NEWS RELEASE

Merck Announces Third-Quarter 2022 Financial Results

10/27/2022

- Third-Quarter Results Reflect Sustained Strong Business Momentum Across Key Growth Drivers as Well as Investment and Progress in the Pipeline
- Third-Quarter 2022 Worldwide Sales Were $15.0 Billion, an Increase of 14% From Third-Quarter 2021; LAGEVRIO Sales Were $436 Million; Growth Excluding LAGEVRIO Was 10%; Growth Excluding LAGEVRIO and the Impact From Foreign Exchange Was 14%; Sales Growth Favorably Impacted by COVID-19 Recovery
    - KEYTRUDA Sales Grew 20% to $5.4 Billion; Excluding the Impact From Foreign Exchange, Sales Grew 26%
    - GARDASIL/GARDASIL 9 Sales Grew 15% to $2.3 Billion; Excluding the Impact From Foreign Exchange, Sales Grew 20%
- Third-Quarter 2022 GAAP EPS From Continuing Operations Was $1.28; Non-GAAP EPS Was $1.85; GAAP and Non-GAAP EPS Include $0.22 of Charges Related to Collaboration and Licensing Agreements with Moderna, Orna and Orion
- Announced Positive Top-line Results From Pivotal Phase 3 STELLAR Trial Evaluating the Safety and Efficacy of Sotatercept
- 2022 Continuing Operations Financial Outlook:
    - Company Raises and Narrows Expected Full-Year 2022 Worldwide Sales To Be Between $58.5 Billion and $59.0 Billion, Reflecting Full-Year Growth of 20% to 21%, Growth of Approximately 12% Excluding LAGEVRIO; Outlook Includes Negative Impact From Foreign Exchange of Approximately 4%
    - Company Lowers Expected Full-Year 2022 GAAP EPS To Be Between $5.68 and $5.73
    - Company Raises and Narrows Expected Full-Year 2022 Non-GAAP EPS To Be Between $7.32 and $7.37, Including Negative Impact From Foreign Exchange of Approximately 4%

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the third quarter of 2022.

This press release features multimedia. View the full release here:
https://www.businesswire.com/news/home/20221027005289/en/

“We continue to execute on our strategy, invest in leading-edge science and drive innovation as our colleagues deliver meaningful value for patients – which in turn provides value for our shareholders,” said Robert M. Davis, chief executive officer and president, Merck. “Our third quarter results demonstrate exceptional revenue and underlying earnings growth and sustained performance across our key growth drivers. Inspired by our purpose of saving and improving lives around the world, I am confident we are well-positioned to continue to deliver strong operational performance.”

Financial Summary

	Third Quarter			
$ in millions, except EPS amounts	2022	2021	Change	Change Ex-Exchange
Sales	$14,959	$13,154	14%	18%
GAAP net income1	3,248	4,567	-29%	-25%
Non-GAAP net income that excludes certain items1,2*	4,703	4,525	4%	7%
GAAP EPS	1.28	1.80	-29%	-25%
Non-GAAP EPS that excludes certain items2*	1.85	1.78	4%	7%

*Refer to table on page 11.

Generally accepted accounting principles (GAAP) earnings per share (EPS) assuming dilution was $1.28 for the third quarter of 2022. Non-GAAP EPS of $1.85 for the third quarter of 2022 excludes acquisition- and divestiture-related costs 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.

Year-to-date results can be found in the attached tables.

Cardiovascular pipeline highlights

- Merck **announced** positive results from its pivotal Phase 3 STELLAR trial evaluating sotatercept, the company’s investigational activin receptor type IIA-Fc fusion protein, as an add-on to stable background therapy for the treatment of adults with pulmonary arterial hypertension. The trial met its primary efficacy outcome measure, demonstrating a statistically significant and clinically meaningful improvement in six-

minute walk distance (6MWD) from baseline at 24 weeks, and eight out of nine secondary efficacy outcome measures, including the outcome measure of proportion of participants achieving multicomponent improvement [defined as improvement in 6MWD, improvement in N-terminal pro-B-type natriuretic peptide level, and either improvement in WHO Functional Class (FC) or maintenance of WHO FC II] and the outcome measure of time to death or the first occurrence of a clinical worsening event. The Cognitive/Emotional Impacts domain score of PAH-SYMPACT®, which was assessed as the ninth and final secondary outcome measure, did not achieve statistical significance. Results will be presented at an upcoming scientific congress.

