FOR IMMEDIATE RELEASE

Media Contacts:	Melissa Moody (215) 407-3536	Investor Contacts:	Peter Dannenbaum (908) 740-1037
	Johanna Herrmann (617) 216-6029		Steven Graziano (908) 740-6582

Merck Announces Fourth-Quarter and Full-Year 2021 Financial Results

- Fourth-Quarter and Full-Year Results Reflect Continued Strong Business Momentum and Operational Strength
- Fourth-Quarter 2021 Worldwide Sales From Continuing Operations Were $13.5 Billion, an Increase of 24% From Fourth-Quarter 2020; Excluding the Impact From Foreign Exchange, Sales Grew 23%; Includes $952 Million of Molnupiravir Sales
- Fourth-Quarter 2021 GAAP EPS From Continuing Operations was $1.51; Fourth-Quarter 2021 Non-GAAP EPS was $1.80
- Full-Year 2021 Worldwide Sales From Continuing Operations Were $48.7 Billion, an Increase of 17% From Full-Year 2020; Excluding the Impact From Foreign Exchange, Sales Grew 16%; Includes $952 Million of Molnupiravir Sales
    - KEYTRUDA Sales Grew 20% to $17.2 Billion; Excluding the Impact From Foreign Exchange, Sales Grew 18%
    - GARDASIL/GARDASIL 9 Sales Grew 44% to $5.7 Billion; Excluding the Impact From Foreign Exchange, Sales Grew 39%
    - Animal Health Sales Grew 18% to $5.6 Billion; Excluding the Impact From Foreign Exchange, Sales Grew 16%
- Full-Year 2021 GAAP EPS From Continuing Operations was $4.86; Full-Year 2021 Non-GAAP EPS was $6.02
- Grew Innovative Product Pipeline With Key Acquisitions, While Securing Multiple Regulatory Approvals and Announcing Positive Data in Growth Pillars
- 2022 Financial Outlook
    - Anticipates Full-Year 2022 Worldwide Sales to be Between $56.1 Billion and $57.6 Billion
    - Expects Full-Year 2022 GAAP EPS to be Between $5.76 and $5.91; Expects Non-GAAP EPS to be Between $7.12 and $7.27

KENILWORTH, N.J., Feb. 3, 2022 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the fourth quarter and full year of 2021.

"Our business achieved strong revenue and earnings growth this quarter and for the full year. Throughout 2021, we invested in the discovery, development, production and commercialization of medicines and vaccines, furthering the sustainability of our business," said chief executive officer and president, Robert M. Davis. "We enter 2022 with strong momentum and are moving with speed to bring forward innovations that address critical unmet needs and contribute to global health. This remains at the core of our strategy, and why we are focused on benefitting the patients we serve, and in turn creating long-term value for our shareholders."

Financial Summary – Continuing Operations

Financial information presented in this release reflects Merck's results on a continuing operations basis, which excludes Organon & Co. that was spun-off on June 2, 2021.

	Fourth Quarter				Year Ended			
$ in millions, except EPS amounts	2021	2020	Change	Change Ex-Exchange	Dec. 31, 2021	Dec. 31, 2020	Change	Change Ex-Exchange
Sales	$13,521	$10,948	24%	23%	$48,704	$41,518	17%	16%
GAAP net income (loss)[1]	3,820	(2,617)	**	**	12,345	4,519	**	**
Non-GAAP net income that excludes certain items[1,2]*	4,575	2,492	84%	81%	15,282	11,506	33%	31%
GAAP EPS	1.51	(1.03)	**	**	4.86	1.78	**	**
Non-GAAP EPS that excludes certain items[2]*	1.80	0.98	84%	82%	6.02	4.53	33%	32%

*Refer to table on page 14.
**>100%

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) was $1.51 for the fourth quarter and $4.86 for the full year of 2021. Non-GAAP EPS was $1.80 for the fourth quarter and $6.02 for the full year of 2021. GAAP and Non-GAAP EPS for the fourth quarter and full year of 2021 reflect strong underlying business performance, as well as the favorable impacts of molnupiravir and effective tax rates. Non-GAAP EPS excludes acquisition- and divestiture-related costs, restructuring costs, income and losses from investments in equity securities and certain other items. Refer to the GAAP to non-GAAP reconciliation table on page 14 for further details.

