News Release

FOR IMMEDIATE RELEASE

Merck Announces Fourth-Quarter and Full-Year 2022 Financial Results

- Fourth-Quarter and Full-Year 2022 Results Reflect Sustained Strong Revenue Growth
- Fourth-Quarter 2022 Worldwide Sales Were $13.8 Billion, an Increase of 2% From Fourth Quarter 2021; Growth Excluding the Impact of Foreign Exchange Was 8%
- Fourth-Quarter 2022 GAAP EPS From Continuing Operations Was $1.18; Fourth-Quarter 2022 Non-GAAP EPS Was $1.62
- Full-Year 2022 Worldwide Sales Were $59.3 Billion, an Increase of 22% From Full Year 2021; Growth Excluding LAGEVRIO Was 12%; Growth Excluding LAGEVRIO and the Impact of Foreign Exchange Was 15%
    - KEYTRUDA Sales Grew 22% to $20.9 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 27%
    - GARDASIL/GARDASIL 9 Sales Grew 22% to $6.9 Billion; Excluding the Impact of Foreign Exchange, Sales Grew 27%
- Full-Year 2022 GAAP EPS From Continuing Operations Was $5.71; Full-Year 2022 Non-GAAP EPS Was $7.48
- In 2022, Augmented Pipeline Through Strategic Business Development, Including Acquisition of Imago and Key Agreements With Moderna, Orna, Orion and Kelun-Biotech
- 2023 Financial Outlook
    - Anticipates Full-Year 2023 Worldwide Sales To Be Between $57.2 Billion and $58.7 Billion; Outlook Includes Approximately $1.0 Billion of LAGEVRIO Sales
    - Expects Full-Year 2023 GAAP EPS To Be Between $5.86 and $6.01; Expects Non-GAAP EPS To Be Between $6.80 and $6.95

RAHWAY, N.J., Feb. 2, 2023 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the fourth quarter and full year of 2022.

"2022 was an exceptional year for Merck, which is a testament to the profound impact our medicines and vaccines are having on patients globally," said Robert M. Davis, chairman and chief executive officer. “I am extremely proud of what our talented and dedicated colleagues have accomplished scientifically, commercially and operationally. Our science-led strategy is working as we continue to build a sustainable engine that will drive innovation and generate long-term value for patients and shareholders well into the next decade.”

Financial Summary

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

$ in millions, except EPS amounts	Fourth Quarter				Year Ended			
	2022	2021	Change	Change Ex-Exchange	Dec. 31, 2022	Dec. 31, 2021	Change	Change Ex-Exchange
Sales	$13,830	$13,521	2%	8%	$59,283	$48,704	22%	26%
GAAP net income[1]	3,017	3,820	-21%	-17%	14,519	12,345	18%	21%
Non-GAAP net income that excludes certain items[1,2]*	4,129	4,592	-10%	-7%	19,005	13,623	40%	43%
GAAP EPS	1.18	1.51	-22%	-17%	5.71	4.86	17%	21%
Non-GAAP EPS that excludes certain items[2]*	1.62	1.81	-10%	-7%	7.48	5.37	39%	43%

*Refer to table on page 11.

Generally Accepted Accounting Principles (GAAP) earnings per share (EPS) assuming dilution was $1.18 for the fourth quarter and $5.71 for the full year of 2022. Non-GAAP EPS was $1.62 for the fourth quarter and $7.48 for the full year of 2022. The declines in GAAP and non-GAAP EPS in the fourth quarter versus the prior year were primarily due to lower fourth quarter 2021 effective tax rates and the unfavorable impact of foreign exchange, partially offset by strong underlying business performance. The GAAP EPS decline in the fourth quarter also reflects the unfavorable impact of losses from investments in equity securities compared with gains in the prior year. Full-year 2022 and 2021 GAAP and non-GAAP EPS were negatively impacted by $0.22 and $0.65, respectively, related to an asset acquisition, and collaboration and licensing agreements.

