News Release

FOR IMMEDIATE RELEASE

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Merck Announces Fourth-Quarter and Full-Year 2020 Financial Results

- Fourth-Quarter 2020 Worldwide Sales Were $12.5 Billion, an Increase of 5%
- Fourth-Quarter 2020 GAAP Loss per Share Was $0.83, Reflecting Charges Related to Acquisitions and Intangible Asset Impairments; Fourth-Quarter Non-GAAP EPS Was $1.32
- Full-Year 2020 Worldwide Sales Were $48.0 Billion, an Increase of 2%; Excluding the Impact from Foreign Exchange, Sales Grew 4%
  - KEYTRUDA 2020 Worldwide Sales Grew 30% to $14.4 Billion
  - BRIDION 2020 Worldwide Sales Grew 6% to $1.2 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 7%
  - Animal Health 2020 Worldwide Sales Grew 7% to $4.7 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 10%
- Full-Year 2020 GAAP EPS Was $2.78, Reflecting Charges Related to Acquisitions, Collaborations and Intangible Asset Impairments; Full-Year Non-GAAP EPS Was $5.94
- 2021 Financial Outlook
  - Anticipates Full-Year 2021 Worldwide Sales to Be Between $51.8 Billion and $53.8 Billion, Including a Positive Impact from Foreign Exchange of Approximately 2%
  - Expects Full-Year 2021 GAAP EPS to Be Between $5.52 and $5.72; Expects Non-GAAP EPS to Be Between $6.48 and $6.68, Including a Positive Impact from Foreign Exchange of Approximately 3%
    - Changes to the Treatment of Certain Items for Purposes of Non-GAAP Reporting to Begin in 2021
- Expects Organon & Co. Spinoff in Late Second-Quarter 2021

KENILWORTH, N.J., Feb. 4, 2021 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the fourth quarter and full year of 2020.

“Despite extraordinary challenges brought on by the COVID-19 pandemic, Merck achieved solid growth and made meaningful progress in our pipeline in 2020. We remain focused on our science-led strategy and are confident that this approach will continue to deliver value to patients and shareholders,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “Our scientists continue to advance our internal pipeline of promising medicines and vaccines, including in oncology, HIV, and pneumococcal disease, and, more recently, therapeutics for COVID-19.

These pipeline developments provide us with increasing line-of-sight to significant potential growth drivers later this decade and into the next."

Financial Summary

$ in millions, except EPS amounts	Fourth Quarter				Year Ended			
	2020	2019	Change	Change Ex-Exchange	Dec. 31, 2020	Dec. 31, 2019	Change	Change Ex-Exchange
Sales	$12,514	$11,868	5%	5%	$47,994	$46,840	2%	4%
GAAP net (loss) income[1]	(2,094)	2,357	*	*	7,067	9,843	-28%	-25%
Non-GAAP net income that excludes certain items[1,2]**	3,350	2,978	12%	16%	15,082	13,382	13%	16%
GAAP EPS	(0.83)	0.92	*	*	2.78	3.81	-27%	-24%
Non-GAAP EPS that excludes certain items[2]**	1.32	1.16	14%	17%	5.94	5.19	14%	17%

*Greater than 100%.
**Refer to table on page 12.

GAAP (generally accepted accounting principles) (loss) earnings per share assuming dilution (EPS) was $(0.83) for the fourth quarter and $2.78 for the full year of 2020. Non-GAAP EPS was $1.32 for the fourth quarter and $5.94 for the full year of 2020. GAAP EPS for the fourth quarter and full year of 2020 reflect a $2.7 billion charge for the acquisition of VelosBio Inc. (VelosBio). The fourth quarter and full year of 2020 also include a $1.6 billion pretax intangible asset impairment charge related to ZERBAXA (ceftolozane and tazobactam), resulting from a recall in December 2020 and a temporary suspension of sales which reduced expected future cash flows of this product. In addition, the full year of 2020 reflects pretax charges of $1.1 billion related to certain license and collaboration agreements. Non-GAAP EPS excludes the charges noted above, other acquisition- and divestiture-related costs, restructuring costs and certain other items. Refer to the GAAP to non-GAAP reconciliation table on page 12 for further details.

