval** as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥ 10 mutations/ megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. The approval was based on the KEYNOTE 158 trial;

- **U.S. approval** for use at an additional recommended dose of 400 mg every six weeks (Q6W) across all adult indications, including monotherapy and combination therapy. This dosing regimen was approved under accelerated approval based on pharmacokinetic data, the relationship of exposure to efficacy and the relationship of exposure to safety;
 - **China approval** as monotherapy for second-line treatment of patients with locally advanced or metastatic esophageal squamous cell carcinoma whose tumors express PD-L1 (Combined Positive Score [CPS] ≥ 10) based on the KEYNOTE-181 trial;
 - **U.S. filing acceptance** for priority review by the U.S. Food and Drug Administration (FDA) as monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) based on data from the Phase 3 KEYNOTE-204 trial that was presented during the virtual scientific program of the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting. A Prescription Drug User Fee Act (PDUFA) date is set for Oct. 30, 2020;
 - **U.S. filing acceptance** for priority review by the FDA seeking accelerated approval in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥ 10), based on the Phase 3 KEYNOTE-355 trial that was presented at the 2020 ASCO Annual Meeting. A PDUFA date is set for Nov. 28, 2020; and
 - **U.S. filing acceptance** for standard review by the FDA for the treatment of patients with high-risk early-stage TNBC, in combination with chemotherapy as neoadjuvant treatment, and then as a single agent as adjuvant treatment after surgery, based on the Phase 3 KEYNOTE-522 trial. A PDUFA date is set for March 29, 2021.
- Merck **presented** new combination lung data for KEYTRUDA at the 2020 ASCO Annual Meeting that included initial results from the Phase 2 KEYNOTE-799 trial evaluating KEYTRUDA plus concurrent chemoradiation therapy (CCRT) in patients with unresectable, locally advanced stage III non-small cell lung cancer (NSCLC) as well as two-year, long-term survival data from the final analysis of the pivotal Phase 3 KEYNOTE-189 trial in patients with metastatic nonsquamous NSCLC; and
 - Merck **announced** that the Phase 3 KEYNOTE-361 trial investigating KEYTRUDA as monotherapy and in combination with chemotherapy in patients with advanced or metastatic urothelial carcinoma did not meet the dual primary endpoints of overall survival (OS) or progression-free survival (PFS) compared with standard of care chemotherapy.
 - Merck and AstraZeneca announced the following regulatory milestones for Lynparza:
 - **U.S. approval** for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone based on the findings from the Phase 3 PROfound trial;

- **U.S. approval** as a combination therapy with bevacizumab for the first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability based on results from the Phase 3 PAOLA-1 trial; and
- **European Union approval** as a monotherapy for the maintenance treatment of adult patients with germline BRCA1/2 mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen based on results from the Phase 3 POLO trial.
- Merck and Eisai **presented** results from two trials evaluating KEYTRUDA plus Lenvima at the 2020 ASCO Annual Meeting: tumor response data from the KEYNOTE-524/Study 116 trial in patients with hepatocellular carcinoma (HCC) with no prior systemic therapy and tumor response data from the KEYNOTE-146/Study 111 trial in patients with metastatic clear cell renal cell carcinoma (ccRCC) who progressed following immune checkpoint inhibitor therapy; and
- Merck and Eisai **announced** receipt of a Complete Response Letter (CRL) from the FDA for the applications seeking accelerated approval of KEYTRUDA plus Lenvima for the first-line treatment of patients with unresectable HCC based on data from the Phase 1b KEYNOTE-524/Study 116 trial, as another combination therapy was approved ahead of the PDUFA action dates, based on a randomized, controlled trial that demonstrated OS. Consequently, the CRL stated that Merck's and Eisai's applications do not provide evidence that KEYTRUDA in combination with Lenvima represents a meaningful advantage over available therapies for the treatment of unresectable or metastatic HCC with no prior systemic therapy for advanced disease.
- Merck also **presented** first-time results from a Phase 2 trial evaluating the hypoxia-inducible factor-2 alpha (HIF-2 α) inhibitor MK-6482, a novel investigational candidate in Merck's oncology pipeline, for the treatment of von Hippel-Lindau (VHL) disease-associated ccRCC at the 2020 ASCO Annual Meeting.

