



Merck Q3 2023 Earnings

October 26, 2023



Agenda



Strategy and Business Update

Rob Davis
Chairman and Chief
Executive Officer



Business/Financial Results and Outlook

Caroline Litchfield
Chief Financial Officer



Research Update

Dr. Dean Li
President, Merck
Research Laboratories



Question & Answer Session

Forward-looking statement of Merck & Co., Inc., Rahway, N.J., USA

This presentation 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, 2022 and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).



Strategy and Business Update

Rob Davis

Chairman and Chief Executive Officer



Delivered on our key strategic priorities in Q3 2023



Advanced the pipeline to meet patient unmet need



Executed on strategic business development to augment pipeline



Achieved strong commercial and financial performance



Created long-term value for patients and shareholders



Strong Q3 sales performance and earnings growth¹

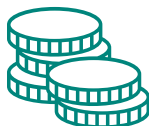


Q3 Worldwide Sales

\$16.0B

+7%

+8% ex-Exchange, ex-LAGEVRIO²

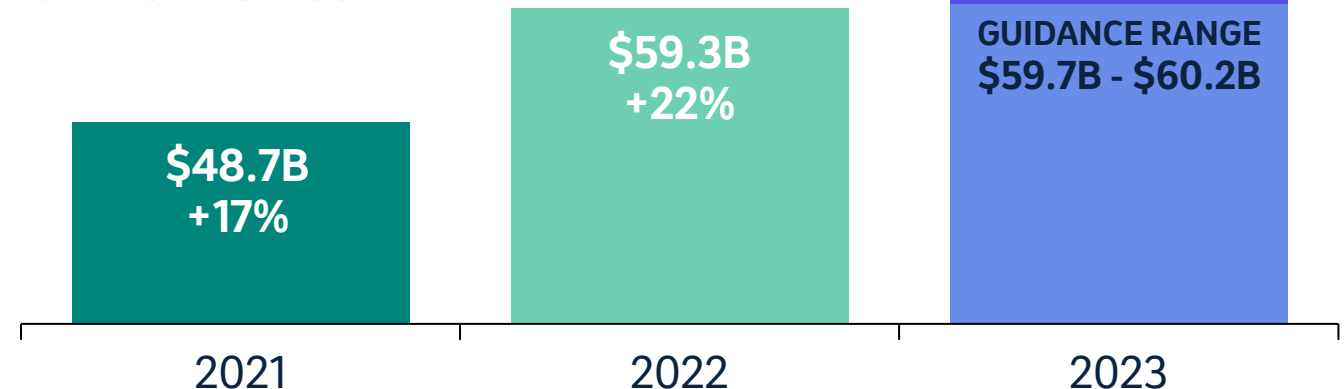


Q3 Non-GAAP EPS^{3,4}

\$2.13

+15%

Full Year Sales



Full Year Non-GAAP EPS³



1. Results from continuing operations attributable to Merck & Co., Inc. 2. Excludes Lagevrio sales of \$640 million in 3Q23 and \$436 million in 3Q22. 3. Merck does not exclude expenses for upfront and milestone payments related to collaborations and licensing agreements, or charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions from its non-GAAP results. YTD 2023 non-GAAP results include an aggregate \$11.6 billion or \$4.52 per share of R&D expenses related to the Prometheus and Imago acquisitions and upfront payment for the license and collaboration agreement with Kelun-Biotech. Full year 2022 non-GAAP results include \$690 million or \$0.22 of such charges. Full year 2021 non-GAAP results include \$1.7 billion or \$0.65 of such charges. For 2023, guidance includes an additional \$5.5 billion or \$1.70 per share related to the collaboration with Daiichi Sankyo, and guidance does not assume any additional significant potential business development transactions. 4. GAAP EPS of \$1.86.

Advancing and enhancing our deep pipeline

Oncology Highlights

- **KEYNOTE-671:** Received FDA approval for KEYTRUDA for the neoadjuvant and adjuvant treatment of certain patients with resectable non-small cell lung cancer
- **ESMO:** Compelling data presented across a wide range of molecules, tumor types and indications

Cardiometabolic Highlights

- **Sotatercept:** FDA accepted for priority review the BLA for sotatercept for the treatment of adults with pulmonary arterial hypertension based on STELLAR
- **MK-0616:** Started Phase 3 program for oral PCSK9 inhibitor candidate