[1] Net income (loss) from continuing operations attributable to Merck & Co., Inc.

[2] Merck is providing certain 2021 and 2020 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 non-GAAP adjustments, see Table 2a attached to this release.

Maintaining Positive Business Momentum from a Position of Strength

Merck achieved significant and meaningful progress against its strategic priorities in 2021, culminating in strong operational performance in the fourth quarter. The company advanced its broad pipeline, closed the acquisition of Acceleron Pharma Inc. (Acceleron) and delivered initial shipments of molnupiravir, an investigational oral antiviral COVID-19 treatment. At the same time, Merck reported very strong commercial results across all of its key performance drivers, including KEYTRUDA (pembrolizumab), GARDASIL [Human Papillomavirus Quadrivalent (Types 6,11,16 and 18) Vaccine, Recombinant], GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and Animal Health.

Molnupiravir Highlights

Merck and Ridgeback Biotherapeutics (Ridgeback) are advancing molnupiravir, an investigational oral antiviral COVID-19 treatment. Molnupiravir has received many authorizations or approvals worldwide to-date, with additional applications under review. Within the next few days, Merck will have shipped more than 4 million courses of therapy to more than 25 countries, including approximately 3 million courses to the U.S. Government as part of its procurement agreement. Additionally, Merck and Ridgeback are engaged in numerous efforts to accelerate broad, equitable access globally, including a recent agreement on the allocation of up to 3 million courses of therapy to the United Nations Children's Fund (UNICEF) for use in adults.

- Merck and Ridgeback announced the following regulatory milestones:
    - U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) to treat mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate.
    - Japan's Ministry of Health, Labor and Welfare (MHLW) Special Approval for Emergency for molnupiravir for infectious disease caused by SARS-CoV-2.
    - U.K. Medicines and Healthcare products Regulatory Agency authorization for molnupiravir for the treatment of mild to moderate COVID-19 in adults with a positive SARS-CoV-2 diagnostic test and who have at least one risk factor for developing severe illness.

- Merck and Ridgeback announced data from six preclinical studies from multiple independent laboratories demonstrating that molnupiravir was active against the SARS-CoV-2 variant, Omicron (B1.1.529) in *in vitro* settings.
- Merck and Ridgeback announced the signing of a long-term supply agreement with UNICEF to facilitate broad global access for molnupiravir. Under the agreement, Merck will allocate up to 3 million courses of molnupiravir to UNICEF throughout the first half of 2022 for distribution in more than 100 low- and middle-income countries (LMICs) following regulatory authorizations. This announcement is another example of Merck's commitment to providing timely access to molnupiravir globally, in addition to granting voluntary licenses to generic manufacturers and to the Medicines Patent Pool to make generic molnupiravir available in more than 100 LMICs.
- Merck and Ridgeback announced new and amended supply agreements for molnupiravir with several countries, including Japan, the U.K. and the U.S.
- Merck and Ridgeback announced the *New England Journal of Medicine* published findings from the Phase 3 MOVe-OUT trial evaluating molnupiravir in non-hospitalized high risk adults with mild to moderate COVID-19. The publication highlighted findings from the planned interim analysis as well as findings from all randomized patients demonstrating that early treatment with molnupiravir significantly reduced the risk of hospitalization or death in high risk, unvaccinated adults with COVID-19.