COVID-19 Research Highlights

Building on the company's experience with antivirals, Merck advanced its scientific programs in an effort to help combat SARS-CoV-2, specifically:

- **Molnupiravir** (also known as MK-4482) – Merck continued the clinical development of molnupiravir, an orally available antiviral candidate for the treatment of COVID-19, in collaboration with Ridgeback Biotherapeutics LP. It is currently being evaluated in Phase 2/3 clinical trials in both the hospital and outpatient settings. The primary completion date

[1] Net (loss) 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 Tables 2a and 2b attached to this release.

for the Phase 2/3 studies is May 2021. The company anticipates interim efficacy data in the first quarter of 2021.

- **MK-7110** (also known as CD24Fc) – In December 2020, Merck acquired OncoImmune, a privately held, clinical-stage biopharmaceutical company, to accelerate the development of MK-7110, a therapeutic candidate for the treatment of patients with severe and critical COVID-19.
    - In December 2020, Merck entered into a supply agreement with the U.S. government to support the development, manufacture and initial distribution of MK-7110 upon approval or Emergency Use Authorization from the U.S. Food and Drug Administration (FDA).
    - Topline results from a pre-planned interim efficacy analysis from a Phase 3 study of MK-7110 were released in Sept. 2020. Full study results are expected in the first quarter of 2021.

Oncology Pipeline Highlights

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

- Merck announced the following regulatory milestones for KEYTRUDA:
    - Approval in the United States by the FDA in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 (Combined Positive Score [CPS]≥10), based on results from the KEYNOTE-355 study;
    - Approval in the United States by the 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;
    - Filing acceptance with priority review by the FDA for a supplemental Biologics License Application (sBLA) for KEYTRUDA plus chemotherapy as first-line treatment for locally advanced unresectable or metastatic esophageal and gastroesophageal junction cancer based on results from the KEYNOTE-590 study. A Prescription Drug User Fee Act (PDUFA) date is set for April 18, 2021;
    - Filing acceptance in January 2021 by the FDA for an sBLA seeking use of KEYTRUDA for the treatment of patients with locally advanced cutaneous squamous cell carcinoma (cSCC)

that is not curable by surgery or radiation based on the results of the KEYNOTE-629 trial. The FDA has set a PDUFA date of Sept. 9, 2021; and

  - Approval in January 2021 in the European Union for KEYTRUDA as first-line treatment in adult patients with metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer based on results from the KEYNOTE-177 study.

- Merck announced that the FDA's Oncologic Drugs Advisory Committee will discuss Merck's application for KEYTRUDA for the treatment of patients with high-risk, early-stage triple-negative breast cancer based on the results from the Phase 3 KEYNOTE-522 study. The meeting will be held on Feb. 9, 2021.
- Merck's Phase 3 KEYNOTE-122 trial evaluating KEYTRUDA versus standard of care (capecitabine, gemcitabine, or docetaxel) for the treatment of recurrent or metastatic nasopharyngeal cancer (NPC) did not meet its primary endpoint of overall survival (OS). Full results will be presented at a future medical meeting.
- Merck and Eisai announced the Phase 3 KEYNOTE-581/CLEAR trial (Study 307) met its primary endpoint of progression free survival (PFS) and its key secondary endpoints of OS and objective response rate (ORR) for KEYTRUDA plus Lenvima as a first-line treatment for patients with advanced renal cell carcinoma (RCC). In a second arm of the trial, Lenvima plus everolimus also met the trial's primary endpoint of OS and the key secondary endpoint of ORR as a first-line treatment for patients with advanced RCC. Full results from the trial will be presented at the 2021 Genitourinary Cancers Symposium (ASCO GU) on Feb. 13, 2021.
- Merck and Eisai announced the Phase 3 KEYNOTE-775/Study 309 trial evaluating the investigational use of KEYTRUDA and Lenvima met its dual primary endpoints of OS and PFS and its secondary endpoint of ORR in patients with advanced endometrial cancer following at least one prior platinum-based regimen.
- Merck and AstraZeneca announced two European Union approvals of Lynparza:
  - As monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and *BRCA*1/2 mutations (germline and/or somatic) who have progressed following a prior therapy that included a new hormonal agent; and
  - As first-line maintenance treatment in combination with bevacizumab for adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a breast susceptibility gene 1/2 (*BRCA*1/2) mutation and/or genomic instability.
- Merck and AstraZeneca announced three approvals of Lynparza in Japan for:
  - Maintenance treatment after first-line chemotherapy containing bevacizumab (genetical recombination) in patients with HRD ovarian cancer;

- Treatment of patients with *BRCA* gene-mutated (*BRCA*m) castration-resistant prostate cancer with distant metastasis; and
- Maintenance treatment after platinum-based chemotherapy for patients with *BRCA*m curatively unresectable pancreas cancer.