- Merck **received** a Fast Track designation from the U.S. Food and Drug Administration (FDA) for MK-2060, an investigational anticoagulant therapy for the reduction in risk of major thrombotic cardiovascular events in patients with end-stage renal disease.

Oncology program highlights

- Merck announced clinical trial results for KEYTRUDA (pembrolizumab), the company's anti-PD-1 therapy, and Lynparza (olaparib), an oral poly (ADP-ribose) PARP inhibitor being co-developed and co-commercialized with AstraZeneca, at the European Society for Medical Oncology Congress 2022, including:
    - Five-year overall survival (OS) **data** from the pivotal Phase 3 KEYNOTE-189 trial (KEYTRUDA plus pemetrexed and either cisplatin or carboplatin) in patients with metastatic nonsquamous non-small cell lung cancer (NSCLC) and the Phase 3 KEYNOTE-407 trial (KEYTRUDA plus carboplatin-paclitaxel or nab-paclitaxel) in patients with metastatic squamous NSCLC.
    - In collaboration with Seagen and Astellas, the first presentation of **data** from Cohort K of the Phase 1b/2 EV-103/KEYNOTE-869 trial evaluating Padcev (enfortumab vedotin-ejfv) in combination with KEYTRUDA as first-line treatment for patients with cisplatin-ineligible unresectable locally advanced or metastatic urothelial cancer.
    - Seven-year OS **data** from the Phase 3 SOLO-1 trial evaluating Lynparza as maintenance treatment in patients with advanced BRCA-mutated ovarian cancer, following first-line platinum-based chemotherapy, and final OS results from the Phase 3 PAOLA-1 trial evaluating Lynparza in combination with bevacizumab as maintenance treatment in patients with advanced ovarian cancer who were without evidence of disease after surgery or following response to platinum-based chemotherapy. The results of both trials were clinically meaningful in certain types of patients, but did not reach statistical significance.
- Merck **announced** that KEYTRUDA received four new approvals in Japan; KEYTRUDA is now approved in Japan for 23 uses in 11 different types of cancer, plus microsatellite instability-high (MSI-H) and tumor mutational burden-high solid tumors.
- Merck announced the following regulatory milestones for Lynparza:
    - Priority review **granted** by the FDA for a supplemental New Drug Application for Lynparza in

combination with abiraterone and prednisone or prednisolone for patients with metastatic castration-resistant prostate cancer (mCRPC), based on results from the Phase 3 PROpel trial. The Prescription Drug User Fee Act (PDUFA) date is in the fourth quarter of 2022.
    - Approved in the **European Union (EU)** and **Japan** as adjuvant treatment for patients with germline BRCA-mutated, HER2-negative high-risk early breast cancer, based on results from the Phase 3 OlympiA trial.
    - **Approved** in China as first-line maintenance treatment with bevacizumab for patients with homologous recombination deficient-positive advanced ovarian cancer, based on results from the Phase 3 PAOLA-1 trial.
- Merck provided updates on three Phase 3 trials: **KEYNOTE-412**, **KEYNOTE-921** and **LEAP-002**.

Vaccines program highlights

- Merck **announced** European Commission approval of an expanded indication for VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine) to include active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae (S. pneumoniae) in infants, children and adolescents from 6 weeks to less than 18 years of age.
- Merck received approval from China's National Medical Products Administration to expand the use of GARDASIL 9 [Human Papillomavirus (HPV) 9-valent Vaccine, Recombinant] for use in girls and women ages 9 to 45. The vaccine was previously approved for use in women ages 16 to 26.

Infectious diseases pipeline highlights

- Merck will **initiate** a new Phase 3 clinical program with islatravir for the treatment of people with HIV-1 infection. These new Phase 3 studies will evaluate a once-daily oral combination of doravirine 100 mg and islatravir (DOR/ISL) 0.25 mg.
- Merck and Gilead Sciences will **resume** the Phase 2 clinical trial evaluating an investigational oral once-weekly combination treatment regimen of islatravir and Gilead's lenacapavir in adults with HIV-1 infection who are virologically suppressed.
- Merck and Ridgeback Biotherapeutics (Ridgeback) **provided** an update on a preliminary analysis of the University of Oxford's open label prospective real-world evidence study, PANORAMIC, of LAGEVRIO (molnupiravir).