Continuing to deliver on our purpose for patients



**Pursuing
transformative
science to save
and improve lives
around the world**



Business/Financial Results and Outlook

Caroline Litchfield
Chief Financial Officer



Strong underlying Q3 worldwide sales growth



Merck

WORLDWIDE SALES^{1,2}

\$16.0B

+7% growth
+6% ex-LAGEVRIO³
+8% ex-exchange, ex-LAGEVRIO³



Human Health

\$14.3B

+10% growth
+9% ex-LAGEVRIO³
+10% ex-exchange, ex-LAGEVRIO³



Animal Health

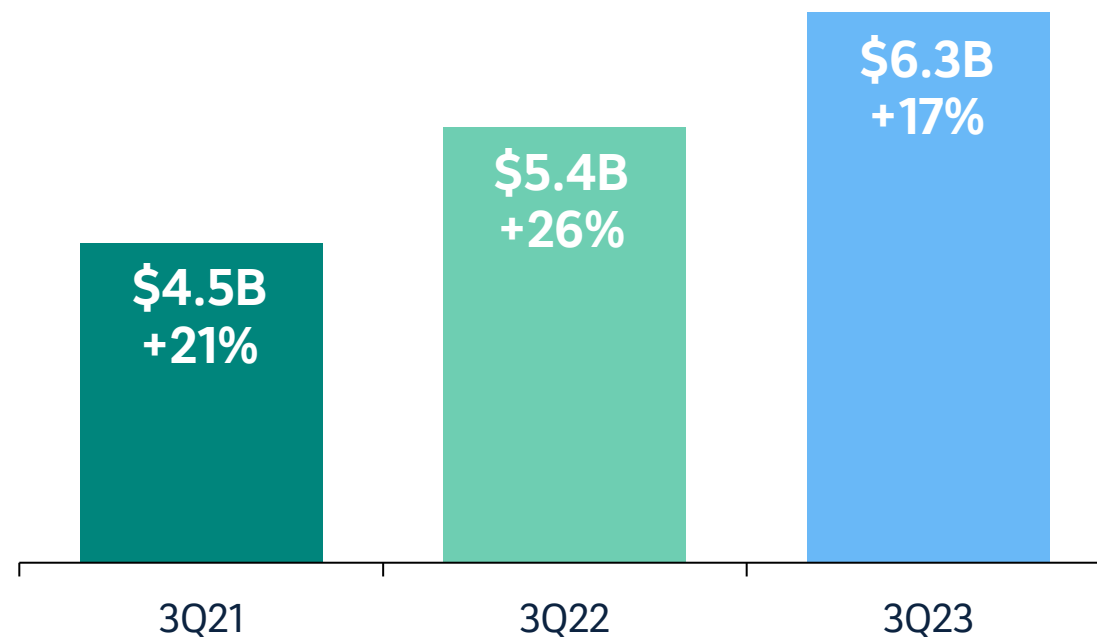
\$1.4B

+2% growth
+2% ex-exchange

Oncology: KEYTRUDA continues to drive exceptional growth

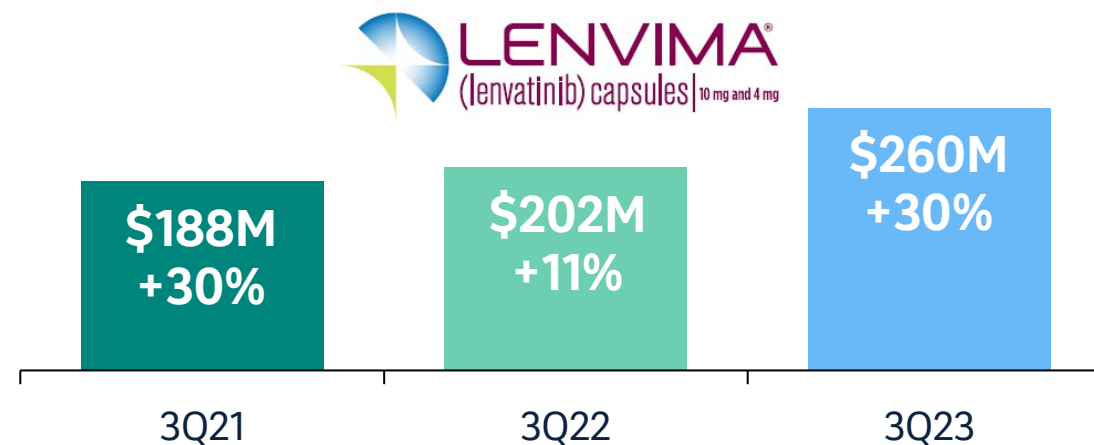
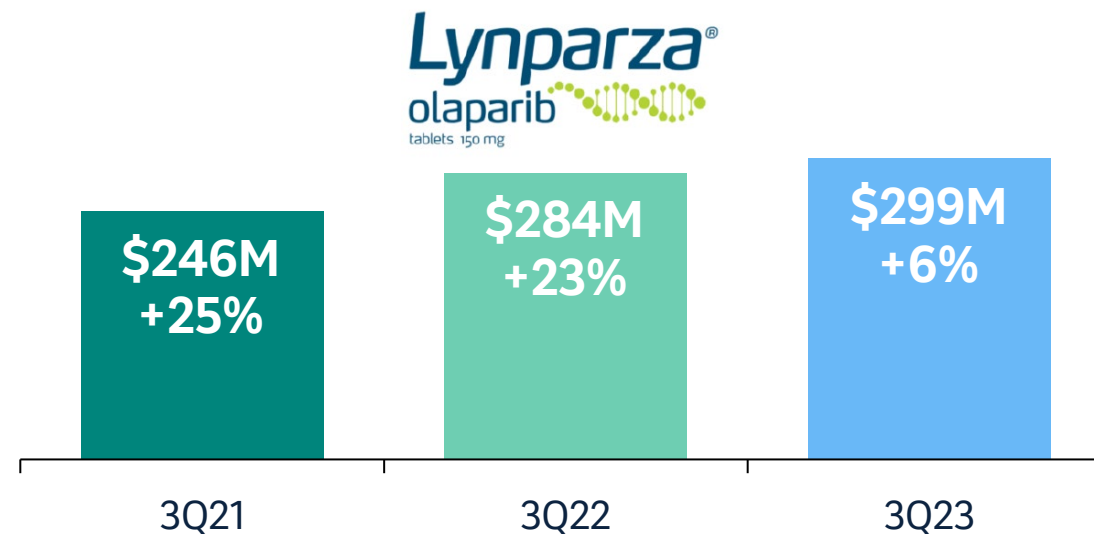
- KEYTRUDA sales of \$6.3B increased 17% year-over-year, driven by global uptake in earlier stage cancers and continued strong global demand from metastatic indications
 - In the U.S., growth of 14% reflects strong utilization across metastatic indications and earlier stage cancers, such as TNBC
 - Ex-U.S., 22% increase driven by uptake in earlier stage cancers, including high-risk early-stage TNBC and adjuvant RCC, as well as increased demand in advanced RCC and certain types of H&N cancer

KEYTRUDA®
(pembrolizumab) Injection 100 mg



Oncology: Solid performance across broad portfolio

- Lynparza¹ sales grew 6% driven primarily by pricing in the U.S. and increased demand in Latin America
- Lenvima² sales grew 30% driven by timing of shipments in China and increased demand in advanced RCC and endometrial cancer indications in the U.S.