Other Pipeline Highlights

- In January 2021, Merck announced approval in the United States by the FDA of Verquvo (vericiguat), a soluble guanylate cyclase (sGC) stimulator, to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous (IV) diuretics in adults with symptomatic chronic heart failure and ejection fraction less than 45%, based on the results of the Phase 3 VICTORIA trial. Verquvo is being jointly developed with Bayer AG.
- In January 2021, Merck announced filing acceptance with priority review by the FDA of a Biologics License Application (BLA) for V114, Merck's investigational 15-valent pneumococcal conjugate vaccine for use in adults 18 years of age and older. A PDUFA date is set for July 18, 2021. Previously, Merck also announced the submission of an application for V114 to the European Medicines Agency.
- Merck announced that two Phase 3 adult studies (the PNEU-PATH [V114-016] and PNEU-DAY [V114-017] trials), evaluating the safety, tolerability and immunogenicity of V114, each met their primary immunogenicity objectives.
- Merck presented Week 96 data from the Phase 2b trial (NCT03272347) 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.
- Merck announced a collaboration with the Bill & Melinda Gates Foundation where the foundation will provide funding to support the Phase 3 IMPOWER 22 trial evaluating the safety and efficacy of investigational islatravir for both treatment and prevention in women and adolescent girls at high-risk for acquiring HIV-1 infection in sub-Saharan Africa.
- Merck also announced plans to conduct additional studies in HIV prevention with investigational islatravir including IMPOWER 24, a global Phase 3 clinical trial to evaluate islatravir as a once-monthly oral agent for pre-exposure prophylaxis (PrEP) at sites across the world and among other key populations impacted by the epidemic, including men who have sex with men and transgender women.
- In January 2021, Merck announced interim data from the Phase 2a trial (NCT04003103) in adults evaluating the safety, tolerability and pharmacokinetics (PK) of the investigational once-monthly oral islatravir tablet for PrEP. Interim findings demonstrated that once-monthly oral

islatravir achieved the pre-specified efficacy PK threshold for PrEP at both of the two doses studied (60 mg and 120 mg).

- Merck continued to advance MK-8507, the company's investigational once-weekly oral non-nucleoside reverse transcriptase inhibitor (NNRTI). The company presented results from Phase 1/1b studies that supported further investigation for once-weekly oral administration as part of combination antiretroviral therapy. Enrollment in a Phase 2 trial evaluating a switch to islatravir and MK-8507 once weekly in adult participants with HIV-1 who have been virologically suppressed for ≥6 months on bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) once-daily, is currently ongoing.

Business Development

- In December 2020, Merck acquired VelosBio, a privately held, clinical-stage biopharmaceutical company, to strengthen Merck's oncology pipeline with MK-2140 (formerly known as VLS-101), an investigational antibody-drug conjugate to treat hematological malignancies and solid tumors.

Fourth-Quarter and Full-Year Financial Impact of COVID-19

In the fourth quarter, the estimated negative impact of the COVID-19 pandemic to Merck's pharmaceutical revenue was approximately $400 million. As expected, within the company's human health business, revenue was negatively impacted by reduced access to health care providers given social distancing measures, which negatively affected vaccine sales in particular.

Operating expenses were positively impacted in the fourth quarter by approximately $50 million, primarily driven by lower promotional and selling costs, partially offset by higher research and development (R&D) expenses, net of investments in COVID-19-related antiviral and vaccine research programs.

The estimated overall negative impact of the COVID-19 pandemic to Merck's revenue for the full year 2020 was approximately $2.5 billion, largely attributable to the human health business but including approximately $50 million attributable to Animal Health.

Operating expenses for the full year were positively impacted by approximately $600 million, primarily driven by lower promotional and selling costs, as well as lower R&D expenses, net of investments in COVID-19-related antiviral and vaccine research programs.