Business development highlights

- Merck and Moderna, Inc. (Moderna) **announced** that Merck has exercised its option to jointly develop and commercialize personalized cancer vaccine mRNA-4157/V940 pursuant to the terms of its existing collaboration and license agreement. mRNA-4157/V940 is currently being evaluated in combination with

KEYTRUDA as adjuvant treatment for patients with high-risk melanoma in a Phase 2 clinical trial being conducted by Moderna.

- Merck and Orna Therapeutics (Orna) **announced** a collaboration agreement to discover, develop and commercialize multiple programs, including vaccines and therapeutics in the areas of infectious diseases and oncology. This collaboration will combine Merck's expertise in nucleic acid biology, clinical development, and manufacturing with Orna's circular RNA technology.
- Merck and Orion Corporation (Orion) **formed** a global development and commercialization agreement for Orion's investigational candidate ODM-208/MK-5684 and other drugs targeting cytochrome P450 11A1 (CYP11A1), an enzyme important in steroid production. ODM-208/MK-5684 is an oral, non-steroidal inhibitor of CYP11A1 currently being evaluated in a Phase 2 clinical trial for the treatment of patients with mCRPC.
- Merck **acquired** Vence, an innovator in virtual fencing for rotational grazing and livestock management, which complements Merck Animal Health's broad portfolio of veterinary pharmaceuticals, vaccines and animal intelligence solutions.

Environmental, Social and Governance (ESG) highlights

- Merck **issued** its 2021/2022 ESG Progress Report, highlighting the company's performance and progress in ESG efforts across four main focus areas: Access to Health, Employees, Environmental Sustainability and Ethics & Values. These efforts come as part of a long-standing commitment to operating responsibly and creating value for patients and shareholders.
- Merck **launched** the Alliance for Equity in Cancer Care, an initiative to advance equity in cancer care in the U.S. by helping patients living in underserved communities receive timely access to high-quality, culturally responsive care.
- Merck was **recognized** on Fortune's 2022 Change the World list for its work to make HPV vaccines broadly available in underserved countries through partnerships and manufacturing investments.

Third-quarter revenue performance

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

	Third Quarter			
$ in millions	2022	2021	Change	Change Ex-Exchange
Total Sales	$14,959	$13,154	14%	18%
Pharmaceutical	12,963	11,496	13%	19%
KEYTRUDA	5,426	4,534	20%	26%
GARDASIL / GARDASIL 9	2,294	1,993	15%	20%

JANUVIA / JANUMET	1,133	1,339	-15%	-9%
PROQUAD, M-M-R II and VARIVAX	668	661	1%	3%
LAGEVRIO	436	0	-	-
BRIDION	423	369	15%	22%
Lynparza*	284	246	16%	23%
ROTATEQ	256	227	12%	16%
Lenvima*	202	188	7%	11%
SIMPONI	173	203	-15%	-2%
Animal Health	1,371	1,417	-3%	4%
Livestock	829	864	-4%	4%
Companion Animals	542	553	-2%	4%
Other Revenues**	625	241	***	41%

*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

Third-quarter pharmaceutical sales increased 13% to $13.0 billion. Pharmaceutical sales growth in the third quarter was 9% excluding LAGEVRIO sales and 15% excluding LAGEVRIO sales and the impact of foreign exchange, primarily driven by oncology, vaccines and hospital acute care products. The COVID-19 pandemic unfavorably affected sales in the third quarter of 2021 by approximately $350 million, which favorably impacted the growth rate in the third quarter of 2022.

Growth in oncology was largely driven by higher sales of KEYTRUDA, which rose 20% to $5.4 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 MSI-H cancers, and increased uptake across recent earlier-stage launches including certain types of neoadjuvant/adjuvant TNBC in the U.S.