Cardiovascular Program Highlights

- Merck announced the successful completion of its acquisition of Acceleron. The acquisition complements and strengthens Merck's cardiovascular pipeline with Acceleron's lead therapeutic candidate, sotatercept, a potentially first-in-class therapy for the treatment of pulmonary arterial hypertension (PAH). Sotatercept is in Phase 3 trials as an add-on to current standard of care for the treatment of PAH.
- Merck presented results from two early Phase 1 clinical studies evaluating its investigational oral PCSK9 inhibitor (MK-0616) at the American Heart Association Scientific Sessions 2021. The studies evaluated the safety and efficacy of this candidate being studied for cholesterol-lowering and measured reduction of high levels of LDL cholesterol. Merck plans to progress MK-0616 to Phase 2 in 2022.
- Merck announced the initiation of VICTOR (VerICiguaT in adults with ChrOnic heart failure and Reduced ejection fraction), a pivotal Phase 3 randomized, placebo-controlled cardiovascular clinical trial of Verquvo (vericiguat) in patients with chronic heart failure

and reduced ejection fraction of 40% or less who have not had a recent worsening heart failure event.

Oncology Program Highlights

Merck continued to advance development programs across its oncology portfolio, anticipating more than 90 potential new indications by 2028, including notable progress for KEYTRUDA, the company's anti-PD-1 therapy; Lynparza (olaparib), a PARP inhibitor being co-developed and co-commercialized with AstraZeneca; Lenvima (lenvatinib mesylate), an orally available tyrosine kinase inhibitor being co-developed and co-commercialized with Eisai Co., Ltd. (Eisai); and WELIREG (belzutifan), an oral hypoxia-inducible factor-2 alpha inhibitor (HIF-2α).

- Merck announced the following regulatory milestones for KEYTRUDA:
  - FDA approval and European Commission (EC) approval of KEYTRUDA for the adjuvant treatment of certain patients with renal cell carcinoma (RCC) following nephrectomy, or following nephrectomy and resection of metastatic lesions, based on data from the Phase 3 KEYNOTE-564 trial.
  - FDA approval of KEYTRUDA for the adjuvant treatment of adult and pediatric (12 years and older) patients with stage IIB or IIC melanoma following complete resection, based on data from the Phase 3 KEYNOTE-716 trial.
  - Japan's MHLW approval of KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with radically unresectable, advanced or recurrent esophageal carcinoma, based on data from the Phase 3 KEYNOTE-590 trial.
- Merck announced topline results and study updates for KEYTRUDA:
  - Positive topline results for the Phase 3 KEYNOTE-091 trial (EORTC-1416-LCG/ETOP-8-15 – PEARLS) that showed KEYTRUDA met one of its dual primary endpoints of disease-free survival (DFS) in the all-comer population of patients with stage IB-IIIA non-small cell lung cancer (NSCLC) for the adjuvant treatment of patients following surgical resection regardless of PD-L1 expression. At the interim analysis, there was also an improvement in DFS for patients whose tumors express PD-L1 (tumor proportion score ≥50%) treated with KEYTRUDA compared to placebo; however, this dual primary endpoint did not meet statistical significance per the pre-specified statistical plan.

    - Merck presented exploratory 7-year follow-up data from KEYNOTE-006, the pivotal trial that supported the indication for KEYTRUDA in advanced melanoma, and updated findings from the KEYNOTE-716 trial that is evaluating KEYTRUDA as an adjuvant treatment for patients with resected stage IIB or IIC melanoma at the Society for Melanoma Research 2021 Congress.
- Merck and Eisai announced the following regulatory milestones for Lenvima:
    - EC approval and Japan's MHLW approval of KEYTRUDA plus Lenvima for the treatment of certain types of advanced endometrial carcinoma, based on results from the Phase 3 KEYNOTE-775/Study 309 trial. In Europe, KEYTRUDA plus Lenvima is approved for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation. In Japan, this combination is approved for the treatment of patients with unresectable, advanced or recurrent endometrial carcinoma that progressed after cancer chemotherapy.
    - EC approval of the combination of KEYTRUDA plus Lenvima for the first-line treatment of adult patients with advanced RCC, based on results from the Phase 3 CLEAR study (KEYNOTE-581/Study 307).
- Merck and AstraZeneca announced filing acceptance and priority review for a supplemental New Drug Application (sNDA) for Lynparza for the adjuvant treatment of certain patients with *BRCA*-mutated, HER2-negative high-risk early breast cancer, who have already been treated with chemotherapy either before or after surgery based on the Phase 3 OlympiA trial. The Prescription Drug User Fee Act (PDUFA) date is during the first quarter of 2022.