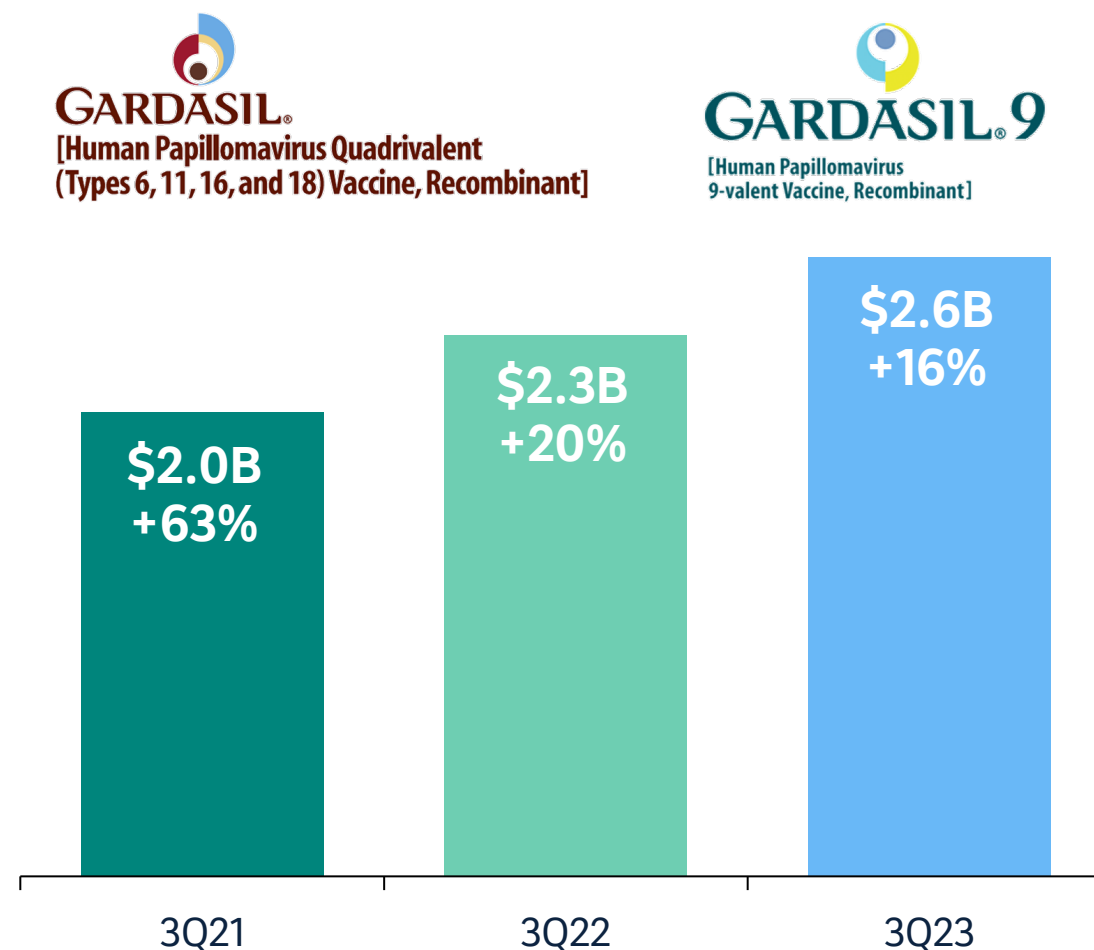


Growth rates exclude the impact of foreign exchange.

1. In collaboration with AstraZeneca 2. In collaboration with Eisai

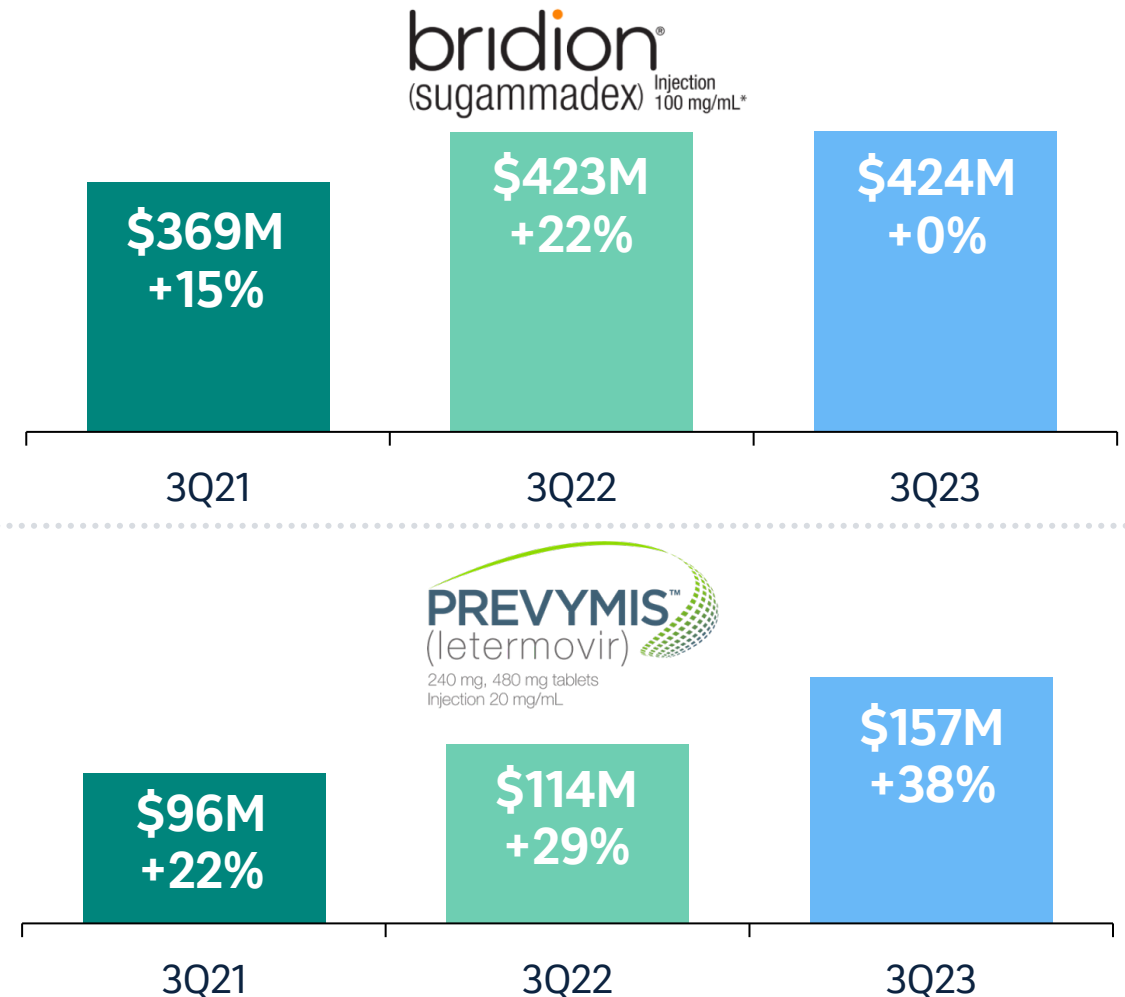
Vaccines: Robust growth driven by GARDASIL