Fourth-Quarter and Full-Year Revenue Performance

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

$ in millions	Fourth Quarter				Year Ended			
	2020	2019	Change	Change Ex-Exchange	Dec. 31, 2020	Dec. 31, 2019	Change	Change Ex-Exchange
Total Sales	$12,514	$11,868	5%	5%	$47,994	$46,840	2%	4%
Pharmaceutical	11,367	10,533	8%	6%	43,021	41,751	3%	4%
KEYTRUDA	3,993	3,111	28%	27%	14,380	11,084	30%	30%
JANUVIA / JANUMET	1,328	1,418	-6%	-7%	5,276	5,524	-4%	-4%
GARDASIL / GARDASIL 9	998	693	44%	41%	3,938	3,737	5%	6%
PROQUAD, M-M-R II and VARIVAX	488	481	2%	1%	1,878	2,275	-17%	-17%
BRIDION	355	313	13%	13%	1,198	1,131	6%	7%
PNEUMOVAX 23	339	334	1%	0%	1,087	926	17%	18%
SIMPONI	223	205	9%	4%	838	830	1%	1%
ISENTRESS / ISENTRESS HD	211	223	-5%	-6%	857	975	-12%	-11%
Lynparza*	206	132	56%	53%	725	444	63%	62%
ROTATEQ	196	227	-14%	-14%	797	791	1%	1%
IMPLANON / NEXPLANON	165	206	-20%	-20%	680	787	-14%	-13%
Lenvima*	158	124	28%	26%	580	404	44%	43%
Animal Health	1,168	1,122	4%	6%	4,703	4,393	7%	10%
Livestock	794	777	2%	4%	2,939	2,784	6%	9%
Companion Animals	374	345	8%	9%	1,764	1,609	10%	11%
Other Revenues**	(21)	213	-110%	-45%	270	696	-61%	-22%

*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. The revenue hedging activities resulted in negative revenue in the fourth quarter of 2020.

Pharmaceutical Revenue

Fourth-quarter pharmaceutical sales increased 8% to $11.4 billion. Excluding the favorable effect from foreign exchange, sales grew 6%.The increase was driven by growth in oncology, vaccines, reflecting the replenishment of GARDASIL 9 doses previously borrowed from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile as discussed below, and hospital acute care, 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 sales of KEYTRUDA, which were $4.0 billion for the quarter. Global sales growth of KEYTRUDA reflects continued strong momentum from the non-small-cell lung cancer indications as well as continued uptake in other indications, including adjuvant melanoma, RCC, bladder, head and neck squamous cell carcinoma (HNSCC) and MSI-H cancers, as well as uptake following the recent launch of the 400mg every 6 week adult 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.

Growth in vaccines for the fourth quarter was driven by higher sales of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] and GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant). Fourth-quarter 2020 GARDASIL 9 sales

were increased by $120 million due to the replenishment of doses that were borrowed in the fourth quarter of 2019 from the CDC Pediatric Vaccine Stockpile. GARDASIL 9 sales in the fourth quarter of 2019 were decreased by $120 million due to the borrowing. GARDASIL/GARDASIL 9 sales growth also reflects higher demand in China. Growth was partially offset by the negative impact of the COVID-19 pandemic globally. Excluding the borrowing-related activity in both periods, GARDASIL/GARDASIL 9 sales grew 8% in the quarter, or 6% excluding the favorable impact from foreign exchange.

Growth in hospital acute care reflects higher demand globally for BRIDION (sugammadex) Injection 100 mg/mL, a medicine for the reversal of neuromuscular blockade induced by rocuronium bromide or vecuronium bromide in adults undergoing surgery; and the continued uptake 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 in the quarter were negatively affected by the ongoing impacts from the loss of market exclusivity, including for NUVARING (etonogestrel/ethinyl estradiol vaginal ring), ZETIA (ezetimibe) and certain products in diversified brands. In addition, the decline in sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl) reflects continued pricing pressure in the United States, which more than offset higher demand in certain international markets.

Full-year 2020 pharmaceutical sales increased 3% to $43.0 billion; excluding the unfavorable effect from foreign exchange, sales grew 4%, primarily due to higher sales in oncology, reflecting strong growth in KEYTRUDA, higher sales of certain vaccines including PNEUMOVAX 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, and higher sales of certain hospital acute care products, including PREVYMIS and BRIDION. As discussed above, the COVID-19 pandemic negatively affected sales in 2020. Also negatively affecting sales in 2020 was the ongoing impacts of the loss of market exclusivity for several products, lower sales of pediatric vaccines, as well as pricing pressure in diabetes.

Animal Health Revenue

Animal Health sales totaled $1.2 billion for the fourth quarter of 2020, an increase of 4% compared with the fourth quarter of 2019; excluding the unfavorable effect from foreign exchange, Animal Health sales grew 6%. Growth in the quarter reflects a net favorable impact of one-time items, including an additional month of sales in the current quarter related to the 2019 acquisition of Antelliq Corporation (Antelliq), partially offset by distributor purchasing patterns. Also contributing to growth were contributions from smaller acquisitions, as well as the underlying performance of the business driven by companion animal products, reflecting higher demand in companion animal vaccines and parasiticides.