Non-GAAP EPS excludes acquisition- and divestiture-related costs (including pretax intangible asset impairment research and development [R&D] charges of $780 million and $1.7 billion in the fourth quarter and full year of 2022, respectively, largely related to nemtabrutinib) and restructuring costs, as well as income and losses from investments in equity securities.

In 2022, the company changed the treatment of certain items for purposes of its non-GAAP reporting. Results for 2021 have been recast to conform to the new presentation. For more information, refer to the Form 8-K filed by the company on April 21, 2022.

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

[2] Merck is providing certain 2022 and 2021 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 because management uses non-GAAP results to assess performance. Management uses non-GAAP 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 a non-GAAP pre-tax income metric. 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. Non-GAAP results for 2021 have been recast to conform to presentation changes implemented in 2022.

Oncology Program Highlights

- Merck announced the following regulatory and clinical milestones for KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy:
    - KEYTRUDA approved by the U.S. Food and Drug Administration (FDA) as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥4 centimeters), II, or IIIA non-small cell lung cancer (NSCLC), based on the pivotal Phase 3 KEYNOTE-091 trial.
    - In collaboration with Moderna, Inc. (Moderna), positive topline results from the Phase 2b KEYNOTE-942/mRNA-4157-P201 trial, which showed that KEYTRUDA in combination with mRNA-4157/V940, an investigational personalized mRNA therapeutic cancer vaccine, demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of recurrence-free survival versus KEYTRUDA alone for the adjuvant treatment of patients with stage III/IV melanoma following complete resection.
    - In collaboration with Seagen Inc. and Astellas Pharma Inc., acceptance by the FDA for priority review of the supplemental Biologics License Application for KEYTRUDA in combination with Padcev®[3] (enfortumab vedotin-ejfv) for the treatment of patients with locally advanced or metastatic urothelial cancer who are not eligible to receive cisplatin-containing chemotherapy.
    - Positive topline results from the pivotal Phase 3 KEYNOTE-859 trial investigating KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with human epidermal growth factor receptor 2 (HER2)-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma.
    - Positive topline results from the Phase 3 KEYNOTE-966 trial investigating KEYTRUDA in combination with standard of care chemotherapy (gemcitabine and cisplatin) for the first-line treatment of patients with advanced or unresectable biliary tract cancer.
- Merck announced that Lynparza (olaparib), an oral PARP inhibitor being co-developed and co-commercialized with AstraZeneca, was approved in the European Union (EU) in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration-resistant prostate cancer in whom chemotherapy is not clinically indicated, based on the Phase 3 PROpel trial.

Vaccine Program Highlights

- Merck announced that an updated systematic literature review of 138 peer-reviewed studies observed that use of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] led to reductions in the rates of high-grade (precancerous) and low-grade cervical lesions, as well as reductions in certain non-cervical HPV-related diseases and HPV infection in women and men.

[3] Registered trademark of Seagen and Agensys.

Cardiovascular Program Highlights

- Merck will present results from the Phase 3 STELLAR study evaluating investigational sotatercept for the treatment of patients with pulmonary arterial hypertension, and from the Phase 2 study evaluating MK-0616, the company's investigational oral macrocyclic peptide PCSK9 inhibitor for the treatment of patients with hypercholesterolemia, at the American College of Cardiology's 72nd Annual Scientific Session together with the World Heart Federation's World Congress of Cardiology (ACC.23/WCC). Merck will host an investor event at ACC.23/WCC on March 6, 2023, to discuss these results. Further details will be announced at a later date.

Business Development Highlights

- Merck announced and successfully completed the acquisition of Imago BioSciences, Inc. (Imago), for an approximate total equity value of $1.35 billion, expanding Merck's growing hematology portfolio.
- Merck announced that it has expanded its relationship and entered into an exclusive license and collaboration agreement with Kelun-Biotech (a holding subsidiary of Sichuan Kelun Pharmaceutical Co., Ltd) to develop up to seven investigational preclinical antibody-drug conjugates (ADCs) for the treatment of cancer.