- GARDASIL sales of \$2.6B increased 16% year-over-year driven by strong demand, particularly in China
 - In the U.S., sales decreased due to the timing of CDC purchases
- Strong uptake of the pediatric indication of VAXNEUVANCE in the U.S. and launches in key European markets



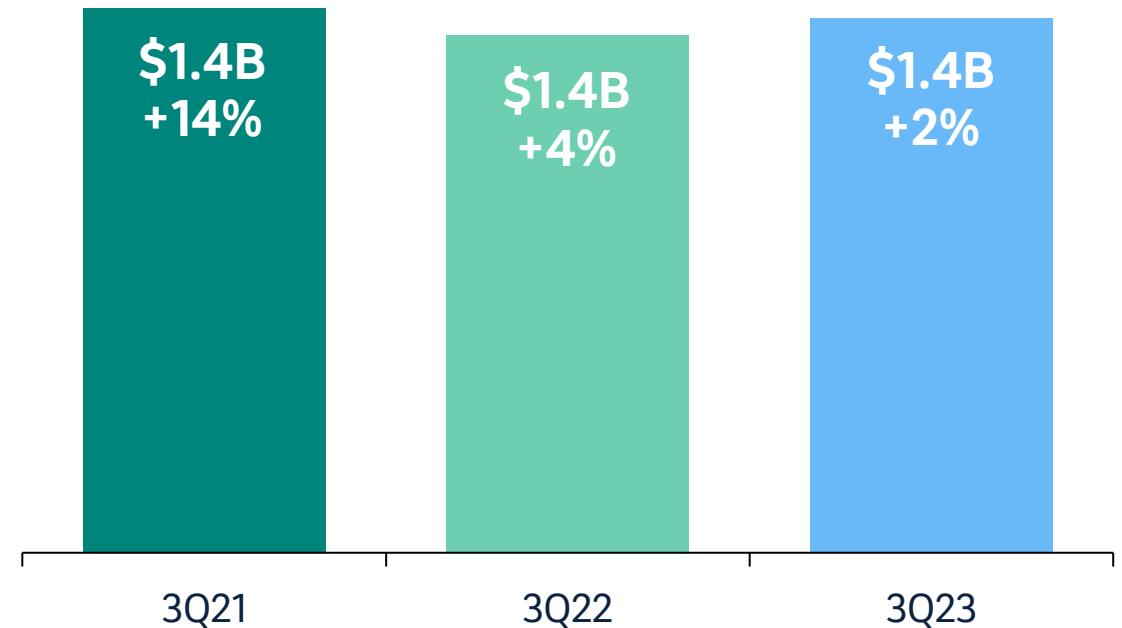
Hospital: Contributions from key products

- BRIDION sales of \$424M were flat as greater share among neuromuscular blockade reversal agents in the U.S. was offset by the impact of generic entry primarily in Europe
- PREVYMIS sales grew 38% driven by continued strong global demand