Vaccine Pipeline Highlights

- Merck **announced** results from two initial Phase 3 studies that showed V114, the company's investigational 15-valent pneumococcal conjugate vaccine, met safety and immunogenicity objectives in the PNEU-WAY (V114-018) and PNEU-FLU (V114-021) studies in adults; and
- Merck **announced** FDA approval of an expanded indication for GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.

Other Pipeline Highlights

- Merck **announced** U.S. filing acceptance for priority review by the FDA for a New Drug Application (NDA) seeking approval for vericiguat, an orally administered soluble guanylate cyclase (sGC) stimulator being jointly developed with Bayer AG, to reduce the risk of cardiovascular death and heart failure hospitalization following a worsening heart failure event in patients with symptomatic chronic heart failure with reduced ejection fraction (HFrEF), in combination with other heart failure therapies. A PDUFA date is set for Jan. 20, 2021;
- Merck **presented** new supportive analyses from the Phase 2b trial evaluating the safety and efficacy of islatravir, the company's investigational oral nucleoside reverse transcriptase translocation inhibitor (NRTTI), in combination with PIFELTRO (doravirine), in adults with HIV-1 infection who had not previously received antiretroviral treatment at the 23rd International AIDS Conference; and
- Merck **announced** FDA approval of RECARBRIO (imipenem, cilastatin, and relebactam) for the treatment of adults with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP).

Business Developments

- Merck signed an **agreement** to acquire U.S. rights from Virbac to the SENTINEL brand of combination parasiticides, used to protect dogs against fleas and common intestinal parasites including heartworm, broadening its companion animal business. The acquisition closed in July; and
- Merck **announced** the completion of its acquisition of Quantified Ag, a leading data and analytics company that monitors cattle body temperature and movement in order to detect illness early.

Organon & Co.

- Merck **announced** the external appointments of Organon & Co. Chief Financial Officer and Chief Information Officer as well as the external **appointment** of Organon's General Counsel. Merck remains fully committed to its spinoff transaction and continues to expect completion in the first half of 2021.

Second-Quarter Financial Impact of COVID-19

In the second quarter, the estimated overall negative impact of the COVID-19 pandemic to Merck's revenue was approximately \$1.6 billion, consisting of approximately \$1.5 billion for pharmaceuticals and approximately \$100 million for Animal Health. As expected, within the company's human health business, revenue was negatively impacted by reduced access to health care providers given social distancing measures and within Animal Health, by reduced veterinary visits and decreased protein and milk demand.

Operating expenses were positively impacted in the second quarter by approximately \$325 million, primarily driven by lower promotional and selling costs as well as lower research and development (R&D) expenses.

Second-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	Second Quarter			Change Ex- Exchange
	2020	2019	Change	
Total Sales	\$10,872	\$11,760	-8%	-5%
Pharmaceutical	9,679	10,460	-7%	-6%
KEYTRUDA	3,388	2,634	29%	31%
JANUVIA / JANUMET	1,344	1,441	-7%	-5%
GARDASIL / GARDASIL 9	656	886	-26%	-24%
PROQUAD, M-M-R II and VARIVAX	378	675	-44%	-43%
BRIDION	224	278	-19%	-18%
ISENTRESS / ISENTRESS HD	196	247	-21%	-17%
SIMPONI	191	214	-11%	-8%
Lynparza*	178	111	61%	62%
ZETIA / VYTORIN	175	232	-24%	-23%
ROTATEQ	168	172	-2%	-1%
Lenvima*	151	97	57%	57%
Animal Health	1,101	1,124	-2%	3%
Livestock	648	671	-3%	3%
Companion Animals	453	453	0%	3%
Other Revenues	92	176	-47%	-23%

*Alliance revenue for these products represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.

Pharmaceutical Revenue

Second-quarter pharmaceutical sales decreased by \$780 million, or 7%, to \$9.7 billion; excluding the unfavorable effect from foreign exchange, sales declined by 6%. The decrease was driven primarily by the negative impact of the COVID-19 pandemic on vaccines and hospital acute care products and the ongoing impacts of the loss of market exclusivity for several products, partially offset by growth in oncology.

