



NEWS RELEASE

Merck Announces Third-Quarter 2020 Financial Results

10/27/2020

- Third-Quarter 2020 Worldwide Sales Were \$12.6 Billion, an Increase of 1%; Excluding the Impact from Foreign Exchange, Sales Grew 2%
 - KEYTRUDA Sales Grew 21% to \$3.7 Billion
 - Animal Health Sales Grew 9% to \$1.2 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 12%
- Third-Quarter 2020 GAAP EPS Was \$1.16; Third-Quarter Non-GAAP EPS Was \$1.74
- Advanced and Expanded Broad Pipeline
 - Announced Additional Positive Phase 3 Results for Investigational Pneumococcal Conjugate Vaccine (V114) in Adults
 - Presented Phase 3 Data for Investigational Gefapixant in Development for Chronic Cough; Early Data for MK-4830 in Oncology and MK-8507 for HIV
 - Expanded Pipeline with Seagen Collaborations in Oncology
- Company Advances Research Programs and Clinical Trials for COVID-19-Related Vaccine and Orally Available Antiviral Research Candidates
- Company Narrows and Raises 2020 Full-Year Revenue Range to be Between \$47.6 Billion and \$48.6 Billion, Including a Negative Impact from Foreign Exchange of Approximately 1.5%
- Company Narrows and Lowers 2020 Full-Year GAAP EPS Range to be Between \$4.55 and \$4.65; Narrows and Raises 2020 Full-Year Non-GAAP EPS Range to be Between \$5.91 and \$6.01, Including a Negative Impact from Foreign Exchange of Approximately 2.5%

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

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

<https://www.businesswire.com/news/home/20201027005447/en/>

"We continue to execute on our strategic priorities and remain confident we will achieve solid full-year revenue growth despite the impact of the ongoing COVID-19 pandemic. Demand for our products remains robust, and production, supply and distribution of our medicines, vaccines and animal health products are moving forward with minimal disruption," said Kenneth C. Frazier, chairman and chief executive officer, Merck. "I am confident in our ability to advance our promising pipeline and clinical trials despite the challenging environment, and I believe that our leadership and track record of solid commercial execution will continue to drive long-term growth."

Financial Summary

	Third Quarter			
	2020	2019	Change	Change Ex-Exchange
\$ in millions, except EPS amounts				
Sales	\$12,551	\$12,397	1%	2%
GAAP net income ¹	2,941	1,901	55%	59%
Non-GAAP net income that excludes certain items ^{1,2*}	4,427	3,873	14%	17%
GAAP EPS	1.16	0.74	57%	62%
Non-GAAP EPS that excludes certain items ^{2*}	1.74	1.51	16%	18%

*Refer to table on page 11.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) was \$1.16 for the third quarter of 2020. Non-GAAP EPS of \$1.74 for the third quarter of 2020 excludes acquisition- and divestiture-related costs, restructuring costs, pretax charges of \$1.1 billion related to certain license and collaboration agreements, and certain other items. 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 advanced its multiple scientific programs in an effort to help combat SARS-CoV-2, specifically,

- Molnupiravir (formerly known as MK-4482) -- an orally available antiviral candidate in development for the treatment of COVID-19 in collaboration with Ridgeback Bio with the initiation of two large pivotal Phase 2/3 trials: a trial anticipated to enroll approximately 1,450 non-hospitalized adult COVID-19 patients (outpatient) and another planned to enroll approximately 1,300 hospitalized adult COVID-19 patients;
- V591 -- a SARS-CoV-2 vaccine candidate that uses a measles virus vector platform has entered Phase 1

development; and

- V590 -- a SARS-CoV-2 vaccine candidate in development in collaboration with the International AIDS Vaccine Initiative (IAVI) that uses a recombinant vesicular stomatitis virus (rVSV) platform, the same platform used for Merck's approved Ebola Zaire virus vaccine, will enter Phase 1 development shortly.