Animal Health: Growth driven by livestock

- Animal Health sales increased 2% to \$1.4B
 - Livestock growth of 7% reflects price actions and increased demand for ruminant, poultry and swine products
 - Companion Animal sales declined 4% due to a reduction in vet visits in the U.S., partially offset by pricing actions



Q3 2023 non-GAAP financial results summary¹

\$ in billions, except EPS amounts

	Q3 2023	Q3 2022	Change	Change Ex-FX
Sales	\$16.0	\$15.0	+7%	+9%
Non-GAAP Gross Margin	77.0%	77.0%	-0.1pts	+0.8pts
Non-GAAP Operating Expenses	\$5.8	\$6.0	-4%	-3%
Non-GAAP Tax Rate	15.0%	13.6%	+1.4pts	N/A
Non-GAAP EPS^{2,3}	\$2.13	\$1.85	+15%	+22%

1. Merck is providing certain 2023 and 2022 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 the earnings release. 2. Q3 2022 includes \$690 million of R&D expense for collaborations and licensing agreements with Moderna, Orna and Orion, or \$0.22 of negative impact to EPS. 3. Q3 2023 GAAP EPS of \$1.86.

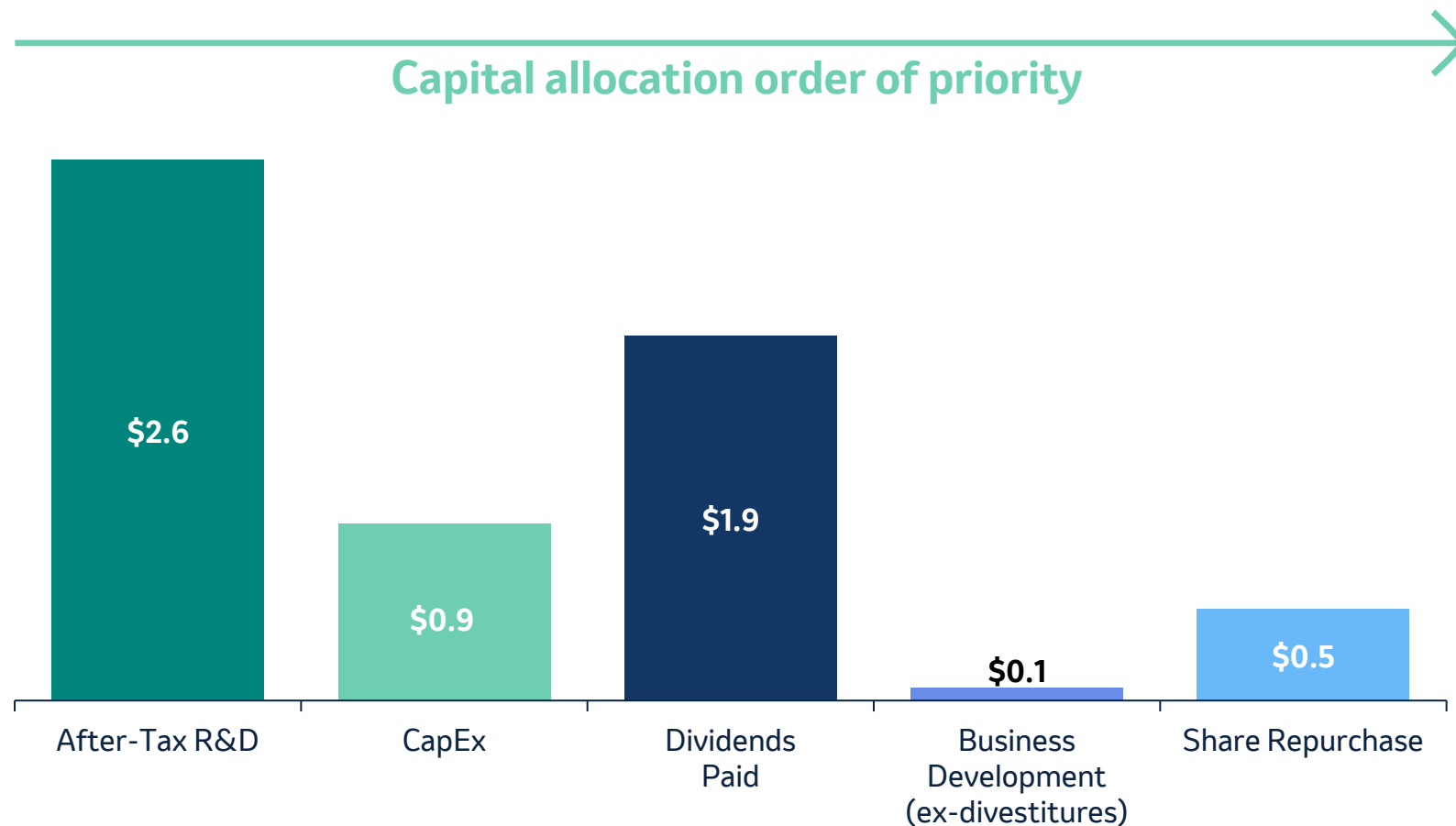
Merck updated full-year 2023 guidance

	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$58.6B to \$59.6B -1% to +1% (+1% to +3% ex-FX)	\$59.7B to \$60.2B +1% to +2% (+3% to +4% ex-FX)	<ul style="list-style-type: none"> Includes approximately \$1.3B of LAGEVRIO revenue Ex-LAGEVRIO, growth of 9% to 10% (11 to 12% ex-FX) Assumes ~2 ppt FX headwind
Non-GAAP Gross Margin Rate	~77.0%	~77.0%	
Non-GAAP Operating Expenses¹	\$34.0B to \$34.6B	\$39.8B to \$40.4B	<ul style="list-style-type: none"> Includes additional \$5.5B related to upfront charge for the collaboration with Daiichi Sankyo as well as investment to advance the assets
Other (Income) / Expense	~\$100M of expense	~\$200M of expense	<ul style="list-style-type: none"> Includes updated FX expectations and higher net interest expense related to the Daiichi Sankyo collaboration
Tax Rate	~30.5% to 31.5%	~39.0% to 40.0%	<ul style="list-style-type: none"> Includes ~24.5 ppt impact related to business development activity
Shares Outstanding	~2.55B	~2.55B	<ul style="list-style-type: none"> Assumes modest share repurchase