The decline in vaccine sales was primarily driven by GARDASIL (Human Papillomavirus Quadrivalent [Types 6,11,16 and 18] Vaccine, Recombinant)/GARDASIL 9, vaccines to prevent certain cancers and other diseases caused by HPV, largely due to lower demand in the U.S. and Hong Kong, SAR, PRC attributable to the COVID-19 pandemic, partially offset by higher demand in China.

Also contributing to the decline in vaccine sales were pediatric vaccines PROQUAD (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a combination vaccine to help protect against measles, mumps, rubella and varicella; M-M-R II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; and VARIVAX (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox, primarily attributable to lower demand in the U.S. related to the COVID-19 pandemic. Lower demand for M-M-R II in the U.S. due to fewer measles outbreaks and the timing of government tenders in Latin America for VARIVAX also contributed to the sales

declines.

Sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, declined in the second quarter, primarily reflecting lower demand in the U.S. related to the COVID-19 pandemic, partially offset by higher volumes in Europe attributable in part to increased demand for pneumococcal vaccination during the COVID-19 pandemic.

Performance in hospital acute care reflects lower demand globally for BRIDION (sugammadex), a medicine for the reversal of neuromuscular blockade induced by rocuronium bromide or vecuronium bromide in adults undergoing surgery, driven by reductions in elective surgeries due to the COVID-19 pandemic, partially offset by 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 performance for the quarter also was negatively affected by the ongoing impacts from the loss of market exclusivity, including for NUVARING (etonogestrel/ethinyl estradiol vaginal ring), NOXAFIL (posaconazole), EMEND (aprepitant)/EMEND (fosaprepitant dimeglumine) for Injection, VYTORIN (ezetimibe/simvastatin), CUBICIN (daptomycin) and REMICADE (infliximab). In addition, the decline in sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl) reflects continued pricing pressure in the U.S.

Growth in oncology partially offset the decline in pharmaceutical revenue, largely driven by higher sales of KEYTRUDA, which grew 29% to \$3.4 billion for the quarter. Continued strong momentum from the NSCLC indications as well as continued uptake in other indications, including adjuvant melanoma, renal cell carcinoma (RCC), bladder, head and neck squamous cell carcinoma (HNSCC) and microsatellite instability-high (MSI-H) cancers, was partially offset by the negative impacts of the COVID-19 pandemic globally. Also contributing to growth in oncology was higher alliance revenue related to Lynparza and Lenvima reflecting continued uptake in approved indications in the U.S., Europe and China.

Animal Health Revenue

Animal Health sales totaled \$1.1 billion for the second quarter of 2020, a decrease of 2% compared with the second quarter of 2019; excluding the unfavorable effect from foreign exchange, Animal Health sales grew 3%.

Performance in livestock products reflects lower demand driven by reduced protein and milk demand due to restaurant and school closures resulting from the COVID-19 pandemic, partially offset by an additional month of sales included in the current quarter related to the 2019 acquisition of Antellic Corporation. Performance in companion animal products was driven largely by lower demand in companion animal vaccines due to reduced veterinary access resulting from the COVID-19 pandemic, offset by higher demand for the BRAVECTO (fluralaner) line of products for parasitic control.

Second-Quarter Expense, EPS and Related Information

The tables below present selected expense information.

\$ in millions	GAAP	Acquisition- and Divestiture- Related Costs ³	Restructuring Costs	Certain Other Items	Non-GAAP ²
Second-Quarter 2020					
Cost of sales	\$3,159	\$282	\$25	\$-	\$2,852
Selling, general and administrative	2,378	163	11	-	2,204
Research and development	2,123	(65)	31	-	2,157
Restructuring costs	83	-	83	-	-
Other (income) expense, net	(390)	63	-	(16)	(437)
Second-Quarter 2019					
Cost of sales	\$3,401	\$447	\$65	\$-	\$2,889
Selling, general and administrative	2,712	61	32	-	2,619
Research and development	2,189	4	3	-	2,182
Restructuring costs	59	-	59	-	-
Other (income) expense, net	140	148	-	48	(56)

GAAP Expense, EPS and Related Information

Gross margin was 70.9% for the second quarter of 2020 compared to 71.1% for the second quarter of 2019. The decrease reflects higher amortization of intangible assets related to collaborations and unfavorable manufacturing variances, partially offset by the favorable effects of foreign exchange, product mix and lower acquisition- and divestiture-related costs.