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:
 - Approval in the **United States** by the Food and Drug Administration (FDA) of an expanded indication as monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) based on the Phase 3 KEYNOTE-204 trial and an updated pediatric indication for the treatment of pediatric patients with refractory cHL or cHL that has relapsed after two or more lines of therapy, both of which were previously approved under the FDA's accelerated approval process; and
 - Two approvals in **Japan**: (1) as monotherapy for the treatment of patients whose tumors are PD-L1-positive and have radically unresectable, advanced or recurrent esophageal squamous cell carcinoma (ESCC) who have progressed after chemotherapy based on the KEYNOTE-181 trial; and (2) use at an additional recommended dosage of 400 mg every six weeks (Q6W) administered as an intravenous infusion over 30 minutes across all adult indications, including KEYTRUDA monotherapy and combination therapy.
- Merck **presented** results from the pivotal Phase 3 KEYNOTE-590 trial for the first-line treatment of patients with locally advanced or metastatic esophageal and gastroesophageal junction (GEJ) cancer at the European Society for Medical Oncology (ESMO) Virtual Congress 2020. In the study, KEYTRUDA in combination with platinum-based chemotherapy (cisplatin plus 5-fluorouracil [5-FU]) significantly improved overall survival (OS) and progression-free survival (PFS) versus chemotherapy regardless of histology or PD-L1 expression status.
- Merck **presented** five-year survival results from the pivotal Phase 3 KEYNOTE-024 trial at the ESMO Virtual Congress 2020, which demonstrated a sustained, long-term survival benefit and durable responses with KEYTRUDA versus chemotherapy as a first-line treatment in patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (tumor proportion score [TPS] $\geq 50\%$) with no EGFR or ALK genomic tumor aberrations. Results from KEYNOTE-024 represent the longest follow-up survival data for an immunotherapy in a randomized Phase 3 study for the first-line treatment of metastatic NSCLC.
- Merck **presented** long-term findings from the EORTC1325/KEYNOTE-054 trial evaluating KEYTRUDA as

adjuvant therapy in resected, high-risk stage III melanoma at the ESMO Virtual Congress 2020.

- Merck **presented** three-year survival data from the KEYNOTE-021 (Cohort G) study that evaluated KEYTRUDA in combination with chemotherapy in patients with advanced nonsquamous NSCLC regardless of PD-L1 expression with no EGFR or ALK genomic tumor aberrations at the IASLC 2020 North America Conference on Lung Cancer (NACLC). Updated follow-up data from a Phase 1/2 study of quavonlimab (MK-1308), a novel investigational anti-CTLA-4 antibody, in combination with KEYTRUDA in patients with advanced NSCLC also was presented; a Phase 3 study of quavonlimab coformulated with KEYTRUDA in first-line advanced NSCLC is planned.
- Merck and AstraZeneca announced the adoption of two positive opinions by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for Lynparza:
 - As a **first-line maintenance treatment** with bevacizumab for homologous recombination deficient (HRD)-positive advanced ovarian cancer who are in complete or partial response following completion of first-line platinum-based chemotherapy in combination with bevacizumab based on the Phase 3 PAOLA-1 trial, and
 - As **monotherapy for the treatment** of BRCA1/2 metastatic castration-resistant prostate cancer (mCRPC) patients who have progressed following a prior therapy that included a new hormonal agent based on the Phase 3 PROfound trial. Final results from this study were recently **presented** at the ESMO Virtual Congress 2020.
- Merck and AstraZeneca **presented** positive five-year follow-up data from the Phase 3 SOLO-1 trial, which demonstrated a long-term PFS benefit of Lynparza versus placebo as a first-line maintenance treatment in patients with newly diagnosed, advanced BRCA-mutated (BRCAm) ovarian cancer who were in complete or partial response to platinum-based chemotherapy.
- Merck and Eisai **presented** first-time data from two studies evaluating KEYTRUDA plus Lenvima at the ESMO Virtual Congress 2020: data from the Phase 2 LEAP-004 study for the second-line treatment of patients with unresectable or advanced melanoma who progressed on anti-PD-1/PD-L1 therapy and from the Phase 2 LEAP-005 study in previously-treated patients with six tumor types, including biliary tract cancer, colorectal cancer, gastric cancer, glioblastoma multiforme, ovarian cancer and triple-negative breast cancer.
- Merck also **presented** new data for three investigational medicines from its oncology pipeline at the ESMO Virtual Congress 2020:
 - New Phase 1 data for the company's anti-TIGIT therapy vibostolimab (MK-7684) as monotherapy and in combination with KEYTRUDA in patients with metastatic NSCLC,
 - First-time Phase 1 results for the novel anti-immunoglobulin-like transcript 4 (ILT4) therapy MK-4830 in patients with advanced solid tumors, and
 - New Phase 2 data evaluating the hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor MK-6482 in von Hippel-Lindau (VHL) patients with non-renal cell carcinoma (RCC) tumors and updated data in VHL

patients with clear cell RCC.