Non-GAAP EPS²	\$2.95 to \$3.05	\$1.33 to \$1.38	<ul style="list-style-type: none"> Includes \$1.70 one-time charge for the Daiichi Sankyo collaboration and an additional \$0.04 to advance the assets and finance the transaction Assumes 6 ppt FX headwind (additional \$0.05 headwind)

1. Updated guidance includes an aggregate \$17.1 billion of R&D expenses related to the Prometheus and Imago acquisitions, and upfront payments for the license and collaboration agreement with Kelun-Biotech and collaboration agreement with Daiichi Sankyo. Guidance does not assume any additional significant potential business development transactions. 2. Updated guidance includes \$6.22 of one-time charges related to the Prometheus and Imago acquisitions and upfront payments to Kelun-Biotech and Daiichi Sankyo.

Remain committed to balanced capital allocation strategy

\$ Billions¹



Continue to invest in our **pipeline** and **business** while augmenting our pipeline with value enhancing **business development**

1. Reflects Q3 spend.



Research Update

Dr. Dean Li

President, Merck Research Laboratories



Continuing to advance our oncology strategy

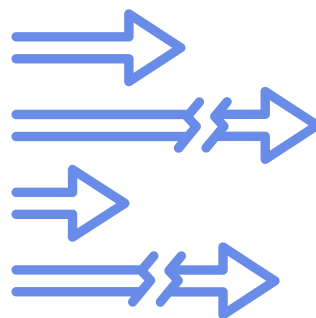
Immuno-oncology

Boost anti-tumor
immune responses



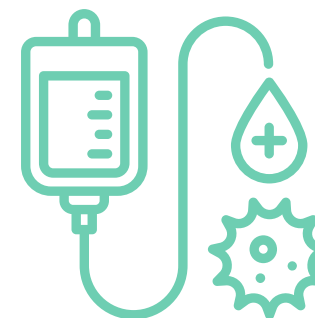
Precision Molecular Targeting

Impact pathways that
can drive cancer growth

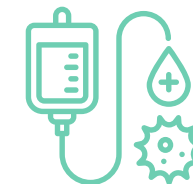


Tissue Targeting

Increase cancer cell
sensitivity with ADCs
and immune-engagers



Broadening and advancing our ADC presence



	U3-1402 (HER3-DXd)	MK-2870	DS-7300 (I-DXd)	DS-6000 (R-DXd)	MK-1200	1 additional clinical asset
Collaborator	Daiichi Sankyo	Kelun Biotech	Daiichi Sankyo	Daiichi Sankyo	Kelun Biotech	Kelun Biotech
Generic Name	Patritumab deruxtecan	Sacituzumab tirumotecan	Ifinatamab deruxtecan	Raludotatug deruxtecan	Undisclosed	Undisclosed
Target	HER3	TROP2	B7H3	CDH6	Claudin 18.2	Undisclosed
Status	Phase 3 ¹	Phase 3	Phase 2	Phase 1	Phase 1	Phase 1
Current Tumor Types ²	EGFRm NSCLC, Breast	NSCLC, Breast	ES-SCLC, Advanced Solid Tumors	Ovarian	GI Tumors	Undisclosed