Worldwide sales for the full year of 2020 were $4.7 billion, an increase of 7%; excluding the unfavorable effect from foreign exchange, sales grew 10%. Full-year sales growth was primarily driven by livestock sales which included an additional five months of sales in the year related to the 2019 acquisition of Antelliq, along with higher sales of companion animal products, primarily the BRAVECTO (fluralaner) line of products for parasitic control, and companion animal vaccines.

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

The tables below present selected expense information.

$ in millions		Acquisition- and Divestiture-			
Fourth-Quarter 2020	**GAAP**	**Related Costs[3,4]**	**Restructuring Costs**	**Certain Other Items**	**Non-GAAP[2]**
Cost of sales	$5,532	$1,855	$44	$260	$3,373
Selling, general and administrative	3,086	287	10	–	2,789
Research and development	5,838	13	16	3,161	2,648
Restructuring costs	309	–	309	–	–
Other (income) expense, net	(258)	(2)	–	(3)	(253)
Fourth-Quarter 2019					
Cost of sales	$3,669	$325	$90	$–	$3,254
Selling, general and administrative	2,888	44	1	–	2,843
Research and development	2,548	166	–	11	2,371
Restructuring costs	194	–	194	–	–
Other (income) expense, net	(223)	(37)	–	7	(193)

$ in millions		Acquisition- and Divestiture-			
Year Ended Dec. 31, 2020	**GAAP**	**Related Costs[3,4]**	**Restructuring Costs**	**Certain Other Items**	**Non-GAAP[2]**
Cost of sales	$15,485	$2,718	$175	$260	$12,332
Selling, general and administrative	10,468	935	47	–	9,486
Research and development	13,558	1	83	4,243	9,231
Restructuring costs	578	–	578	–	–
Other (income) expense, net	(886)	50	–	(20)	(916)
Year Ended Dec. 31, 2019					
Cost of sales	$14,112	$2,126	$251	$–	$11,735
Selling, general and administrative	10,615	126	34	–	10,455
Research and development	9,872	145	4	993	8,730
Restructuring costs	638	–	638	–	–
Other (income) expense, net	139	284	–	55	(200)

[3] Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories recognized as a result of acquisitions 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] Fourth-quarter and full-year 2020 include a $1.6 billion impairment charge related to ZERBAXA. Full-year 2019 includes a $612 million impairment charge related to SIVEXTRO (tedizolid phosphate).

GAAP Expense, EPS and Related Information

Gross margin was 55.8% for the fourth quarter of 2020 compared to 69.1% for the fourth quarter of 2019. The decrease reflects higher acquisition- and divestiture-related costs, including an impairment charge related to ZERBAXA, a charge related to the discontinuation of COVID-19 vaccine development programs, higher inventory write-offs due to a recall of ZERBAXA, pricing pressure and foreign exchange, partially offset by the favorable effects of product mix and manufacturing variances.

Gross margin was 67.7% for the full year of 2020 compared to 69.9% for the full year of 2019. The decrease in gross margin for the full year of 2020 reflects higher acquisition- and divestiture-related costs, including an impairment charge related to ZERBAXA, pricing pressure, a charge related to the discontinuation of COVID-19 vaccine development programs, higher amortization of intangible assets related to collaborations, and higher inventory write-offs, partially offset by the favorable effects of product mix and lower restructuring costs.

Selling, general and administrative expenses were $3.1 billion in the fourth quarter of 2020, an increase of 7% compared to the fourth quarter of 2019. The increase was largely driven by higher acquisition- and divestiture-related costs, primarily reflecting costs related to the company's planned spinoff of Organon & Co. (Organon), as well as a $100 million contribution to the Merck Foundation to support philanthropic programs and initiatives that help address health disparities and strengthen communities in the U.S. and around the world; partially offset by lower selling and administrative costs, including less travel and meeting expenses, due in part to the COVID-19 pandemic. Full-year 2020 selling, general and administrative expenses were $10.5 billion, a decrease of 1% compared to the full year of 2019. The decrease primarily reflects lower administrative, selling and promotional costs, due in part to the COVID-19 pandemic, largely offset by higher acquisition- and divestiture-related costs, primarily reflecting costs related to the company's planned spinoff of Organon.