Environmental, Social and Governance (ESG) Updates

- Merck was named one of America's most JUST companies by JUST Capital and CNBC, ranking No. 1 in the pharmaceuticals and biotech industry for the third straight year and No. 26 overall of all companies named.
- Merck published its Sustainability Bond Allocation Report, which highlighted how the company's initial $1.0 billion sustainability bond is helping to drive progress across ESG focus areas.

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			
	2022	2021	Change	Change Ex-Exchange	Dec. 31, 2022	Dec. 31, 2021	Change	Change Ex-Exchange
Total Sales	$13,830	$13,521	2%	8%	$59,283	$48,704	22%	26%
Pharmaceutical	12,180	12,039	1%	9%	52,005	42,754	22%	28%
KEYTRUDA	5,450	4,577	19%	26%	20,937	17,186	22%	27%
GARDASIL / GARDASIL 9	1,470	1,528	-4%	6%	6,897	5,673	22%	27%
LAGEVRIO	825	952	-13%	2%	5,684	952	***	***
JANUVIA / JANUMET	913	1,393	-34%	-29%	4,513	5,288	-15%	-9%
PROQUAD, M-M-R II and VARIVAX	526	509	3%	6%	2,241	2,135	5%	7%
BRIDION	441	436	1%	7%	1,685	1,532	10%	16%
Lynparza*	292	268	9%	14%	1,116	989	13%	18%
Lenvima*	216	206	5%	9%	876	704	24%	28%
ROTATEQ	139	213	-35%	-31%	783	807	-3%	0%
SIMPONI	166	206	-19%	-8%	706	825	-14%	-4%
Animal Health	1,230	1,261	-2%	6%	5,550	5,568	0%	6%
Livestock	814	791	3%	12%	3,300	3,295	0%	7%
Companion Animals	416	470	-11%	-5%	2,250	2,273	-1%	4%
Other Revenues**	420	221	90%	-25%	1,728	382	***	87%

*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 revenues from third-party manufacturing arrangements and miscellaneous corporate revenues, including revenue-hedging activities.

***>100%

Pharmaceutical Revenue

Fourth-quarter pharmaceutical sales grew 1% to $12.2 billion. Excluding the unfavorable impact of foreign exchange, pharmaceutical sales grew 9%, primarily driven by oncology and hospital acute care, partially offset by diabetes.

Growth in oncology was largely driven by higher sales of KEYTRUDA, which rose 19% to $5.5 billion in the quarter. Global sales growth of KEYTRUDA reflects continued strong momentum from metastatic indications including certain types of NSCLC, renal cell carcinoma, head and neck squamous cell carcinoma, triple-negative breast cancer (TNBC) and microsatellite instability-high (MSI-H) cancers, and increased uptake across recent earlier-stage launches, including certain types of neoadjuvant/adjuvant TNBC in the U.S. Also contributing to growth in oncology was increased alliance revenue from Lynparza, which grew 9% to $292 million, driven primarily by higher demand in the U.S. In addition, sales of WELIREG (belzutifan), an oral hypoxia-inducible factor-2 alpha inhibitor, increased to $40 million due to continued uptake in the U.S. following the product's launch in 2021.

Growth in hospital acute care reflects higher sales of ZERBAXA (ceftolozane and tazobactam), a combination cephalosporin antibacterial and beta-lactamase inhibitor for the treatment of patients with certain bacterial infections. ZERBAXA sales of $49 million in the fourth quarter of 2022 increased from $10 million in the fourth quarter of 2021, reflecting uptake

from the completion of the phased resupply in 2022 that was initiated in the fourth quarter of 2021. Growth in hospital acute care also reflects higher sales of PREVYMIS (letermovir), a medicine for prophylaxis of CMV infection and disease in adult CMV-seropositive recipients of an allogenic hematopoietic stem cell transplant, which increased 17% to $118 million, reflecting higher demand globally.