Other Pipeline Highlights

- Merck **announced** that two Phase 3 adult studies [the pivotal PNEU-AGE trial (V114-019) as well as the PNEU-TRUE trial (V114-020)] and **separately** two other Phase 3 adult studies [the PNEU-PATH (V114-016) and PNEU-DAY (V114-017) trials], evaluating the safety, tolerability and immunogenicity of V114, the company's investigational 15-valent pneumococcal conjugate vaccine, each met their primary immunogenicity objectives. These findings, and additional Phase 3 data from the clinical program, will form the basis of global regulatory licensure applications beginning with the FDA before the end of the year.
- Merck **presented** results from two pivotal Phase 3 trials (COUGH-1 and COUGH-2) evaluating gefapixant, an investigational, orally administered selective P2X3 receptor antagonist, in which gefapixant 45 mg twice daily demonstrated a statistically significant reduction in 24-hour cough frequency compared to placebo at Week 12 and 24 in adult patients with refractory or unexplained chronic cough. The gefapixant 15 mg twice daily treatment arms did not meet the primary efficacy endpoint in either Phase 3 study. The results were presented at the Virtual European Respiratory Society (ERS) International Congress 2020.
- Merck **presented** Week 96 data from the Phase 2b trial that showed islatravir, the company's investigational oral nucleoside reverse transcriptase translocation inhibitor (NRTTI), in combination with doravirine (PIFELTRO), maintained viral suppression in treatment-naïve adults with HIV-1 infection. Also presented at the virtual 2020 International Congress on Drug Therapy in HIV Infection (HIV Glasgow 2020 Virtual) were results from Phase 1/1b studies for MK-8507, the company's investigational once-weekly, oral non-nucleoside reverse transcriptase inhibitor (NNRTI), that support further investigation for once-weekly oral administration as part of combination antiretroviral therapy.
- The FDA has granted V181, the company's investigational dengue vaccine in Phase 1 development, Fast Track designation.

Business Developments

- Merck and Seagen Inc. (formerly known as Seattle Genetics, Inc.) **announced** two strategic oncology collaborations, in which Merck will make \$810 million of upfront payments in the aggregate as well as acquire a \$1 billion equity stake in Seagen common stock:
 - Companies to co-develop and co-commercialize Seagen's ladiratuzumab vedotin, an investigational antibody-drug conjugate targeting LIV-1, globally; and
 - Companies enter into exclusive license and co-development agreement to accelerate global reach of Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor for the treatment of HER-2 positive cancers. Merck was granted an exclusive license to commercialize Tukysa in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe.

- Merck and Hanmi Pharmaceutical **announced** that the companies have entered into an exclusive licensing agreement for the development, manufacture and commercialization of efinopegdutide (formerly HM12525A), Hanmi's investigational once-weekly glucagon-like peptide-1 (GLP-1)/glucagon receptor dual agonist, for the treatment of nonalcoholic steatohepatitis (NASH);
- Merck **announced** the completion of its acquisition of IdentiGEN, a leader in DNA-based animal traceability solutions for livestock and aquaculture; and
- Merck **announced** the completion of its acquisition of the worldwide rights to VECOXAN (diclazuril), an oral suspension for the prevention of coccidiosis in calves and lambs.

Organon & Co.

- Merck continued to make progress on the Organon & Co. (Organon) spinoff, including additional leadership appointments, and expects the transaction to be completed in the second quarter of 2021.

Third-Quarter Financial Impact of COVID-19

In the third quarter, the estimated negative impact of the COVID-19 pandemic to Merck's pharmaceutical revenue was approximately \$475 million, bringing the company's year-to-date negative impact on revenue to approximately \$2.1 billion. Lower back-to-school demand negatively impacted vaccine sales, in particular GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) in the U.S. In addition, access to health care providers remains reduced, although improved from the second quarter. The negative impact to Animal Health sales in the third quarter was immaterial.