Vaccines Highlights

- Merck announced that the EC approved VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine) for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age or older.
- Merck announced that the FDA accepted for priority review a supplemental Biologics License Application for VAXNEUVANCE for the prevention of invasive pneumococcal disease in children 6 weeks through 17 years of age. The FDA set a PDUFA date of April 1, 2022.

Other Updates

- Merck announced that the FDA placed full or partial clinical holds on the investigational new drug applications for the oral and implant formulations of islatravir (MK-8591) for HIV-1 pre-exposure prophylaxis; the injectable formulation of islatravir for HIV-1 treatment and prophylaxis; and the oral doravirine/islatravir HIV-1 once-daily treatment. The FDA's clinical holds are based on observations of decreases in total lymphocyte and CD4+ T-cell counts in some participants receiving islatravir in clinical studies. Merck has stopped dosing in the Phase 2 IMAGINE-DR clinical trial of islatravir in combination with MK-8507 (MK-8591-013) and paused enrollment in the once-monthly Phase 3 PrEP studies, (MK-8591-022 and MK-8591-024) (see announcements here and here).
- As a result of the holds discussed above, Merck and Gilead announced a temporary pause in enrollment for the Phase 2 clinical study evaluating an investigational once-weekly oral combination treatment regimen of islatravir and lenacapavir in people living with HIV who are virologically suppressed on antiretroviral therapy.
- Merck announced that the FDA issued a Complete Response Letter regarding gefapixant, which is under development for the treatment of refractory chronic cough or unexplained chronic cough in adults. Additionally, Japan's MHLW approved gefapixant for adults with refractory or unexplained chronic cough.
- Merck received FDA approval for the sNDAs for PIFELTRO (doravirine) and DELSTRIGO (doravirine/lamivudine/tenofovir disoproxil fumarate) last month, based on the results of the IMPAACT 2014 study. The approvals expand the indications for PIFELTRO and DELSTRIGO to include pediatric patients weighing more than 35kg with HIV-1 infection.
- Merck will hold a virtual Investor Event on Wednesday, Feb. 23, 2022, at which senior management will discuss details of the company's Environmental, Social & Governance (ESG) approach to create long-term value for the business and society. The company looks to strengthen its performance and progress in its four ESG priority areas: Access to Health, Employees, Environmental Sustainability and Ethics & Value. Further details regarding logistics will be announced at a later date.

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			
	2021	2020	Change	Change Ex-Exchange	Dec. 31, 2021	Dec. 31, 2020	Change	Change Ex-Exchange
Total Sales	$13,521	$10,948	24%	23%	$48,704	$41,518	17%	16%
Pharmaceutical	12,039	9,813	23%	23%	42,754	36,610	17%	15%
KEYTRUDA	4,577	3,993	15%	16%	17,186	14,380	20%	18%
GARDASIL / GARDASIL 9	1,528	998	53%	50%	5,673	3,938	44%	39%
JANUVIA / JANUMET	1,393	1,328	5%	6%	5,288	5,276	0%	-2%
PROQUAD, M-M-R II and VARIVAX	509	488	4%	4%	2,135	1,878	14%	13%
BRIDION	436	355	23%	24%	1,532	1,198	28%	27%
Lynparza**	268	206	30%	33%	989	725	36%	35%
Molnupiravir	952	0	-	-	952	0	-	-
PNEUMOVAX 23	292	339	-14%	-13%	893	1,087	-18%	-19%
SIMPONI	206	223	-8%	-6%	825	838	-2%	-6%
ROTATEQ	213	196	9%	8%	807	797	1%	0%
ISENTRESS / ISENTRESS HD	178	211	-15%	-15%	769	857	-10%	-11%
Lenvima**	206	158	30%	31%	704	580	21%	20%
Animal Health	1,261	1,168	8%	8%	5,568	4,703	18%	16%
Livestock	791	794	0%	0%	3,295	2,939	12%	10%
Companion Animals	470	374	26%	26%	2,273	1,764	29%	26%
Other Revenues***	221	(33)	*	*	382	205	86%	*

*>100%

**Alliance revenue for this product 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. Other revenues in full-year 2021 include $185 million related to the receipt of milestone payments for an out-licensed product.