Vaccines sales performance reflects lower combined sales of GARDASIL and GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to prevent certain cancers and other diseases caused by HPV, which declined 4% to $1.5 billion. Excluding the unfavorable impact of foreign exchange, GARDASIL/GARDASIL 9 sales grew 6%, reflecting higher demand outside of the U.S., particularly in China. Vaccines sales performance also reflects lower sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, which declined 50% to $145 million, primarily reflecting lower U.S. demand as the market continues to shift toward newer adult pneumococcal conjugate vaccines. In addition, sales of ROTATEQ (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, declined 35% to $139 million, primarily due to lower sales in China, which benefited in the fourth quarter of 2021 from increased supply, and lower sales in the U.S. largely due to the timing of public-sector purchases. Vaccines sales performance benefited from the ongoing pediatric launch of VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine), a vaccine to help prevent invasive pneumococcal disease, which had sales of $138 million, largely due to inventory stocking in the U.S.

Pharmaceutical sales growth was partially offset by lower combined sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl), for the treatment of type 2 diabetes, which declined 34% to $913 million, primarily reflecting generic competition in certain international markets, particularly in Europe and the Asia Pacific region, and lower demand and net pricing in the U.S.

Sales of LAGEVRIO (molnupiravir), an investigational oral antiviral COVID-19 medicine, decreased 13% to $825 million. Excluding the unfavorable impact of foreign exchange, sales increased 2%, primarily driven by strong growth in Japan and the U.K. and the launch in Australia, offset by a decline in the U.S.

Full-year 2022 pharmaceutical sales grew 22% to $52.0 billion. Pharmaceutical sales growth was 16% excluding LAGEVRIO and the unfavorable impact of foreign exchange, primarily driven by higher sales in oncology, particularly KEYTRUDA, higher sales of vaccines, reflecting strong growth of GARDASIL/GARDASIL 9 and the ongoing pediatric launch of VAXNEUVANCE, as well as growth in hospital acute care products, including ZERBAXA and 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 ages 2 years and older undergoing surgery. Pharmaceutical sales growth in 2022 was partially offset by lower sales of JANUVIA and JANUMET, primarily reflecting lower demand in Europe as a result of generic competition, and a decline in PNEUMOVAX 23 sales as the U.S. market continues to shift toward newer adult pneumococcal conjugate vaccines. COVID-19-

related disruptions negatively affected sales in 2022, but to a lesser extent than in 2021, which benefited year-over-year sales growth.

Animal Health Revenue

Animal Health sales totaled $1.2 billion for the fourth quarter of 2022, a 2% decline compared with the fourth quarter of 2021. Excluding the unfavorable effect of foreign exchange, Animal Health sales increased 6%. Sales growth of livestock products reflects higher demand, notably in the ruminant and poultry product portfolio, which includes technology solutions products, as well as higher pricing. Sales of companion animal products were negatively impacted by a reduction in veterinary visits in the broader companion animal market following the more favorable trend during the pandemic, as well as supply constraints for certain vaccines, partially offset by higher pricing.

Full-year 2022 Animal Health sales were $5.5 billion, in line with the prior year. Excluding the unfavorable effect of foreign exchange, Animal Health sales grew 6%, primarily due to higher pricing. Full-year sales growth was also driven by higher demand of livestock products, led by ruminant, poultry and swine products. Sales of companion animal products also reflect higher demand for the BRAVECTO (fluralaner) parasiticide line of products, which had sales of $1.0 billion, partially offset by supply constraints for certain vaccines.

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

The tables below present selected expense information.

$ in millions **Fourth Quarter 2022**	**GAAP**	**Acquisition- and Divestiture-Related Costs**[4]	**Restructuring Costs**	**(Income) Loss From Investments in Equity Securities**	**Certain Other Items**	**Non-GAAP**[2]
Cost of sales	$3,881	$482	$38	$-	$-	$3,361
Selling, general and administrative	2,687	39	20	-	-	2,628
Research and development	3,775	740	-	-	-	3,035
Restructuring costs	49	-	49	-	-	-
Other (income) expense, net	(75)	(69)	-	80	-	(86)
Fourth Quarter 2021						
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	-	-	2,664
Restructuring costs	174	-	174	-	-	-
Other (income) expense, net	(333)	(3)	-	(381)	-	51