Operating expenses were positively impacted in the third quarter by approximately \$115 million, primarily driven by lower promotional and selling costs as well as lower research and development (R&D) expenses, net of investments in COVID-19-related antiviral and vaccine research programs.

Third-Quarter Revenue Performance

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

\$ in millions	Third Quarter			Change
	2020	2019	Change	Ex-Exchange
Total Sales	\$12,551	\$12,397	1%	2%
Pharmaceutical	11,320	11,095	2%	2%
KEYTRUDA	3,715	3,070	21%	21%

JANUVIA / JANUMET	1,327	1,311	1%	2%
GARDASIL / GARDASIL 9	1,187	1,320	-10%	-10%
PROQUAD, M-M-R II and				
VARIVAX	576	623	-8%	-7%
PNEUMOVAX 23	375	237	58%	58%
BRIDION	320	284	13%	13%
ROTATEQ	210	180	16%	17%
SIMPONI	209	203	3%	0%
ISENTRESS / ISENTRESS HD	205	250	-18%	-18%
Lynparza*	196	123	59%	58%
IMPLANON / NEXPLANON	189	199	-5%	-4%
Lenvima*	142	109	30%	29%
Animal Health	1,220	1,122	9%	12%
Livestock	758	726	5%	8%
Companion Animals	462	396	17%	18%
Other Revenues**	11	180	-94%	-33%

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

**Other revenues are comprised primarily of third-party manufacturing sales and miscellaneous corporate revenues, including revenue hedging activities.

Pharmaceutical Revenue

Third-quarter pharmaceutical sales increased by \$225 million, or 2%, to \$11.3 billion. The increase was driven primarily by growth in oncology and certain hospital acute care products, partially offset by the negative impact of the COVID-19 pandemic and the ongoing impacts of the loss of market exclusivity for several products.

Growth in oncology was largely driven by higher sales of KEYTRUDA, which grew 21% to \$3.7 billion in the quarter. In the U.S., sales of KEYTRUDA grew 24% to \$2.2 billion. Global sales growth of KEYTRUDA reflects continued strong momentum from the NSCLC indications as well as continued uptake in other indications, including adjuvant melanoma, RCC, bladder, head and neck squamous cell carcinoma (HNSCC) and microsatellite instability-high (MSI-H) cancers as well as uptake following the recent launch of the Q6W dosing regimen in the U.S., partially offset by the negative impacts of the COVID-19 pandemic and pricing in Japan. 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.

Performance in hospital acute care reflects higher demand globally for BRIDION (sugammadex), a medicine for the reversal of neuromuscular blockade induced by rocuronium bromide or vecuronium bromide in adults undergoing surgery and the ongoing launch of PREVYMIS (letermovir), a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant.

In addition, sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl) increased slightly in the quarter reflecting strong demand from certain international markets, partially offset by continued pricing pressure in the U.S.

Vaccine sales performance reflects higher sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, primarily driven by higher volumes in the U.S., Europe and Japan attributable in part to increased demand for pneumococcal vaccination during the COVID-19 pandemic.

Vaccine sales were negatively affected by declines in sales of 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 volumes in China and in Europe.

Combined sales of pediatric vaccines VARIVAX (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox; PROQUAD (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a combination vaccine to help protect against measles, mumps, rubella and varicella; and M-M-R II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella, declined in the third quarter, primarily due to lower demand in the U.S. related to the COVID-19 pandemic.

Pharmaceutical sales in the quarter were negatively affected by the ongoing impacts from the loss of market exclusivity, including for NUVARING (etonogestrel/ethinyl estradiol vaginal ring), NOXAFIL (posaconazole) and EMEND (aprepitant)/EMEND (fosaprepitant dimeglumine) for Injection.

Animal Health Revenue

Animal Health sales totaled \$1.2 billion in the third quarter of 2020, an increase of 9% compared with the third quarter of 2019; excluding the unfavorable effect from foreign exchange, Animal Health sales grew 12%. Growth in companion animal products was driven largely by higher demand in companion animal vaccines and higher demand for the BRAVECTO (fluralaner) line of products for parasitic control. Performance in livestock products reflects higher demand globally for ruminant, poultry and swine products.