Pharmaceutical Revenue

Fourth-quarter pharmaceutical sales increased 23% to $12.0 billion reflecting sales of molnupiravir and growth in oncology, vaccines and hospital acute care products. COVID-19-related disruptions negatively affected sales in the fourth quarter of 2020, which benefited year-over-year sales growth.

Molnupiravir sales were $952 million in the fourth quarter of 2021, primarily consisting of sales in the U.S., the U.K. and Japan.

Growth in oncology was largely driven by higher sales of KEYTRUDA, which rose 15% to $4.6 billion in the quarter. Global sales growth of KEYTRUDA reflects continued strong momentum from the NSCLC indications as well as uptake in other indications, including RCC, head and neck squamous cell carcinoma, triple-negative breast cancer (TNBC) and microsatellite instability-high (MSI-H) cancers. Also contributing to higher sales in oncology was a 30% increase in Lynparza alliance revenue, primarily reflecting continued uptake in the U.S. and Europe, as well as a 30% increase in Lenvima alliance revenue driven primarily by higher demand in the U.S.

Growth in vaccines for the fourth quarter was primarily driven by higher combined sales of GARDASIL and GARDASIL 9, vaccines to prevent certain cancers and other diseases caused by HPV. Fourth-quarter 2021 GARDASIL/GARDASIL 9 sales grew 53% to $1.5 billion, primarily driven by strong global demand, particularly in China, which also benefited from increased supply. Fourth-quarter 2021 GARDASIL/GARDASIL 9 sales growth was partially offset by lower sales in the U.S. due to the timing of public sector purchases, as well as the replenishment in the fourth quarter of 2020 of doses that were borrowed from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile which increased fourth-quarter 2020 sales by $120 million.

Vaccine performance was negatively affected by lower sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, which declined 14% to $292 million primarily driven by lower demand in the U.S. reflecting prioritization of COVID-19 vaccines.

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 and pediatric patients aged 2 years and older undergoing surgery, which increased 23% to $436 million due in part to increased usage of neuromuscular blockade reversal agents and BRIDION's growing share within the class. Also contributing to growth in hospital acute care were higher sales of DIFICID (fidaxomicin), a macrolide antibacterial drug for treatment of *Clostridioides difficile*-associated diarrhea in adults and pediatric patients aged 6 months and older, which increased 89% to $60 million due to higher demand in the U.S.

Combined sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl) grew 5% to $1.4 billion reflecting a pricing benefit in the U.S. due to a favorable rebate adjustment and mix of business, as well as higher demand in certain international markets.

Full-year 2021 pharmaceutical sales increased 17% to $42.8 billion. Excluding the favorable effect of foreign exchange, sales grew 15% primarily due to higher sales in oncology, reflecting strong growth of KEYTRUDA, higher sales of vaccines, particularly GARDASIL/GARDASIL 9, sales of molnupiravir, as well as growth in hospital acute care products, including BRIDION and 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. COVID-19-related disruptions negatively affected sales in 2021, but to a lesser extent than in 2020, which benefited year-over-year sales growth. Pharmaceutical sales growth in 2021 was partially offset by lower sales of

PNEUMOVAX 23 and ZERBAXA (ceftolozane and tazobactam) for injection, a combination cephalosporin antibacterial and beta-lactamase inhibitor for the treatment of adults with certain bacterial infections, following a product recall and the suspension of sales in the fourth quarter of 2020. A phased resupply of ZERBAXA was initiated in the fourth quarter of 2021, which the company expects to continue in 2022.