Growth in vaccines was primarily driven by higher combined sales of GARDASIL (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant) and GARDASIL 9 vaccines to prevent certain cancers and other diseases caused by HPV. Third-quarter GARDASIL/GARDASIL 9 sales grew 15% to $2.3 billion, primarily driven by strong demand outside of the U.S., particularly in China, which also benefited from increased supply. Additionally, higher sales in the U.S. reflect public sector buying patterns. Growth in vaccines was partially offset by lower sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, which declined 53% to $131 million primarily reflecting lower U.S. demand as the market continues to shift toward newer adult pneumococcal conjugate 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 ages 2 years and older undergoing surgery. Sales increased 15% to $423 million, primarily due to an increase in its share among neuromuscular blockade reversal agents and an increase in surgical procedures. Growth in hospital acute care also reflects higher sales of ZERBAXA (ceftolozane and tazobactam), a combination cephalosporin antibacterial and beta-lactamase inhibitor for the treatment of adults with certain

bacterial infections. Sales of $43 million resulted from the phased resupply initiated in the fourth quarter of 2021, which has been completed in 2022.

Pharmaceutical sales growth was partially offset by lower combined sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl), which declined 15% to $1.1 billion, primarily reflecting lower demand and pricing in certain international markets as a result of generic competition, particularly in Europe, and lower demand in the U.S. The company lost market exclusivity for JANUVIA and JANUMET in China in July and in the EU in September, although JANUMET currently continues to have exclusivity in certain European markets.

Animal Health revenue

Animal Health sales totaled $1.4 billion for the third quarter of 2022, a decline of 3% compared with the third quarter of 2021. Excluding the unfavorable effect from foreign exchange, Animal Health sales grew 4% primarily reflecting higher pricing. Sales of livestock products also reflect higher demand for poultry products. Sales of companion animal products also reflect higher demand for the BRAVECTO (fluralaner) parasiticide line of products, partially offset by supply constraints for certain vaccines.

Third-quarter expense information

The tables below present selected expense information.

$ in millions	GAAP	Acquisition- and Divestiture-Related Costs [3]	Restructuring Costs	(Income) Loss from Investments in Equity Securities	Non-GAAP [2]
Third Quarter 2022					
Cost of sales	$3,934	$446	$54	$-	$3,434
Selling, general and administrative	2,520	22	26	-	2,472
Research and development	4,399	902	1	-	3,496
Restructuring costs	94	-	94	-	-
Other (income) expense, net	429	(26)	-	350	105
Third Quarter 2021					
Cost of sales	$3,450	$346	$48	$-	$3,056
Selling, general and administrative	2,336	61	5	-	2,270
Research and development	2,445	48	8	-	2,389
Restructuring costs	107	-	107	-	-
Other (income) expense, net	(450)	(10)	-	(684)	244

GAAP expense, EPS and related information

Gross margin was 73.7% for the third quarter of 2022 compared to 73.8% for the third quarter of 2021. The decrease primarily reflects the impacts of higher revenue from third-party manufacturing arrangements and sales of LAGEVRIO, both of which have lower gross margins, as well as higher acquisition- and divestiture-related costs.

The gross margin decline was largely offset by the favorable effects of product mix and foreign exchange.

Selling, general and administrative (SG&A) expenses were $2.5 billion in the third quarter of 2022, an increase of 8% compared to the third quarter of 2021. The increase primarily reflects higher administrative costs, including compensation and benefit costs, as well as higher promotional spending, partially offset by the favorable impact of foreign exchange.

Research and development (R&D) expenses were $4.4 billion in the third quarter of 2022 compared to $2.4 billion in the third quarter of 2021. The increase primarily reflects $887 million of intangible asset impairment charges related to the ArQule, Inc. acquisition, charges related to collaboration and licensing agreements with Moderna, Orna and Orion and higher clinical development spending.

Other (income) expense, net, was $429 million of expense in the third quarter of 2022 compared to $450 million of income in the third quarter of 2021, primarily due to net unrealized losses from investments in equity securities in the third quarter of 2022, compared to net unrealized income from investments in equity securities in the third quarter of 2021. Other (income) expense, net, in the third quarter of 2022 also reflects lower pension costs compared to the third quarter of 2021.

The effective income tax rate was 9.2% for the third quarter of 2022 compared to 13.2% in the third quarter of 2021.

GAAP EPS was $1.28 for the third quarter of 2022 compared to $1.80 for the third quarter of 2021.