Third-Quarter Expense, EPS and Related Information

The tables below present selected expense information.

\$ in millions					
Third-Quarter 2020	GAAP	Acquisition- and Divestiture- Related Costs ³	Restructuring Costs	Certain Other Items	Non-GAAP ²
Cost of sales	\$3,481	\$285	\$38	\$-	\$3,158
Selling, general and	2,152	227	17	-	2,396

administrative	2,450	207	15	—	2,228
Research and development	3,390	16	19	1,082	2,273
Restructuring costs	114	—	114	—	—
Other (income) expense, net	(312)	—	—	(1)	(311)
Third-Quarter 2019					
Cost of sales	\$3,990	\$941	\$62	\$—	\$2,987
Selling, general and administrative	2,589	22	1	—	2,566
Research and development	3,204	6	1	982	2,215
Restructuring costs	232	—	232	—	—
Other (income) expense, net	35	6	—	—	29

GAAP Expense, EPS and Related Information

Gross margin was 72.3% for the third quarter of 2020 compared to 67.8% for the third quarter of 2019. The increase reflects lower acquisition- and divestiture-related costs and the favorable effect of product mix, partially offset by the unfavorable effects of pricing pressure, inventory write-offs, higher amortization of intangible assets related to collaborations and foreign exchange.

Selling, general and administrative expenses were \$2.5 billion in the third quarter of 2020, a decrease of 5% compared to the third quarter of 2019. The decrease primarily reflects lower administrative and selling costs, including less travel and meeting expenses, due in part to the COVID-19 pandemic, partially offset by higher acquisition- and divestiture-related costs, primarily reflecting costs related to the company's planned spinoff of Organon.

Research and development expenses were \$3.4 billion in the third quarter of 2020, an increase of 6% compared with the third quarter of 2019. The increase was primarily driven by higher upfront payments related to collaborations and license agreements, higher expenses related to clinical development and increased investment in discovery research and early drug development, partially offset by lower charges for the acquisitions of businesses, as well as lower laboratory, travel and meeting expenses due to the COVID-19 pandemic.

Other (income) expense, net, was \$312 million of income in the third quarter of 2020 compared to \$35 million of expense in the third quarter of 2019, primarily due to higher income from investments in equity securities, net, which was \$360 million in 2020 compared with \$16 million in 2019, largely from the recognition of unrealized gains on securities.

The effective income tax rate was 14.1% for the third quarter of 2020 compared to 18.7% in the third quarter of 2019. The effective income tax rate in 2019 reflects the unfavorable impact of a charge for the acquisition of Peloton Therapeutics, Inc. (Peloton) for which no tax benefit was recognized.

GAAP EPS was \$1.16 for the third quarter of 2020 compared with \$0.74 for the third quarter of 2019.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 74.8% for the third quarter of 2020 compared to 75.9% for the third quarter of 2019. The decrease in non-GAAP gross margin reflects the unfavorable effects of pricing pressure, inventory write-offs, higher amortization of intangible assets related to collaborations and foreign exchange, partially offset by the favorable effect of product mix.

Non-GAAP selling, general and administrative expenses were \$2.2 billion in the third quarter of 2020, a decrease of 13% compared to the third quarter of 2019. The decrease primarily reflects lower administrative and selling costs, including less travel and meeting expenses, due in part to the COVID-19 pandemic.

Non-GAAP R&D expenses were \$2.3 billion in the third quarter of 2020, a 3% increase compared to the third quarter of 2019. The increase was primarily driven by higher expenses related to clinical development and increased investment in discovery research and early drug development, partially offset by lower laboratory, travel and meeting expenses due to the COVID-19 pandemic.

Non-GAAP other (income) expense, net, was \$311 million of income in the third quarter of 2020 compared to \$29 million of expense in the third quarter of 2019, primarily due to higher income from investments in equity securities, net, which was \$360 million in 2020 compared with \$16 million in 2019, largely from the recognition of unrealized gains on securities.

The non-GAAP effective income tax rate was 14.8% for the third quarter of 2020 compared to 15.7% for the third quarter of 2019, reflecting the favorable impact of earnings mix.