Animal Health Revenue

Animal Health sales totaled $1.3 billion for the fourth quarter of 2021, an increase of 8% compared with the fourth quarter of 2020, reflecting growth across geographies and species. Higher sales of companion animal products were primarily driven by the BRAVECTO (fluralaner) parasiticide line of products, as well as vaccines. Livestock sales in the fourth quarter of 2021 were relatively flat compared with the fourth quarter of 2020 due to an extra month of sales recorded in the fourth quarter of 2020 related to the 2019 acquisition of Antelliq Corporation (Antelliq), offset by higher demand globally for poultry and swine products.

Full-year Animal Health sales were $5.6 billion, an increase of 18%. Excluding the favorable effect from foreign exchange, Animal Health sales grew 16%. Full-year sales growth was primarily driven by companion animal products, led by the BRAVECTO line of products and vaccines. Livestock sales reflect growth across ruminant, poultry and swine products, partially offset by an additional month of sales in 2020 related to the 2019 acquisition of Antelliq.

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

The tables below present selected expense information.

$ in millions Fourth-Quarter 2021	GAAP	Acquisition- and Divestiture-Related Costs[3,4]	Restructuring Costs	(Income) Loss from Investments in Equity Securities	Certain Other Items	Non-GAAP[2]
Cost of sales	$3,873	$419	$47	$-	$(4)	$3,411
Selling, general and administrative	2,830	226	10	-	-	2,594
Research and development	3,068	397	7	-	(17)	2,681
Restructuring costs	174	-	174	-	-	-
Other (income) expense, net	(333)	(3)	-	(381)	-	51
Fourth-Quarter 2020						
Cost of sales	$5,029	$1,986	$44	$-	$260	$2,739
Selling, general and administrative	2,619	42	10	-	-	2,567
Research and development	5,788	16	16	-	3,161	2,595
Restructuring costs	310	-	310	-	-	-
Other (income) expense, net	(253)	(2)	-	(348)	(3)	100

$ in millions Year Ended Dec. 31 2021	GAAP	Acquisition- and Divestiture-Related Costs[3,4]	Restructuring Costs	(Income) Loss from Investments in Equity Securities	Certain Other Items	Non-GAAP[2]
Cost of sales	$13,626	$1,607	$160	$-	$221	$11,638
Selling, general and administrative	9,634	322	19	-	-	9,293
Research and development	12,245	479	28	-	1,661	10,077
Restructuring costs	661	-	661	-	-	-
Other (income) expense, net	(1,341)	76	-	(1,884)	-	467
Year Ended Dec. 31 2020						
Cost of sales	$13,618	$3,355	$175	$-	$260	$9,828
Selling, general and administrative	8,955	225	47	-	-	8,683
Research and development	13,397	12	83	-	4,243	9,059
Restructuring costs	575	-	575	-	-	-
Other (income) expense, net	(890)	50	-	(1,292)	(20)	372

GAAP Expense, EPS and Related Information

Gross margin was 71.4% for the fourth quarter of 2021 compared to 54.1% for the fourth quarter of 2020. Gross margin was 72.0% for the full year of 2021 compared to 67.2% for the full year of 2020. The increase for both periods primarily reflects lower acquisition- and divestiture-related costs, driven in part by an impairment charge related to ZERBAXA recorded in the fourth quarter of 2020, as well as the favorable effects of product mix and lower inventory write-offs. The gross margin improvement in the fourth quarter of 2021 also reflects the favorable impact of foreign exchange and charges in the fourth quarter of 2020 related to the

[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 acquisitions and divestitures.

[4] Fourth-quarter and full-year 2020 cost of sales includes a $1.6 billion impairment charge related to ZERBAXA.

discontinuation of COVID-19 vaccine development programs. Partially offsetting the gross margin improvement in both periods were the impacts from molnupiravir, which has a lower gross margin due to profit sharing with Ridgeback, as well as higher manufacturing costs.

Selling, general and administrative (SG&A) expenses were $2.8 billion in the fourth quarter of 2021, an increase of 8% compared to the fourth quarter of 2020. Full-year SG&A expenses were $9.6 billion, an increase of 8% compared to the full year of 2020. The increase in both periods was largely driven by higher acquisition- and divestiture- related costs, as well as higher administrative costs, including compensation and benefit costs, and increased promotional expenses in support of the company's growth pillars. The increase in SG&A expenses in both periods was partially offset by a $100 million charge in the fourth quarter of 2020 for a Merck Foundation contribution. Additionally, the increase in SG&A expenses for the full year was partially offset by a favorable foreign exchange impact.