Non-GAAP expense, EPS and related information

Non-GAAP gross margin was 77.0% for the third quarter of 2022 compared to 76.8% for the third quarter of 2021. The increase in non-GAAP gross margin primarily reflects the favorable effects of product mix and foreign exchange, largely offset by the impacts of higher revenue from third-party manufacturing arrangements and sales of LAGEVRIO, both of which have lower gross margins.

Non-GAAP SG&A expenses were $2.5 billion in the third quarter of 2022, an increase of 9% compared to the third quarter of 2021. The increase primarily reflects higher administrative costs, including compensation and benefit costs, as well as higher promotional spending, partially offset by the favorable impact of foreign exchange.

Non-GAAP R&D expenses were $3.5 billion in the third quarter of 2022 compared to $2.4 billion in the third quarter of 2021. The increase primarily reflects charges related to collaboration and licensing agreements with Moderna, Orna and Orion and higher clinical development spending.

Non-GAAP other (income) expense, net, was $105 million of expense in the third quarter of 2022 compared to $244 million of expense in the third quarter of 2021, reflecting lower pension costs.

The non-GAAP effective income tax rate was 13.6% for the third quarter of 2022 compared to 12.8% in the third quarter of 2021.

Non-GAAP EPS was $1.85 for the third quarter of 2022 compared to $1.78 for the third quarter of 2021.

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

	Third Quarter	
$ in millions, except EPS amounts	2022	2021
EPS		
GAAP EPS	$1.28	$1.80
Difference	0.57	(0.02)
Non-GAAP EPS that excludes items listed below2	$1.85	$1.78
Net Income		
GAAP net income1	$3,248	$4,567
Difference	1,455	(42)
Non-GAAP net income that excludes items listed below1,2	$4,703	$4,525
Decrease (Increase) in Net Income Due to Excluded Items:		
Acquisition- and divestiture-related costs3	$1,344	$445
Restructuring costs	175	168
Loss (income) from investments in equity securities	350	(684)
Net decrease (increase) in income before taxes	1,869	(71)
Estimated income tax (benefit) expense	(414)	29
Decrease (increase) in net income	$1,455	$(42)

Financial outlook

Beginning in 2022, Merck no longer excludes expenses for upfront and milestone payments related to collaboration and licensing agreements, or charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions from its non-GAAP results. Historically, the company excluded these charges to the extent they were considered by the company to be significant to the results of a particular period. These changes were made to align with views expressed by the U.S. Securities and Exchange Commission. Prior periods have been recast to reflect this change. For 2021, non-GAAP results have been recast to include $1.7 billion of incremental R&D expense, resulting in revised full-year 2021 EPS of $5.37.

Full-year 2022 GAAP and non-GAAP results include $690 million of incremental R&D expense, recorded in the third quarter of 2022, for collaboration and licensing agreements with Moderna, Orna and Orion which negatively impacts expected full-year EPS by $0.22.

As an on-going practice, the financial outlook will not include significant potential business development

transactions.

Merck continues to experience strong global momentum across its key pillars of growth, particularly in oncology and vaccines. As a result, Merck is raising and narrowing its full-year outlook for sales and non-GAAP EPS, despite a negative impact from foreign exchange.

At mid-October 2022 exchange rates, Merck expects sales growth of 20% to 21% in 2022, with full-year sales estimated to be between $58.5 billion and $59.0 billion, including a negative impact from foreign exchange of approximately 4%, including a less than 1% incremental negative impact from prior sales outlook. Excluding LAGEVRIO, Merck expects sales growth of approximately 12% for full-year 2022.

Merck expects its full-year non-GAAP effective income tax rate to be approximately 14%.

Merck is lowering its expected full-year 2022 GAAP EPS to be between $5.68 and $5.73.

Merck is raising and narrowing its expected full-year 2022 non-GAAP EPS to be between $7.32 and $7.37, including a negative impact from foreign exchange of approximately 4% at mid-October exchange rates. Operational strength of approximately $0.20 is partially offset by the following negative impacts, which were not reflected previously in the outlook:

- An option payment to Moderna of $250 million
- A less than 1% incremental impact from foreign exchange

The non-GAAP range excludes acquisition- and divestiture-related costs and costs related to restructuring programs as well as income and losses from investments in equity securities.