Non-GAAP EPS was \$1.74 for the third quarter of 2020 compared with \$1.51 for the third 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		Third Quarter	
		2020	2019
EPS			
GAAP EPS		\$1.16	\$0.74
Difference		0.58	0.77
Non-GAAP EPS that excludes items listed below ²		\$1.74	\$1.51
Net Income			
GAAP net income ¹		\$2,941	\$1,901
Difference		1,486	1,972
Non-GAAP net income that excludes items listed below ^{1,2}		\$4,427	\$3,873
Decrease (Increase) in Net Income Due to Excluded Items:			
Acquisition- and divestiture-related costs ³		\$508	\$975
Restructuring costs		186	296
Charges for acquisitions and collaborations ⁴		1,082	982
Other		(1)	—
Net decrease (increase) in income before taxes		1,775	2,253
Income tax (benefit) expense ⁵		(289)	(281)
		\$1,486	\$1,972

Financial Outlook

The updated full-year guidance that Merck is providing below includes its current assumption of the impact from the COVID-19 pandemic, which is expected to continue to be offset by favorability from underlying business strength. The company continues to assume that the majority of the negative impact occurred during the second quarter. However, it now expects some residual negative impacts in the fourth quarter, largely in Europe and certain emerging markets. In addition, the phasing of the recovery of GARDASIL 9 demand is slower than originally anticipated, in particular in the U.S.

For the full-year 2020, Merck now expects an unfavorable impact to revenue of approximately \$2.35 billion (excluding the impact of foreign exchange) due to the COVID-19 pandemic, comprised of approximately \$2.3 billion for pharmaceuticals and approximately \$50 million for Animal Health, including the impacts in the first three quarters of the year.

For the full-year 2020, Merck now expects a net favorable impact to operating expenses of approximately \$625 million, reflecting continued lower spending due to the COVID-19 pandemic, partially offset by spending on its COVID-19-related antiviral and vaccine research programs.

Merck narrowed and raised its full-year 2020 revenue range to be between \$47.6 billion and \$48.6 billion, including a negative impact from foreign exchange of approximately 1.5% at mid-October exchange rates. The company's guidance assumes \$120 million of revenue for the replenishment of doses of GARDASIL 9 that were borrowed from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile in the fourth quarter of 2019.

Merck narrowed and lowered its full-year 2020 GAAP EPS range to be between \$4.55 and \$4.65. Merck narrowed and raised its full-year 2020 non-GAAP EPS range to be between \$5.91 and \$6.01, including a negative impact from foreign exchange of approximately 2.5% at mid-October exchange rates. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs and certain other items.

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

	GAAP	Non-GAAP 2
Revenue	\$47.6 to \$48.6 billion	\$47.6 to \$48.6 billion*
Operating expenses	Higher than 2019 by a low-single-digit rate	Lower than 2019 by a low-single-digit rate
Effective tax rate	Approximately 15%	Approximately 15.5%
EPS**	\$4.55 to \$4.65	\$5.91 to \$6.01

*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		\$4.55 to \$4.65
Difference		1.36
Non-GAAP EPS that excludes items listed below ²		\$5.91 to \$6.01
Acquisition- and divestiture-related costs		\$2,300
Restructuring costs		800
Charges for collaborations		1,082
Net decrease (increase) in income before taxes		4,182
Income tax (benefit) expense ⁵		(715)
Decrease (increase) in net income		\$3,467

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://www.merck.com/investor-relations/events-and-presentations/>. Institutional investors and analysts can participate in the call (833) 353-0277 or toll free (469) 886-1947 and using ID code number 4664137. 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 4664137. 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 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).

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

² Merck 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.

³ Includes 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.

⁴ 2020 includes \$832 million related to the Seagen collaborations; 2019 represents a charge for the acquisition of Peloton.

⁵ Includes the estimated tax impact on the reconciling items, as well as a tax cost of \$67 million, representing an adjustment to the tax benefits recorded in conjunction with the 2015 acquisition of Cubist Pharmaceuticals, Inc.