R&D expenses were $5.8 billion in the fourth quarter of 2020, compared with $2.5 billion in the fourth quarter of 2019. R&D expenses were $13.6 billion for the full year of 2020, a 37% increase compared to the full year of 2019. The increase in both periods was primarily driven by higher upfront payments for acquisitions and collaborations, including a $2.7 billion charge in 2020 for the acquisition of VelosBio. In addition, the increase in both periods reflects higher expenses related to clinical development and increased investment in discovery research and early drug development. These increases were partially offset by lower travel and meeting expenses due to the COVID-19 pandemic, as well as lower acquisition- and divestiture-related costs.

Other (income) expense, net, was $258 million of income in the fourth quarter of 2020 compared to $223 million of income in the fourth quarter of 2019, primarily reflecting higher income from investments in equity securities, net, which was $375 million in 2020 compared with $119 million in 2019, largely from the recognition of unrealized gains on securities. Other (income)

expense, net, was $886 million of income for the full year of 2020 compared to $139 million of expense for the full year of 2019, primarily reflecting higher income from investments in equity securities, net, which was $1.3 billion in 2020 compared with $170 million in 2019, largely from the recognition of unrealized gains on securities.

The effective income tax rates were (5.0)% for the fourth quarter and 19.4% for the full year of 2020. The effective income tax rates for the fourth quarter and full year of 2020 reflect the unfavorable impact of the charge for the acquisition of VelosBio for which no tax benefit was recognized.

GAAP EPS was $(0.83) for the fourth quarter of 2020 compared with $0.92 for the fourth quarter of 2019. GAAP EPS was $2.78 for the full year of 2020 compared with $3.81 for the full year of 2019.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 73.0% for the fourth quarter of 2020 compared to 72.6% for the fourth quarter of 2019. The increase in the fourth quarter reflects the favorable effects of product mix and manufacturing variances, partially offset by higher inventory write-offs due to a recall of ZERBAXA, pricing pressure and foreign exchange.

Non-GAAP gross margin was 74.3% for the full year of 2020 compared to 74.9% for the full year of 2019. The decrease reflects pricing pressure, higher amortization of intangible assets related to collaborations and higher inventory write-offs, partially offset by the favorable effect of product mix.

Non-GAAP selling, general and administrative expenses were $2.8 billion in the fourth quarter of 2020, a decrease of 2% compared to the fourth quarter of 2019. Full-year 2020 non-GAAP selling, general and administrative expenses were $9.5 billion, a decrease of 9% compared to the full year of 2019. The decrease in both periods primarily reflects lower administrative and selling costs, including less travel and meeting expenses, due in part to the COVID-19 pandemic. The declines were partially offset by the contribution to the Merck Foundation.

Non-GAAP R&D expenses were $2.6 billion in the fourth quarter of 2020, a 12% increase compared to the fourth quarter of 2019. Non-GAAP R&D expenses were $9.2 billion for the full year of 2020, a 6% increase compared to the full year of 2019. The increase in both periods was primarily driven by higher expenses related to clinical development and increased investment in discovery research and early drug development, partially offset by lower travel and meeting expenses due to the COVID-19 pandemic.

Non-GAAP other (income) expense, net, was $253 million of income in the fourth quarter of 2020 compared to $193 million of income in the fourth quarter of 2019, primarily reflecting higher income from investments in equity securities, net, which was $375 million in 2020 compared with $119 million in 2019, largely from the recognition of unrealized gains on securities. Non-GAAP

other (income) expense, net, for the full year of 2020 was $916 million of income compared to $200 million of income for the full year of 2019, primarily driven by higher income from investments in equity securities, net, which was $1.3 billion in 2020 compared with $170 million in 2019, largely from the recognition of unrealized gains on securities.

The non-GAAP effective income tax rates were 15.3% for the fourth quarter of 2020 and 15.5% for the full year of 2020.