$ in millions Year Ended Dec. 31, 2022	GAAP	Acquisition- and Divestiture-Related Costs[4]	Restructuring Costs	(Income) Loss From Investments in Equity Securities	Certain Other Items	Non-GAAP[2]
Cost of sales	$17,411	$2,059	$205	$-	$-	$15,147
Selling, general and administrative	10,042	176	94	-	-	9,772
Research and development	13,548	1,676	30	-	-	11,842
Restructuring costs	337	-	337	-	-	-
Other (income) expense, net	1,501	(207)	-	1,348	-	360
Year Ended Dec. 31, 2021						
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	-	-	11,738
Restructuring costs	661	-	661	-	-	-
Other (income) expense, net	(1,341)	76	-	(1,884)	-	467

GAAP Expense, EPS and Related Information

Gross margin was 71.9% for the fourth quarter of 2022 compared with 71.4% for the fourth quarter of 2021. The increase primarily reflects favorable product mix and foreign exchange. Gross margin was 70.6% for the full year of 2022 compared to 72.0% for the full year of 2021. The decline primarily reflects the unfavorable impacts of higher amortization of intangible assets, as well as higher revenue from third-party manufacturing arrangements and sales of LAGEVRIO, both of which have lower gross margins. The full-year gross margin decline was partially offset by the favorable effects of product mix, foreign exchange and charges in the prior year related to the discontinuation of COVID-19 development programs.

Selling, general and administrative (SG&A) expenses were $2.7 billion in the fourth quarter of 2022, a decrease of 5% compared to the fourth quarter of 2021. The decrease primarily reflects lower acquisition- and divestiture-related costs and the favorable effect of foreign exchange, partially offset by higher promotional spending, as well as higher administrative costs. Full-year SG&A expenses were $10.0 billion, an increase of 4% compared to the full year of 2021. The increase primarily reflects higher administrative costs, as well as higher promotional spending, partially offset by the favorable impact of foreign exchange and lower acquisition- and divestiture-related costs.

R&D expenses were $3.8 billion in the fourth quarter of 2022, an increase of 23% compared to the fourth quarter of 2021. The increase was primarily driven by higher intangible asset impairment charges related to nemtabrutinib, which were $780 million in the fourth quarter of 2022 compared with $275 million in the fourth quarter of 2021, lower reimbursement of

[4] 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. R&D expenses include intangible asset impairment charges of $780 million and $1.7 billion in fourth quarter and full year 2022, respectively, and $275 million in both fourth quarter and full year 2021, largely related to nemtabrutinib, which was obtained as part of the 2020 acquisition of ArQule, Inc. Also includes integration, transaction and certain other costs related to acquisitions and divestitures.

LAGEVRIO R&D costs from Ridgeback Biotherapeutics (Ridgeback), higher compensation and benefit costs reflecting in part increased headcount to support expanded clinical development activity, and higher clinical development spending. R&D expenses were $13.5 billion for the full year of 2022, an increase of 11% compared with the full year of 2021. The increase was primarily driven by higher intangible asset impairment charges, which were $1.7 billion in 2022 compared with $275 million in 2021, largely related to nemtabrutinib, $690 million of charges in 2022 related to collaboration and licensing agreements with Moderna, Orna Therapeutics (Orna) and Orion Corporation (Orion), as well as higher compensation and benefit costs and clinical development spending. The increase was partially offset by a $1.7 billion charge in the prior year for the acquisition of Pandion Therapeutics, Inc. (Pandion).

Other (income) expense, net, was $75 million of income in the fourth quarter of 2022 compared to $333 million of income in the fourth quarter of 2021. Other (income) expense, net, was $1.5 billion of expense in the full year of 2022 compared to $1.3 billion of income in the full year of 2021. The change in both periods is primarily due to net losses from investments in equity securities in 2022 compared with net gains from investments in equity securities in 2021.