(UNAUDITED)

GAAP		% Change	GAAP		% Change
3Q20	3Q19		Sep YTD 2020	Sep YTD 2019	
\$ 12,551	\$ 12,397	1%	\$ 35,479	\$ 34,972	1%
3,481	3,990	-13%	9,952	10,443	-5%
2,450	2,589	-5%	7,383	7,726	-4%
3,390	3,204	6%	7,721	7,324	5%
114	232	-51%	269	444	-39%
(312)	35	*	(630)	362	*
3,428	2,347	46%	10,784	8,673	24%
483	440		1,611	1,259	
2,945	1,907	54%	9,173	7,414	24%
4	6		12	(73)	
\$ 2,941	\$ 1,901	55%	\$ 9,161	\$ 7,487	22%
\$ 1.16	\$ 0.74	57%	\$ 3.61	\$ 2.89	25%
2,538	2,572		2,541	2,587	
14.1%	18.7%		14.9%	14.5%	

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

(3) The effective income tax rates for the third quarter and the first nine months of 2019 include the unfavorable impact of a charge for the acquisition of Peloton Therapeutics, Inc. for which no tax benefit was recognized and the favorable impact of product mix. The effective income tax rate for the first nine months of 2019 reflects a net tax benefit of \$360 million related to the settlement of certain federal income tax matters.

Table 2a

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) Amount included in cost of sales primarily reflects expenses for the amortization of intangible assets recognized as a result of business acquisitions. Amount included in selling, general and administrative expenses reflects \$182 million related to the company's planned spin-off of Organon & Co., and other acquisition and divestiture-related costs.

(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. Acquisition and divestiture-related costs also includes a tax cost of \$67 million, representing an adjustment to the tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition.

(4) Amount included in research and development reflects expenses for upfront payments related to license and collaboration agreements.

MERCK & CO., INC.
GAAP TO NON-GAAP RECONCILIATION
NINE MONTHS ENDED SEPTEMBER 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 (4)	Adjustment Subtotal	Non-GAAP
Cost of sales	\$ 9,952	863	131		994	\$ 8,958
Selling, general and administrative	7,383	648	37		685	6,698
Research and development	7,721	(12)	67	1,082	1,137	6,584
Restructuring costs	269		269		269	-
Other (income) expense, net	(630)	52		(17)	35	(665)
Income Before Taxes	10,784	(1,551)	(504)	(1,065)	(3,120)	13,904
Income Tax Provision (Benefit)	1,611	(248) (3)	(59) (3)	(242) (3)	(549)	2,160
Net Income	9,173	(1,303)	(445)	(823)	(2,571)	11,744
Net Income Attributable to Merck & Co., Inc.	9,161	(1,303)	(445)	(823)	(2,571)	11,732
Earnings per Common Share Assuming Dilution	\$ 3.61	(0.51)	(0.18)	(0.32)	(1.01)	\$ 4.62
Tax Rate	14.9%					15.5%

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) Amount included in cost of sales primarily reflects expenses for the amortization of intangible assets recognized as a result of business acquisitions. Amount included in selling, general and administrative expenses reflects \$466 million 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. Amount included in research and development expenses primarily reflects a reduction in expenses related to a decrease in the estimated fair value measurement of liabilities for contingent consideration. Amount included in other (income) expense, net, primarily reflects 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. Acquisition and divestiture-related costs also includes a tax cost of \$67 million, representing an adjustment to the tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition.

(4) Amount included in research and development reflects expenses for upfront payments related to license and collaboration agreements.