Non-GAAP EPS was $1.32 for the fourth quarter of 2020 compared with $1.16 for the fourth quarter of 2019. Non-GAAP EPS was $5.94 for the full year of 2020 compared with $5.19 for the full year 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	Fourth Quarter		Year Ended	
	2020	2019	Dec. 31, 2020	Dec. 31, 2019
EPS				
GAAP EPS	$(0.83)	$0.92	$2.78	$3.81
Difference	2.15	0.24	3.16	1.38
Non-GAAP EPS that excludes items listed below[2]	$1.32	$1.16	$5.94	$5.19
Net Income				
GAAP net (loss) income[1]	$(2,094)	$2,357	$7,067	$9,843
Difference	5,444	621	8,015	3,539
Non-GAAP net income that excludes items listed below[1,2]	$3,350	$2,978	$15,082	$13,382
Decrease (Increase) in Net Income Due to Excluded Items:				
Acquisition-related intangible asset impairment charges[4]	$1,594	$12	$1,609	$705
Other acquisition- and divestiture-related costs[3]	559	486	2,095	1,976
Total acquisition- and divestiture-related costs	2,153	498	3,704	2,681
Restructuring costs	379	285	883	927
Charge for the acquisition of VelosBio	2,660	–	2,660	–
Charge for the acquisition of OncoImmune	462	–	462	–
Charge for the discontinuation of COVID-19 vaccine development programs	305	–	305	–
Charges for the formation of collaborations[5]	(6)	–	1,076	–
Charge for the acquisition of Peloton Therapeutics, Inc.	–	11	–	993
Other	(3)	7	(20)	55
Net decrease (increase) in income before taxes	5,950	801	9,070	4,656
Income tax (benefit) expense[6]	(506)	(180)	(1,055)	(1,028)
Acquisition- and divestiture-related costs attributable to non-controlling interests	–	–	–	(89)
Decrease (increase) in net income	$5,444	$621	$8,015	$3,539

[5] Amount for full-year 2020 includes $826 million related to collaborations with Seagen, Inc.

[6] Includes the estimated tax impact on the reconciling items. Amount for full-year 2020 includes a tax cost of $67 million, representing an adjustment to the tax benefits recorded in conjunction with the 2015 acquisition of Cubist Pharmaceuticals, Inc. Amount for full-year 2019 includes a $364 million net tax benefit related to the settlement of certain federal income tax matters, an $86 million tax benefit related to the reversal of tax reserves established in conjunction with the divestiture of Merck's Consumer Care business in 2014 as a result of the lapse in the statute of limitations, and a $117 million tax charge related to the finalization of treasury regulations associated with the 2017 enactment of U.S. tax legislation.

Financial Outlook

The guidance provided below is based on the assumption that the Organon business will be part of Merck for all of 2021; however, the Company expects that the Organon spinoff will occur late in the second quarter of 2021. If the spinoff occurs, these financial estimates will be updated.

At mid-January 2021 exchange rates, Merck anticipates full-year 2021 revenue to be between $51.8 billion and $53.8 billion, including a positive impact from foreign exchange of approximately 2%.

Merck expects full-year 2021 GAAP EPS to be between $5.52 and $5.72.

Beginning in 2021, the Company will be changing the treatment of certain items for the purposes of its non-GAAP reporting. Historically, Merck's non-GAAP results excluded the amortization of intangible assets recognized in connection with business acquisitions but did not exclude the amortization of intangibles originating from collaborations, asset acquisitions or licensing arrangements. Beginning in 2021, Merck's non-GAAP results will no longer differentiate between the nature of the intangible assets being amortized and will exclude all amortization of intangible assets. Also, beginning in 2021, Merck's non-GAAP results will exclude gains and losses on investments in equity securities.

On this new basis, Merck expects full-year 2021 non-GAAP EPS to be between $6.48 and $6.68, including an approximately 3% positive impact from foreign exchange. The non-GAAP range also excludes acquisition- and divestiture-related costs and costs related to restructuring programs. The changes to non-GAAP reporting resulted in a positive impact to projected 2021 non-GAAP EPS of approximately $0.08. For comparative purposes, Merck's non-GAAP EPS in 2020 would have been $5.79 if reported under the new basis.

The full-year guidance includes Merck's current assumption of the impact from the COVID-19 pandemic. Merck projects strong underlying business growth for 2021. This growth is partially offset by the anticipated continuing impacts of the pandemic into 2021. Merck believes that global health systems and patients have largely adapted to the impacts of COVID-19 disease, but the company's assumption is that ongoing residual negative impacts will persist, particularly during the first half of 2021 and most notably with respect to vaccine sales, which are expected to be more acute in the United States.