The company is narrowing its expected full year sales range of LAGEVRIO to be between $5.2 billion and $5.4 billion. 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 outlook.

	GAAP	Non-GAAP2
Sales	$58.5 to $59.0 billion	$58.5 to $59.0. billion*
Operating expenses	$22.5 to $22.9 billion	$21.3 to $21.7 billion
Effective tax rate	Approximately 11%	Approximately 14%
EPS**	$5.68 to $5.73	$7.32 to $7.37

*The company does not have any non-GAAP adjustments to sales.
**EPS outlook for 2022 assumes a share count (assuming dilution) of approximately 2.54 billion shares.

A reconciliation of anticipated full-year 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	$5.68 to $5.73
Difference	$1.64
Non-GAAP EPS that excludes items listed below2	$7.32 to $7.37
Acquisition- and divestiture-related costs	$3,400
Restructuring costs	600
(Income) loss from investments in equity securities	1,350
Net decrease (increase) in income before taxes	5,350
Estimated income tax (benefit) expense	(1,175)
Decrease (increase) in net income	$4,175

Earnings conference call

Investors, journalists and the general public may access a live audio webcast of the call Thursday, Oct. 27, 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**.

Participants may join the call by dialing (877) 692-8955 (USA Toll-Free) or (243) 720-6979 (USA Caller Paid). If you are calling from other countries, visit this **weblink**. All dial-in participants can use the access code 9646315. Journalists who wish to ask questions are requested to contact a member of Merck's Media Relations team.

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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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.
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.

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

On June 2, 2021, Merck completed the spin-off of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon). The

historical results of the businesses that were contributed to Organon in the spin-off are excluded from sales and expenses and reflected as discontinued operations in the company's Consolidated Statement of Income provided below.

	GAAP		% Change	GAAP		% Change
	3Q22	3Q21		Sep YTD 2022	Sep YTD 2021	
Sales	$ 14,959	$ 13,154	14%	$ 45,453	$ 35,183	29%
Costs, Expenses and Other						
Cost of sales	3,934	3,450	14%	13,530	9,752	39%
Selling, general and administrative	2,520	2,336	8%	7,355	6,804	8%
Research and development	4,399	2,445	80%	9,773	9,177	6%
Restructuring costs	94	107	-12%	288	487	-41%
Other (income) expense, net	429	(450)	*	1,576	(1,007)	*
Income from Continuing Operations Before Taxes	3,583	5,266	-32%	12,931	9,970	30%
Income Tax Provision	330	695		1,423	1,436	
Net Income from Continuing Operations	3,253	4,571	-29%	11,508	8,534	35%
Less: Net Income Attributable to Noncontrolling Interests	5	4		6	9	
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	3,248	4,567	-29%	11,502	8,525	35%
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	-	-	0%	-	766	*
Net Income Attributable to Merck & Co., Inc.	$ 3,248	$ 4,567	-29%	$ 11,502	$ 9,291	24%
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:						
Income from Continuing Operations	$ 1.28	$ 1.81	-29%	$ 4.55	$ 3.37	35%
Income from Discontinued Operations	-	-	0%	-	0.30	*
Net Income	$ 1.28	$ 1.81	-29%	$ 4.55	$ 3.67	24%
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:						
Income from Continuing Operations	$ 1.28	$ 1.80	-29%	$ 4.53	$ 3.36	35%
Income from Discontinued Operations	-	-	0%	-	0.30	*
Net Income	$ 1.28	$ 1.80	-29%	$ 4.53	$ 3.66	24%
Average Shares Outstanding	2,533	2,530		2,531	2,531	
Average Shares Outstanding Assuming Dilution	2,542	2,536		2,540	2,539	
Tax Rate from Continuing Operations	9.2%	13.2%		11.0%	14.4%	

* 100% or greater

MERCK & CO., INC.
THIRD QUARTER AND NINE MONTHS ENDED SEPTEMBER 30, 2022 GAAP TO NON-GAAP RECONCILIATION - CONTINUING OPERATIONS
(AMOUNTS IN MILLIONS, EXCEPT PER SHARE FIGURES)
(UNAUDITED)
Table 2a