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

	2020				2019						3Q		Sep YTD	
	1Q	2Q	3Q	Sep YTD	1Q	2Q	3Q	Sep YTD	4Q	Full Year	Nom %	Ex-Exch %	Nom %	Ex-Exch %
TOTAL SALES (1)	\$12,057	\$10,872	\$12,551	\$35,479	\$10,816	\$11,760	\$12,397	\$34,972	\$11,868	\$46,840	1	2	1	3
PHARMACEUTICAL	10,655	9,679	11,320	31,654	9,663	10,460	11,095	31,218	10,533	41,751	2	2	1	3
Oncology														
Keytruda	3,284	3,388	3,715	10,387	2,269	2,634	3,070	7,973	3,111	11,084	21	21	30	31
Alliance Revenue - Lynparza (2)	145	178	196	519	79	111	123	313	132	444	59	58	66	67
Alliance Revenue - Lenvima (2)	128	151	142	421	74	97	109	280	124	404	30	29	50	50
Emend	43	33	39	115	117	121	98	336	53	388	-60	-59	-66	-65
Vaccines (3)														
Gardasil / Gardasil 9	1,097	656	1,187	2,941	838	886	1,320	3,044	693	3,737	-10	-10	-3	-2
ProQuad / M-M-R II														
/ Varivax	435	378	576	1,390	496	675	623	1,794	481	2,275	-8	-7	-23	-22
Pneumovax 23	256	117	375	748	185	170	237	592	334	926	58	58	26	27
RotaTeq	222	168	210	601	211	172	180	564	227	791	16	17	7	8
Vaqta	60	28	51	139	47	58	62	167	71	238	-18	-17	-17	-15
Hospital Acute Care														
Bridion	299	224	320	843	255	278	284	817	313	1,131	13	13	3	4
Noxafil	94	73	79	247	190	193	177	560	103	662	-55	-55	-56	-55
Prevymis	60	63	77	200	32	38	45	115	50	165	72	69	74	74
Primaxin	51	64	74	189	59	71	77	207	67	273	-4	-4	-9	-7
Invanz	64	43	51	159	72	78	57	206	57	263	-10	-6	-23	-19
Candidas	55	43	50	148	61	67	62	191	58	249	-20	-19	-22	-20
Cubicin	46	32	39	116	88	67	52	207	50	257	-26	-25	-44	-43
Zerbaxa	37	32	43	112	26	27	35	88	32	121	22	24	27	29
Immunology														
Simponi	215	191	209	615	208	214	203	625	205	830	3		-2	-1
Remicade	88	73	82	242	123	98	101	322	89	411	-19	-20	-25	-24
Neuroscience														
Belsomra	79	84	81	244	67	76	80	223	83	306	1		9	8
Virology														
Isentress / Isentress HD	245	196	205	646	255	247	250	752	223	975	-18	-18	-14	-12
Zepatier	55	39	28	122	114	108	83	304	66	370	-67	-67	-60	-59
Cardiovascular														
Zetia	145	137	103	384	140	156	147	443	146	590	-30	-30	-13	-13
Vytorin	53	39	47	139	97	76	57	231	54	285	-17	-16	-40	-38
Atozet	122	115	111	348	94	92	97	283	108	391	14	12	23	25
Alliance Revenue - Adempas (4)	53	79	83	216	42	51	50	144	60	204	67	67	50	50
Adempas (5)	56	57	55	167	48	53	57	158	57	215	-5	-7	6	6
Diabetes (6)														
Januvia	774	854	821	2,449	824	908	807	2,539	943	3,482	2	2	-4	-3
Janumet	503	490	506	1,499	530	533	503	1,567	475	2,041		2	-4	-2
Women's Health														
Implanon / Nexplanon	195	132	189	515	199	183	199	581	206	787	-5	-4	-11	-10
NuvaRing	63	63	58	184	219	240	241	700	179	879	-76	-76	-74	-73
Diversified Brands														
Singulair	155	100	82	338	191	160	152	503	195	698	-46	-46	-33	-32
Cozaar / Hyzaar	102	98	91	292	103	109	116	329	113	442	-21	-20	-11	-9
Arcoxia	70	65	68	204	75	75	72	221	67	288	-5	-2	-8	-5
Nasonex	71	49	41	161	96	72	58	226	67	293	-30	-29	-29	-27
Follistim AQ	41	44	50	136	57	63	62	182	58	241	-18	-18	-26	-25

Other Pharmaceutical (7)	1,194	1,103	1,186	3,478	1,082	1,203	1,149	3,431	1,183	4,615	3	4	1	3
ANIMAL HEALTH	1,214	1,101	1,220	3,535	1,025	1,124	1,122	3,271	1,122	4,393	9	12	8	12
Livestock	739	648	758	2,145	611	671	726	2,007	777	2,784	5	8	7	11
Companion Animals	475	453	462	1,390	414	453	396	1,264	345	1,609	17	18	10	12
Other Revenues (8)	188	92	11	290	128	176	180	483	213	696	-94	-33	-40	-12

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, \$1,418 million and \$2,521 million in the first, second and third quarters of 2020 and \$1,887 million, \$2,037 million, \$2,517 million and \$1,928 million in 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, \$1,418 million and \$1,405 million in the first, second and third quarters of 2020 and \$1,402 million, \$1,480 million, \$1,360 million and \$1,472 million in 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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