Selling, general and administrative expenses were \$2.4 billion in the second quarter of 2020, a decrease of 12% compared to the second quarter of 2019. The decrease primarily reflects lower promotion, selling and administrative costs, including less travel and meeting expenses, due in part to the COVID-19 pandemic, and the favorable effects of foreign exchange, partially offset by higher acquisition- and divestiture-related costs, including costs related to the company's planned spinoff of Organon.

Research and development expenses were \$2.1 billion in the second quarter of 2020, a decrease of 3% compared with the second quarter of 2019. The decrease was primarily driven by lower acquisition- and divestiture-related costs and lower laboratory, travel and meeting expenses due to the COVID-19 pandemic, partially offset by higher expenses related to clinical development and increased investment in discovery research and early drug development.

Other (income) expense, net, was \$390 million of income in the second quarter of 2020 compared to \$140 million of expense in the second quarter of 2019, primarily due to higher income from investments in equity securities, net, which was \$551 million in 2020 compared with \$58 million in 2019, largely from the recognition of unrealized gains

on securities.

The effective income tax rate was 14.5% for the second quarter of 2020 compared to 18.9% in the second quarter of 2019, reflecting the favorable impact of earnings mix.

GAAP EPS was \$1.18 for the second quarter of 2020 compared with \$1.03 for the second quarter of 2019.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 73.8% for the second quarter of 2020 compared to 75.4% for the second quarter of 2019. The decrease in non-GAAP gross margin reflects higher amortization of intangible assets related to collaborations and unfavorable manufacturing variances, partially offset by the favorable effects of foreign exchange and product mix.

Non-GAAP selling, general and administrative expenses were \$2.2 billion in the second quarter of 2020, a decrease of 16% compared to the second quarter of 2019. The decrease primarily reflects lower promotion, selling and administrative costs, including less travel and meeting expenses, due in part to the COVID-19 pandemic and the favorable effects of foreign exchange.

Non-GAAP R&D expenses were \$2.2 billion in the second quarter of 2020, a 1% decrease compared to the second quarter of 2019. The decrease was primarily driven by lower laboratory, travel and meetings expenses due to the COVID-19 pandemic, partially offset by higher expenses related to clinical development and increased investment in discovery research and early drug development.

Non-GAAP other (income) expense, net, was \$437 million of income in the second quarter of 2020 compared to \$56 million of income in the second quarter of 2019, primarily due to income from investments in equity securities, net, which was \$541 million in 2020 compared with \$58 million in 2019, largely from the recognition of unrealized gains on securities.

The non-GAAP effective income tax rate was 14.7% for the second quarter of 2020 compared to 18.4% for the second quarter of 2019, reflecting the favorable impact of earnings mix.

Non-GAAP EPS was \$1.37 for the second quarter of 2020 compared with \$1.30 for the second quarter of 2019.

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

\$ in millions, except EPS amounts	Second Quarter	
	2020	2019
EPS		
GAAP EPS	\$1.18	\$1.03
Difference	0.19	0.27
Non-GAAP EPS that excludes items listed below ²	\$1.37	\$1.30
Net Income		
GAAP net income ¹	\$3,002	\$2,670
Difference	482	686
Non-GAAP net income that excludes items listed below ^{1,2}	\$3,484	\$3,356
Decrease (Increase) in Net Income Due to Excluded Items:		
Acquisition- and divestiture-related costs ³	\$443	\$660
Restructuring costs	150	159
Other	(16)	48
Net decrease (increase) in income before taxes	577	867
Income tax (benefit) expense ⁴	(95)	(145)
Acquisition- and divestiture-related costs attributable to noncontrolling interests	-	(36)
Decrease (increase) in net income	\$482	\$686

Financial Outlook

The full-year updated guidance that Merck is providing below includes its current assumption of the impact from the COVID-19 pandemic, which is expected to be partially offset by favorability from continued underlying business strength. While the company continues to expect to rely on governmental authorities to determine when operations can return to normal and is cognizant that the duration, spread and severity of the outbreak will be critical determinants, for the purposes of the full-year 2020 guidance estimates, the company has assumed the majority of the negative impact occurred during the second quarter, with a gradual recovery having commenced late in the second quarter and extending through the third quarter, with a return to normal operating levels in the fourth quarter.