The effective tax rate for the fourth quarter of 2022 of 14.1% reflects the unfavorable impact of a higher than anticipated full-year rate of 11.7% due to a less favorable mix of income and expense than previously anticipated, while the effective tax rate for the fourth quarter of 2021 of 2.2% reflects the favorable impact of a lower than previously expected full-year 2021 rate of 11.0%.

GAAP EPS was $1.18 for the fourth quarter of 2022 compared to $1.51 for the fourth quarter of 2021. GAAP EPS was $5.71 for the full year of 2022 compared to $4.86 for the full year of 2021.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 75.7% for the fourth quarter of 2022 compared to 74.8% for the fourth quarter of 2021. The increase primarily reflects the favorable effects of product mix and foreign exchange. Non-GAAP gross margin was 74.4% for the full year of 2022 compared to 76.1% for the full year of 2021. The decrease primarily reflects the impact of higher revenue from third-party manufacturing arrangements and sales of LAGEVRIO, both of which have lower gross margins, partially offset by the favorable effects of product mix and foreign exchange.

Non-GAAP SG&A expenses were $2.6 billion in the fourth quarter of 2022, an increase of 1% compared to the fourth quarter of 2021. Non-GAAP SG&A expenses for the full year were $9.8 billion, an increase of 5% compared to the full year of 2021. The increase in both periods primarily reflects higher administrative costs, as well as higher promotional spending, partially offset by the favorable impact of foreign exchange.

Non-GAAP R&D expenses were $3.0 billion in the fourth quarter of 2022, an increase of 14% compared with the fourth quarter of 2021. The increase was primarily driven by lower reimbursement of LAGEVRIO R&D costs from Ridgeback, higher compensation and benefit costs reflecting in part increased headcount to support expanded clinical development activity,

and higher clinical development spending. Non-GAAP R&D expenses were $11.8 billion for the full year of 2022, an increase of 1% compared with the full year of 2021. The increase was primarily driven by $690 million of charges in 2022 related to collaboration and licensing agreements with Moderna, Orna and Orion, as well as higher compensation and benefit costs and clinical development spending. The increase was partially offset by a $1.7 billion charge in the prior year for the acquisition of Pandion.

Non-GAAP other (income) expense, net, was $86 million of income in the fourth quarter of 2022 compared to $51 million of expense in the fourth quarter of 2021. Non-GAAP other (income) expense, net, was $360 million of expense in the full year of 2022 compared to $467 million of expense in the full year of 2021.

The non-GAAP effective tax rate for the fourth quarter of 2022 of 15.6% reflects the unfavorable impact of a higher than anticipated full-year rate of 14.2% due to a less favorable mix of income and expense than previously anticipated, while the non-GAAP effective tax rate for the fourth quarter of 2021 of 4.3% reflects the favorable impact of a lower than previously expected full-year 2021 rate of 12.4%.

Non-GAAP EPS was $1.62 for the fourth quarter of 2022 compared to $1.81 for the fourth quarter of 2021. Non-GAAP EPS was $7.48 for the full year of 2022 compared to $5.37 for the full year of 2021.

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	
	2022	2021	Dec. 31, 2022	Dec. 31, 2021
EPS				
GAAP EPS	$1.18	$1.51	$5.71	$4.86
Difference	0.44	0.30	1.77	0.51
Non-GAAP EPS that excludes items listed below[2]	$1.62	$1.81	$7.48	$5.37
Net Income				
GAAP net income[1]	$3,017	$3,820	$14,519	$12,345
Difference	1,112	772	4,486	1,278
Non-GAAP net income that excludes items listed below[1,2]	$4,129	$4,592	$19,005	$13,623
Decrease (Increase) in Net Income Due to Excluded Items:				
Acquisition- and divestiture-related costs[4]	$1,192	$1,039	$3,704	$2,484
Restructuring costs	107	238	666	868
Loss (income) from investments in equity securities	80	(381)	1,348	(1,884)
Charges for the discontinuation of COVID-19 development programs	-	-	-	221
Other	-	(4)	-	-
Net decrease (increase) in income before taxes	1,379	892	5,718	1,689
Income tax (benefit) expense[5]	(267)	(120)	(1,232)	(411)
Decrease (increase) in net income	$1,112	$772	$4,486	$1,278

Financial Outlook

The following table summarizes the company's full-year 2023 financial guidance.