	Acquisition and		(Income) Loss from		

	GAAP	Acquisition and Divestiture-Related Costs (1)	Restructuring Costs (2)	Losses from Investments in Equity Securities	Adjustment Subtotal	Non-GAAP
Third Quarter						
Cost of sales	$ 3,934	446	54		500	$ 3,434
Selling, general and administrative	2,520	22	26		48	2,472
Research and development	4,399	902	1		903	3,496
Restructuring costs	94		94		94	-
Other (income) expense, net	429	(26)		350	324	105
Income from Continuing Operations Before Taxes	3,583	(1,344)	(175)	(350)	(1,869)	5,452
Income Tax Provision (Benefit)	330	(302)(3)	(35)(3)	(77)(3)	(414)	744
Net Income from Continuing Operations	3,253	(1,042)	(140)	(273)	(1,455)	4,708
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	3,248	(1,042)	(140)	(273)	(1,455)	4,703
Earnings per Common Share Assuming Dilution from Continuing Operations	$ 1.28	(0.40)	(0.06)	(0.11)	(0.57)	$ 1.85
Tax Rate	9.2%					13.6%
Sep YTD						
Cost of sales	$ 13,530	1,577	167		1,744	$ 11,786
Selling, general and administrative	7,355	137	74		211	7,144
Research and development	9,773	936	30		966	8,807
Restructuring costs	288		288		288	-
Other (income) expense, net	1,576	(138)		1,268	1,130	446
Income from Continuing Operations Before Taxes	12,931	(2,512)	(559)	(1,268)	(4,339)	17,270
Income Tax Provision (Benefit)	1,423	(587)(3)	(97)(3)	(281)(3)	(965)	2,388
Net Income from Continuing Operations	11,508	(1,925)	(462)	(987)	(3,374)	14,882
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	11,502	(1,925)	(462)	(987)	(3,374)	14,876
Earnings per Common Share Assuming Dilution from Continuing Operations	$ 4.53	(0.76)	(0.18)	(0.39)	(1.33)	$ 5.86
Tax Rate	11.0%					13.8%

Only the line items that are affected by non-GAAP adjustments are shown.
Merck is providing certain non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing non-GAAP information enhances investors' understanding of the company's results because management uses non-GAAP measures 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 pretax income metric. The non-GAAP information presented should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP.
(1) Amounts included in cost of sales primarily reflect expenses for the amortization of intangible assets. Amounts included in selling, general and administrative expenses reflect integration, transaction and certain other costs related to acquisitions and divestitures. Amounts included in research and development expenses for the third quarter and nine month period primarily reflect $887 million of intangible asset impairment charges related to the ArQule, Inc. acquisition and expenses for the amortization of intangible assets. Amounts included in other (income) expense, net, for the third quarter and nine month period primarily reflect royalty income and a decrease in the estimated fair value measurement of liabilities for contingent consideration related to the prior termination of the Sanofi-Pasteur MSD joint venture.
(2) Amounts primarily include employee separation costs and accelerated depreciation associated with facilities to be closed or divested related to activities under the company's formal restructuring programs.
(3) Represents the estimated tax impacts on the reconciling items based on applying the statutory rate of the originating territory of the non-GAAP adjustments.