For the full-year 2020, Merck now expects an unfavorable impact to revenue of approximately \$1.95 billion (excluding the impact of foreign exchange) due to the COVID-19 pandemic, comprised of approximately \$1.8 billion for pharmaceuticals and approximately \$150 million for Animal Health, including the impacts in the first half of the year.

For the full-year 2020, Merck continues to expect a net favorable impact to operating expenses of approximately \$400 million, reflecting the favorable impact of lower spending due to the COVID-19 pandemic, largely reflected in the first half of 2020, partially offset by anticipated spending on recently-initiated COVID-19-related vaccine and antiviral research programs.

Merck narrowed and raised its full-year 2020 revenue range to be between \$47.2 billion and \$48.7 billion, including a negative impact from foreign exchange of approximately 2% at mid-July exchange rates.

Merck narrowed and raised its full-year 2020 GAAP EPS to be between \$4.58 and \$4.73. Merck narrowed and raised its full-year 2020 non-GAAP EPS to be between \$5.63 and \$5.78, including a negative impact from foreign exchange

of approximately 3% at mid-July exchange rates. 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	\$47.2 to \$48.7 billion	\$47.2 to \$48.7 billion*
Operating expenses	Lower than 2019 by a low-single-digit rate	Roughly in line with 2019
Effective tax rate	15.0% to 15.5%	16.0% to 16.5%
EPS**	\$4.58 to \$4.73	\$5.63 to \$5.78

*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.

	Full-Year 2020
\$ in millions, except EPS amounts	
GAAP EPS	\$4.58 to \$4.73
Difference	1.05
Non-GAAP EPS that excludes items listed below ²	\$5.63 to \$5.78
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. EDT on Merck's website at <https://investors.merck.com/events-and-presentations/default.aspx>. Institutional investors and analysts can participate in the call (833) 353-0277 or toll free (469) 886-1947 and using ID code number 2753878. Members of the media are invited to monitor the call by dialing (833) 353-0277 or toll free (469) 886-1947 and using ID code number 2753878. 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. 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 the recent global outbreak of novel coronavirus disease (COVID-19); 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 2019 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 2020 and 2019 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. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. 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.

3Includes 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.

4Includes the estimated tax impact on the reconciling items.

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

	GAAP		% Change	GAAP		% Change
	2Q20	2Q19		June YTD 2020	June YTD 2019	
Sales	\$ 10,872	\$ 11,760	-8%	\$ 22,929	\$ 22,575	2%
Costs, Expenses and Other						
Cost of sales (1)	3,159	3,401	-7%	6,471	6,453	0%
Selling, general and administrative (1)	2,378	2,712	-12%	4,933	5,138	-4%
Research and development (1)	2,123	2,189	-3%	4,331	4,119	5%
Restructuring costs (2)	83	59	41%	155	212	-27%
Other (income) expense, net (1)	(390)	140	*	(318)	327	*
Income Before Taxes	3,519	3,259	8%	7,357	6,326	16%
Taxes on Income (1)	509	615		1,128	820	
Net Income	3,010	2,644	14%	6,229	5,506	13%
Less: Net Income (Loss) Attributable to Noncontrolling Interests (1)	8	(26)		8	(79)	
Net Income Attributable to Merck & Co., Inc.	\$ 3,002	\$ 2,670	12%	\$ 6,221	\$ 5,585	11%
Earnings per Common Share Assuming Dilution	\$ 1.18	\$ 1.03	15%	\$ 2.45	\$ 2.15	14%
Average Shares Outstanding Assuming Dilution	2,536	2,588		2,542	2,596	
Tax Rate (3)	14.5%	18.9%		15.3%	13.0%	

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

(3) The effective income tax rate for the first six months of 2019 reflects a net tax benefit of \$360 million related to the settlement of certain federal income tax matters.

MERCK & CO., INC.
GAAP TO NON-GAAP RECONCILIATION
SECOND QUARTER 2020
(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	\$3,159	282	25		307	\$ 2,852
Selling, general and administrative	2,378	163	11		174	2,204
Research and development	2,123	(65)	31		(34)	2,157
Restructuring costs	83		83		83	-
Other (income) expense, net	(390)	63		(16)	47	(437)
Income Before Taxes	3,519	(443)	(150)	16	(577)	4,096
Income Tax Provision (Benefit)	509	(73) (3)	(27) (3)	5 (3)	(95)	604
Net Income	3,010	(370)	(123)	11	(482)	3,492
Less: Net Income Attributable to Noncontrolling Interests	8				-	8
Net Income Attributable to Merck & Co., Inc.	3,002	(370)	(123)	11	(482)	3,484
Earnings per Common Share Assuming Dilution	\$ 1.18	(0.14)	(0.05)	-	(0.19)	\$ 1.37
Tax Rate	14.5%					14.7%

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. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP.