	GAAP	Non-GAAP[2]
Revenue*	$57.2 to $58.7 billion	$57.2 to $58.7 billion
Gross margin	Approximately 73%	Approximately 77%
Operating expenses**	$23.3 to $24.3 billion	$23.1 to $24.1 billion
Effective tax rate	17% to 18%	17% to 18%
EPS***	$5.86 to $6.01	$6.80 to $6.95

*Includes approximately $1.0 billion of LAGEVRIO sales. The company does not have any non-GAAP adjustments to revenue.

**Includes an aggregate $1.4 billion of R&D expenses related to the Imago acquisition and upfront payment for a license and collaboration agreement with Kelun-Biotech.

***Includes $0.53 of charges related to the Imago acquisition and upfront payment to Kelun-Biotech. EPS guidance for 2023 assumes a share count (assuming dilution) of approximately 2.55 billion shares.

Merck anticipates full-year 2023 revenue to be between $57.2 billion and $58.7 billion, including a negative impact of foreign exchange of approximately 2% at mid-January 2023 exchange rates. The company expects a significant decline in sales of LAGEVRIO, which are expected to be approximately $1.0 billion.

Merck expects full-year 2023 GAAP EPS to be between $5.86 and $6.01.

[5] 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.

Merck expects full-year 2023 non-GAAP EPS to be between $6.80 and $6.95, including a negative impact of foreign exchange of approximately 4%. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs, as well as income and losses from investment in equity securities.

In the fourth quarter of 2022, Merck announced the acquisition of Imago for an approximate total value of $1.35 billion and a license and collaboration agreement with Kelun-Biotech, which includes an upfront payment of $175 million. The Imago acquisition closed in January 2023 and the collaboration with Kelun-Biotech is expected to close in the first quarter of 2023, resulting in the inclusion of an aggregate $1.4 billion of R&D expenses in Merck's GAAP and non-GAAP results for the first quarter and full year of 2023. The Imago acquisition is also anticipated to result in an approximate 1 percentage point unfavorable impact to Merck's expected full-year 2023 GAAP and non-GAAP tax rates. The impact of these two transactions on expected full-year 2023 GAAP and non-GAAP EPS is approximately $0.53. GAAP and non-GAAP EPS in 2022 were negatively impacted by $0.22 of charges related to the collaboration and licensing agreements with Moderna, Orna and Orion.

Operating expenses include incremental R&D spending to advance the development of the Imago and Kelun-Biotech programs, as well as other promising programs related to the collaboration and licensing agreements with Moderna, Orna and Orion.

The financial outlook does not assume additional significant potential business development transactions.

A reconciliation of anticipated 2023 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 2023**
GAAP EPS	$5.86 to $6.01
Difference	$0.94
Non-GAAP EPS that excludes items listed below[2]	$6.80 to $6.95
Acquisition- and divestiture-related costs	$2,500
Restructuring costs	400
(Income) loss from investments in equity securities	(20)
Net decrease (increase) in income before taxes	$2,880
Estimated income tax (benefit) expense	(480)
Decrease (increase) in net income	$2,400

Earnings Conference Call

Investors, journalists and the general public may access a live audio webcast of the earnings conference call on Thursday, Feb. 2, at 8:00 a.m. ET via this weblink. A replay of the webcast, along with the sales and earnings news release, supplemental financial disclosures, and slides highlighting the results, will be available at www.merck.com.

All participants may join the call by dialing (888) 769-8514 (U.S. Toll-Free) or (517) 308-9208 (International) and using the access code 8206435.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. 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., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, 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 Annual Report on Form 10-K for the year ended December 31, 2021, 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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