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

	2022				2021						3Q		September YTD	
	1Q	2Q	3Q	Sep YTD	1Q	2Q	3Q	Sep YTD	4Q	Full Year	Nom %	Ex-Exch %	Nom %	Ex-Exch %
TOTAL SALES (1)	$15,901	$14,593	$14,959	$45,453	$10,627	$11,402	$13,154	$35,183	$13,521	$48,704	14	18	29	32
PHARMACEUTICAL	14,107	12,756	12,963	39,826	9,238	9,980	11,496	30,714	12,039	42,754	13	19	30	35
Oncology														
Keytruda	4,809	5,252	5,426	15,487	3,899	4,176	4,534	12,609	4,577	17,186	20	26	23	28
Alliance Revenue – Lynparza (2)	266	275	284	825	228	248	246	721	268	989	16	23	14	20
Alliance Revenue – Lenvima (2)	227	231	202	660	130	181	188	498	206	704	7	11	33	36
Alliance Revenue – Reblozyl (3)	52	33	39	124					17	17	*	*	*	*
Vaccines(4)														
Gardasil / Gardasil 9	1,460	1,674	2,294	5,428	917	1,234	1,993	4,144	1,528	5,673	15	20	31	35
ProQuad / M-M-R II / Varivax	470	578	668	1,716	449	516	661	1,626	509	2,135	1	3	6	7
RotaTeq	216	173	256	644	158	208	227	593	213	807	12	16	9	11
Pneumovax 23	173	153	131	457	171	152	277	600	292	893	-53	-50	-24	-21
Vaqta	36	35	64	134	34	56	48	138	41	179	33	34	-3	-2
Hospital Acute Care														
Bridion	395	426	423	1,244	340	387	369	1,096	436	1,532	15	22	13	19
Prevymis	94	103	114	310	82	93	96	270	100	370	19	29	15	22
Dificid	52	66	77	196	27	34	54	115	60	175	42	42	70	70
Primaxin	58	64	63	185	65	60	70	194	65	259	-9	-5	-5	-3
Noxafil	57	60	62	180	67	66	64	197	62	259	-3	5	-9	-3
Invanz	52	46	50	148	57	48	53	157	45	202	-7	-1	-6	-1
Cancidas	53	42	43	138	57	54	56	168	45	212	-24	-19	-18	-15
Zerbaxa	30	46	43	120	(8)	(1)	(2)	(11)	10	(1)	*	*	*	*
Cardiovascular														
Alliance Revenue - Adempas/Verquvo (5)	72	98	88	258	74	74	100	248	94	342	-12	-12	4	4
Adempas (6)	61	63	57	181	55	74	59	188	63	252	-5	12	-4	8
Virology														
Lagevrio	3,247	1,177	436	4,859					952	952	*	*	*	*
Isentress / Isentress HD	158	147	161	466	209	192	189	590	178	769	-15	-11	-21	-17
Neuroscience														
Belsomra	69	69	62	199	79	78	81	238	80	318	-24	-12	-16	-7
Immunology														
Simponi	186	181	173	540	214	202	203	619	206	825	-15	-2	-13	-2
Remicade	61	53	49	163	85	75	73	233	67	299	-33	-22	-30	-21
Diabetes (7)														
Januvia	779	756	717	2,252	809	784	852	2,445	878	3,324	-16	-10	-8	-3
Janumet	454	476	417	1,347	486	477	487	1,449	514	1,964	-14	-7	-7	-1
Other Pharmaceutical (8)	520	479	564	1,565	554	512	518	1,589	533	2,118	9	17	-1	3
ANIMAL HEALTH	1,482	1,467	1,371	4,320	1,418	1,472	1,417	4,307	1,261	5,568	-3	4	-	6
Livestock	832	826	829	2,486	819	821	864	2,503	791	3,295	-4	4	-1	6
Companion Animals	650	641	542	1,834	599	651	553	1,804	470	2,273	-2	4	2	6
Other Revenues (9)	312	370	625	1,307	(29)	(50)	241	162	221	382	159	41	*	*

* 200% or greater
Sum of quarterly amounts may not equal year-to-date amounts due to rounding.
(1) Only select products are shown.
(2) Alliance Revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.
(3) Alliance Revenue represents royalties and a milestone payment.
(4) Total Vaccines sales were $2,481 million, $2,709 million and $3,552 million in the first, second and third quarter of 2022, respectively, and $1,809 million, $2,293 million, $3,315 million and $2,715 million in the first, second, third and fourth quarter of 2021, respectively.
(5) Alliance Revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs.

(6) Net product sales in Merck's marketing territories.
(7) Total Diabetes sales were $1,305 million, $1,300 million and $1,231 million in the first, second and third quarter of 2022, respectively, and $1,363 million, $1,330 million, $1,417 million and $1,475 million in the first, second, third and fourth quarter of 2021, respectively.
(8) Includes Pharmaceutical products not individually shown above.
(9) Other Revenues are comprised primarily of revenues from third-party manufacturing arrangements and miscellaneous corporate revenues, including revenue-hedging activities. Other Revenues related to the receipt of upfront and milestone payments for out-licensed products were $114 million, $32 million and $10 million in the first, second and third quarter of 2022, respectively, and $56 million, $135 million and $27 million in the first, third and fourth quarter of 2021, respectively.

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