Research and development (R&D) expenses were $3.1 billion in the fourth quarter of 2021 compared with $5.8 billion in the fourth quarter of 2020. The decrease was primarily due to lower upfront payments for acquisitions and collaborations, driven in part by a $2.7 billion charge in the fourth quarter of 2020 for the acquisition of VelosBio Inc. The decrease in R&D expenses also reflects the reimbursement of a portion of molnupiravir R&D costs from Ridgeback. The decline in R&D expense was partially offset by higher compensation and benefit costs, as well as higher acquisition- and divestiture- related costs. R&D expenses were $12.2 billion for the full year of 2021 compared with $13.4 billion for the full year of 2020. The decrease was primarily driven by lower upfront payments for acquisitions and collaborations. The decline in R&D expenses for the full year was partially offset by higher clinical development spending and increased investment in discovery research and early drug development, net of the reimbursement of a portion of molnupiravir R&D costs from Ridgeback. Higher compensation and benefit costs and higher acquisition- and divestiture- related costs also partially offset the decline in R&D expenses for the full year.

Other (income) expense, net, was $333 million of income in the fourth quarter of 2021 compared to $253 million of income in the fourth quarter of 2020. Other (income) expense, net, was $1.3 billion of income in the full year of 2021 compared to $890 million of income in the full year of 2020, primarily reflecting higher income from investments in equity securities, net, largely related to higher realized and unrealized gains on certain investments, partially offset by higher foreign exchange losses and pension settlement costs.

The effective income tax rate was 2.2% for the fourth quarter of 2021 and 11.0% for the full year of 2021. The full year effective tax rate reflects a more favorable mix of income and

expense than previously anticipated. The effective tax rate for the fourth quarter reflects the impact of the lower full-year rate as well as foreign tax credits.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 74.8% for the fourth quarter of 2021 compared to 75.0% for the fourth quarter of 2020. Non-GAAP gross margin was 76.1% for the full year of 2021 compared to 76.3% for the full year of 2020. The decrease in both periods primarily reflects the impacts from molnupiravir, which has a lower gross margin due to profit sharing with Ridgeback, and higher manufacturing costs. The gross margin declines were partially offset by the favorable effects of product mix and lower inventory write-offs. The gross margin decline in the fourth quarter was also partially offset by the favorable impact of foreign exchange.

Non-GAAP SG&A expenses were $2.6 billion in the fourth quarter of 2021, an increase of 1% compared to the fourth quarter of 2020. Non-GAAP full-year SG&A expenses were $9.3 billion, an increase of 7% compared to the full year of 2020. The increase in both periods primarily reflects higher administrative costs, including compensation and benefit costs, and increased promotional expenses in support of the company's growth pillars, partially offset by a charge in fourth quarter of 2020 for a contribution to the Merck Foundation. The increase in non-GAAP SG&A expenses for the full year was also partially offset by a favorable foreign exchange impact.

Non-GAAP R&D expenses were $2.7 billion in the fourth quarter of 2021, a 3% increase compared to the fourth quarter of 2020. The increase primarily reflects higher compensation and benefit costs, partially offset by the reimbursement of a portion of molnupiravir R&D costs from Ridgeback. Non-GAAP R&D expenses were $10.1 billion for the full year of 2021 compared with $9.1 billion for the full year of 2020. The increase was primarily driven by higher clinical development spending and increased investment in discovery research and early drug development, net of the reimbursement of a portion of molnupiravir R&D costs from Ridgeback, as well as higher compensation and benefit costs.

Non-GAAP other (income) expense, net, was $51 million of expense in the fourth quarter of 2021 compared to $100 million of expense in the fourth quarter of 2020. Non-GAAP other (income) expense, net, was $467 million of expense in the full year of 2021 compared to $372 million of expense in the full year of 2020, primarily reflecting higher foreign exchange losses and pension settlement costs.