(1) Amounts included in cost of sales primarily reflect expenses for the amortization of intangible assets recognized as a result of business acquisitions. Amounts included in selling, general and administrative expenses reflect \$119 million of expenses related to the company's planned spin-off of Organon & Co., and other acquisition and divestiture-related costs. Amounts included in research and development expenses primarily reflect a reduction in expenses related to a decrease in the estimated fair value measurement of liabilities for contingent consideration. Amounts included in other (income) expense, net, primarily reflect an increase in the estimated fair value measurement of liabilities for contingent consideration 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.

MERCK & CO., INC.
GAAP TO NON-GAAP RECONCILIATION
SIX MONTHS ENDED JUNE 30, 2020
(AMOUNTS IN MILLIONS, EXCEPT PER SHARE FIGURES)
(UNAUDITED)
Table 2b

	GAAP	Acquisition and Divestiture-Related Costs (1)	Restructuring Costs (2)	Certain Other Items	Adjustment Subtotal	Non-GAAP
Cost of sales	\$ 6,471	578	93		671	\$ 5,800
Selling, general and administrative	4,933	441	22		463	4,470
Research and development	4,331	(28)	48		20	4,311
Restructuring costs	155		155		155	-
Other (income) expense, net	(318)	52		(16)	36	(354)
Income Before Taxes	7,357	(1,043)	(318)	16	(1,345)	8,702
Income Tax Provision (Benefit)	1,128	(231) (3)	(34) (3)	5 (3)	(260)	1,388
Net Income	6,229	(812)	(284)	11	(1,085)	7,314
Less: Net Income Attributable to Noncontrolling Interests	8				-	8
Net Income Attributable to Merck & Co., Inc.	6,221	(812)	(284)	11	(1,085)	7,306

Earnings per Common Share Assuming Dilution	\$ 2.45	(0.32)	(0.10)	-	(0.42)	\$ 2.87
Tax Rate	15.3%					16.0%

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. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP.

(1) Amounts included in cost of sales primarily reflect expenses for the amortization of intangible assets recognized as a result of business acquisitions. Amounts included in selling, general and administrative expenses reflect \$284 million of expenses related to the company's planned spin-off of Organon & Co., approximately \$95 million of costs related to the acquisition of ArQule, Inc., and other acquisition and divestiture-related costs. Amounts included in research and development expenses primarily reflect a reduction in expenses related to a decrease in the estimated fair value measurement of liabilities for contingent consideration. Amounts included in other (income) expense, net, primarily reflect an increase in the estimated fair value measurement of liabilities for contingent consideration related to the termination of the Sanofi-Pasteur MSD joint venture, partially offset by royalty income.

(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.