For full-year 2021, Merck assumes an unfavorable impact to revenue of approximately 2% due to the COVID-19 pandemic, all of which relates to pharmaceutical segment sales. For full-year 2021, with respect to the COVID-19 pandemic, Merck expects a net negative impact on operating expenses, as spending on the development of its COVID-19 antiviral programs is expected to exceed the favorable impact of lower spending in other areas due to the COVID-19 pandemic. Neither the sales nor the EPS guidance ranges provided above include the impact of the potential launches of Merck's COVID-19 antiviral drug candidates.

The following table summarizes the company's full-year 2021 financial guidance.

	GAAP	Non-GAAP[2]
Revenue	$51.8 to $53.8 billion	$51.8 to $53.8 billion*
Operating expenses	Lower than 2020 by a low-double-digit rate	Higher than 2020 by a high-single to low-double-digit rate
Effective tax rate	15% to 16%	15% to 16%
EPS**	$5.52 to $5.72	$6.48 to $6.68

*The company does not have any non-GAAP adjustments to revenue.
**EPS guidance for 2021 assumes a share count (assuming dilution) of approximately 2.53 billion shares.

A reconciliation of anticipated 2021 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 2021
GAAP EPS	$5.52 to $5.72
Difference	$0.96
Non-GAAP EPS that excludes items listed below[2]	$6.48 to $6.68
Acquisition- and divestiture-related costs	$2,900
Restructuring costs	700
(Gains) losses on investments in equity securities	(800)
Net decrease (increase) in income before taxes	2,800
Estimated income tax (benefit) expense	(360)
Decrease (increase) in net income	$2,440

Organon Update

Merck expects the spinoff of Organon to be completed late in the second quarter of 2021. The transaction is expected to create two companies with enhanced strategic and operational focus, improved agility, simplified operating models, optimized capital structures and improved financial profiles. Merck believes the transaction will deliver significant benefits for both Merck and Organon and create value for Merck shareholders.

In 2020, the products that will comprise Organon achieved revenues of $6.5 billion. In 2021, assuming it operated as an independent company for the full year, Organon is expected to generate $6.0 billion to $6.5 billion in revenue. As it nears the end of loss of exclusivity exposure to key brands, Organon will be well positioned for growth led by its Women's Health and Biosimilars portfolios, with expected low to mid-single digit annual revenue growth off of a 2021 base year.

As a standalone company post spinoff, Organon anticipates having non-GAAP operating margins in the mid-30% range. This compares to a non-GAAP operating margin of approximately 45% within Merck, with the difference reflecting additional costs Organon will incur to operate as an independent company. Earnings before interest, taxes, depreciation and amortization (EBITDA) margins are anticipated in the high 30% range post spinoff. Organon's operating and EBITDA margins are expected to increase over time.

At this time, Organon is expected to have $9.0 billion to $9.5 billion in initial debt and is expected to pay a special tax-free dividend to Merck of approximately $8.5 billion to $9.0 billion. The remaining cash, as well as ongoing cash flows from operations, is expected to provide the company with ample cash flow and financial flexibility for potential business development opportunities, debt paydown and a meaningful dividend that will be incremental to the dividend

Merck currently pays its shareholders. Actual debt balances will be determined based on market conditions and desired bond rating.

For Merck, the spinoff of Organon will allow it to increase focus on key growth pillars, result in higher revenue and EPS growth rates and enable incremental operating efficiencies of approximately $1.5 billion which are expected to be achieved ratably over three years, with approximately $500 million reflected in Merck's 2021 financial outlook. Merck will continue to incur overhead costs previously allocated to the Organon products, which are estimated to be approximately $400 million on a full-year basis. These costs are expected to be reduced over time and are netted into the overall efficiency target. In addition, the special tax-free dividend from Organon will be allocated to business development or share repurchase.

As a result of stronger growth Organon is expected to achieve as a standalone company, combined with the benefit of operating efficiencies at Merck enabled by the spinoff, Merck expects combined non-GAAP EPS of the two companies to be higher within 12-24 months post-spinoff versus what would have been achieved assuming no transaction.

Merck will host an investor event prior to the completion of the spinoff at which time Organon management will present its strategy, opportunities for growth and financial outlook. Further details will be announced at a future date.

Earnings Conference Call

Investors, journalists and the general public may access a live audio webcast of the call today at 8:00 a.m. EST on Merck's website at https://www.merck.com/investor-relations/events-and-presentations/. Institutional investors and analysts can participate in the call by dialing (833) 353-0277 or (469) 886-1947 and using ID code number 2268598. Members of the media are invited to monitor the call by dialing (833) 353-0277 or (469) 886-1947 and using ID code number 2268598. 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 130 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).

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