The non-GAAP effective income tax rate was 4.3% for the fourth quarter of 2021 and 11.2% for the full year of 2021. The full year effective tax rate reflects a more favorable mix of

income and expense than previously anticipated. The effective tax rate for the fourth quarter reflects the impact of the lower full-year rate as well as foreign tax credits.

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	
	2021	2020	Dec. 31, 2021	Dec. 31, 2020
EPS				
GAAP EPS	$1.51	$(1.03)	$4.86	$1.78
Difference	0.29	2.01	1.16	2.75
Non-GAAP EPS that excludes items listed below[2]	$1.80	$0.98	$6.02	$4.53
Net Income				
GAAP net income (loss)[1]	$3,820	$(2,617)	$12,345	$4,519
Difference	755	5,109	2,937	6,987
Non-GAAP net income that excludes items listed below[1,2]	$4,575	$2,492	$15,282	$11,506
Decrease (Increase) in Net Income Due to Excluded Items:				
Acquisition- and divestiture-related costs[3]	$1,039	$2,042	$2,484	$3,642
Restructuring costs	238	380	868	880
(Income) loss from investments in equity securities	(381)	(348)	(1,884)	(1,292)
Charge for the acquisition of Pandion	-	-	1,704	-
Charge for the discontinuation of COVID-19 development programs	-	305	225	305
Charge for the acquisition of VelosBio	-	2,660	(43)	2,660
Charge for the formation of collaborations[5]	-	(6)	-	1,076
Charge for the acquisition of OncoImmune	-	462	-	462
Other	(21)	(3)	(4)	(20)
Net decrease (increase) in income before taxes	875	5,492	3,350	7,713
Income tax (benefit) expense[6]	(120)	(383)	(413)	(726)
Decrease (increase) in net income	$755	$5,109	$2,937	$6,987

Financial Outlook

Merck anticipates full-year 2022 revenue to be between $56.1 billion and $57.6 billion, including a negative impact from foreign exchange of approximately 2% at mid-January 2022 exchange rates.

Merck expects full-year 2022 GAAP EPS to be between $5.76 and $5.91.

Merck expects full-year 2022 non-GAAP EPS to be between $7.12 and $7.27, including a negative impact from foreign exchange of approximately 1%. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs as well as income and losses from investments in equity securities.

[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. In addition, the amount for full-year 2021 includes a $207 million net tax benefit related to the settlement of certain federal income tax matters. The 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.

This full year guidance includes expected sales of $5 billion to $6 billion from molnupiravir. Merck shares profits equally with its partner, Ridgeback, which is reflected in cost of sales.

The following table summarizes the company's full-year 2022 financial guidance.

	GAAP	Non-GAAP[2]
Revenue	$56.1 to $57.6 billion	$56.1 to $57.6 billion*
Gross margin	Approximately 68%	Approximately 74%
Operating expenses	Lower than 2021 by a low to mid-single digit rate	Higher than 2021 by a mid to high-single digit rate
Effective tax rate	12% to 13%	13% to 14%
EPS**	$5.76 to $5.91	$7.12 to $7.27

*The company does not have any non-GAAP adjustments to revenue.
**EPS guidance for 2022 assumes a share count (assuming dilution) of approximately 2.53 billion shares.

A reconciliation of anticipated 2022 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 2022
GAAP EPS	$5.76 to $5.91
Difference	$1.36
Non-GAAP EPS that excludes items listed below[2]	$7.12 to $7.27
Acquisition- and divestiture-related costs	$3,285
Restructuring costs	400
(Income) loss from investments in equity securities	485
Net decrease (increase) in income before taxes	$4,170
Estimated income tax (benefit) expense	(725)
Decrease (increase) in net income	$3,445

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 1774118. Members of the media are invited to monitor the call by dialing (833) 353-0277 or (469) 886-1947 and using ID code number 1774118. 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 over 130 years, Merck, known as MSD outside 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 candidates that the candidates 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 2020 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).