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

	2020			2019					2Q		June YTD		
	1Q	2Q	June YTD	1Q	2Q	June YTD	3Q	4Q	Full Year	Nom %	Ex-Exch %	Nom %	Ex-Exch %
TOTAL SALES (1)	\$12,057	\$10,872	\$22,929	\$10,816	\$11,760	\$22,575	\$12,397	\$11,868	\$46,840	-8	-5	2	4
PHARMACEUTICAL	10,655	9,679	20,334	9,663	10,460	20,123	11,095	10,533	41,751	-7	-6	1	3
Oncology													
Keytruda	3,284	3,388	6,672	2,269	2,634	4,903	3,070	3,111	11,084	29	31	36	38
Alliance Revenue - Lynparza (2)	145	178	323	79	111	190	123	132	444	61	62	70	72
Alliance Revenue - Lenvima (2)	128	151	279	74	97	171	109	124	404	57	57	63	64
Emend	43	33	76	117	121	237	98	53	388	-72	-71	-68	-67
Vaccines (3)													
Gardasil / Gardasil 9	1,097	656	1,753	838	886	1,724	1,320	693	3,737	-26	-24	2	4
ProQuad / M-M-R II / Varivax	435	378	813	496	675	1,171	623	481	2,275	-44	-43	-31	-30
RotaTeq	222	168	391	211	172	383	180	227	791	-2	-1	2	3
Pneumovax 23	256	117	373	185	170	355	237	334	926	-31	-29	5	7
Vaqta	60	28	88	47	58	105	62	71	238	-52	-51	-17	-14
Hospital Acute Care													
Bridion	299	224	524	255	278	533	284	313	1,131	-19	-18	-2	
Noxafil	94	73	168	190	193	383	177	103	662	-62	-60	-56	-55
Prevymis	60	63	123	32	38	70	45	50	165	66	67	76	78
Primaxin	51	64	115	59	71	130	77	67	273	-10	-6	-11	-8
Invanz	64	43	108	72	78	150	57	57	263	-45	-39	-28	-24
Candidas	55	43	98	61	67	129	62	58	249	-36	-33	-23	-21
Cubicin	46	32	78	88	67	155	52	50	257	-53	-51	-50	-48
Zerbaxa	37	32	69	26	27	53	35	32	121	19	23	30	33
Immunology													
Simponi	215	191	406	208	214	422	203	205	830	-11	-8	-4	-1
Remicade	88	73	160	123	98	221	101	89	411	-26	-25	-28	-26
Neuroscience													
Belsomra	79	84	163	67	76	143	80	83	306	10	8	14	13

Virology													
Isentress / Isentress HD	245	196	441	255	247	502	250	223	975	-21	-17	-12	-9
Zepatier	55	39	94	114	108	221	83	66	370	-63	-62	-57	-56
Cardiovascular													
Zetia	145	137	282	140	156	296	147	146	590	-12	-12	-5	-4
Vytorin	53	39	92	97	76	174	57	54	285	-49	-46	-47	-45
Atozet	122	115	238	94	92	186	97	108	391	25	28	28	31
Alliance Revenue - Adempas (4)	53	79	133	42	51	94	50	60	204	54	54	41	41
Adempas (5)	56	57	113	48	53	100	57	57	215	8	9	12	14
Diabetes (6)													
Januvia	774	854	1,628	824	908	1,732	807	943	3,482	-6	-5	-6	-5
Janumet	503	490	993	530	533	1,063	503	475	2,041	-8	-5	-7	-4
Women's Health													
Implanon / Nexplanon	195	132	326	199	183	382	199	206	787	-28	-26	-15	-13
NuvaRing	63	63	126	219	240	459	241	179	879	-74	-73	-73	-72
Diversified Brands													
Singulair	155	100	255	191	160	352	152	195	698	-38	-37	-27	-26
Cozaar / Hyzaar	102	98	200	103	109	213	116	113	442	-10	-7	-6	-3
Arcoxia	70	65	135	75	75	149	72	67	288	-13	-9	-9	-7
Nasonex	71	49	120	96	72	168	58	67	293	-32	-28	-29	-26
Follistim AQ	41	44	85	57	63	121	62	58	241	-31	-30	-29	-28
Other Pharmaceutical (7)	1,194	1,103	2,293	1,082	1,203	2,283	1,149	1,183	4,615	-8	-6		2
ANIMAL HEALTH	1,214	1,101	2,314	1,025	1,124	2,149	1,122	1,122	4,393	-2	3	8	12
Livestock	739	648	1,386	611	671	1,282	726	777	2,784	-3	3	8	13
Companion Animals	475	453	928	414	453	867	396	345	1,609		3	7	9
Other Revenues (8)	188	92	281	128	176	303	180	213	696	-47	-23	-8	

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 \$2,155 million and \$1,418 million in the first and second quarters of 2020 and \$1,887 million, \$2,037 million, \$2,517 million and \$1,928 million for the first, second, third and fourth quarters of 2019, respectively.

(4) Alliance Revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs.

(5) Net product sales in Merck's marketing territories.

(6) Total Diabetes sales were \$1,353 million and \$1,418 million in the first and second quarters of 2020 and \$1,402 million, \$1,480 million, \$1,360 million and \$1,472 million for the first, second, third and fourth quarters of 2019, respectively.

(7) Includes Pharmaceutical products not individually shown above.

(8) 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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