KEYNOTE-A39 / EV-302³

Data presented at **ESMO** from **Phase 3** study evaluating **KEYTRUDA** in combination with enfortumab vedotin in 1L locally advanced or metastatic urothelial carcinoma

1. Planning to submit a biologics license application (BLA) in the U.S. by the end of March 2024 based on the Phase 2 HERTHENA-Lung01 data in EGFRm NSCLC that has progressed after EGFR TKI and platinum-based therapies 2. Shows tumor types currently being studied in various phases of development 3. Trial conducted in collaboration with Seagen and Astellas

Sharing data from our earlier stage oncology program



Lung

- **KEYNOTE-671:**

- Presented positive overall survival data at ESMO from Phase 3 study
- KEYTRUDA is the first and only anti-PD(L)-1 therapy to demonstrate statistically significant improvement in OS and EFS as perioperative treatment for resectable stage II, IIIA or IIIB NSCLC versus pre-operative chemotherapy
 - OS benefit generally consistent across majority of subgroups
- 6th KEYTRUDA indication for NSCLC to receive FDA approval

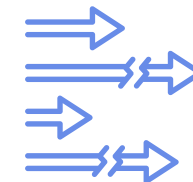
Women's Cancers

- Presented positive data at ESMO:
 - **KEYNOTE-756** in patients with ER+ HER2- breast cancer
 - **KEYNOTE-522** in patients with high-risk early-stage TNBC
 - **KEYNOTE-A18** in patients with high-risk locally advanced cervical cancer
 - FDA granted priority review with target action date of January 20th

Bladder

- **KEYNOTE-123:**
 - Announced Phase 3 trial evaluating KEYTRUDA for the adjuvant treatment of certain patients with localized muscle-invasive urothelial carcinoma and locally advanced urothelial carcinoma significantly improved disease-free survival

Leveraging precision medicine to improve outcomes for patients



WELIREG

- **Presented data at ESMO** from Phase 3 **LITESPARK-005** study for treatment of adults with previously treated **advanced RCC**, which showed statistically significant and clinically meaningful improvement in **progression-free survival** vs. everolimus (standard of care)
- FDA granted **priority review** with target action date of January 17th
- Proceeding with **additional Phase 3 studies**

MK-1084¹

- **Presented data at ESMO** for **oral KRAS inhibitor** as monotherapy in solid tumors and in combination with KEYTRUDA in patients with **metastatic NSCLC** whose tumors harbored KRAS G12C mutations

MK-3543

- **Began enrolling patients in Phase 3 study** evaluating bomedemstat (LSD1 inhibitor) in **2L essential thrombocythemia**

Bringing new cancer treatments to patients around the world

Europe

- Granted approval for **KEYNOTE-091** for adjuvant treatment of certain patients with **NSCLC**
- Granted approval for **KEYNOTE-811** for 1L treatment of patients with certain **gastric or gastroesophageal junction adenocarcinoma**

Japan

- Received approval for **Lynparza**¹ in combination with abiraterone and prednisone for treatment of certain adult patients with **BRCA-mutated metastatic castration-resistant prostate cancer** based on **Phase 3 PROpel study**

Significant advancements across our broader pipeline and portfolio

Vaccines

- **V116:**
 - **STRIDE-3 data** will be presented at **World Vaccine Congress West Coast on November 28th**
 - If approved, V116 would be the **first pneumococcal conjugate vaccine** designed to address serotypes responsible for the majority of **adult invasive pneumococcal disease**

Immunology

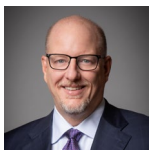
- **MK-7240:**
 - Beginning to enroll patients in **Phase 3 study** for treatment of patients with **ulcerative colitis**

Cardiometabolic

- **Sotatercept:**
 - Presented **post-hoc analysis from STELLAR** and **interim analysis from SOTERIA**, an open label extension study in **PAH**
 - **FDA granted priority review** for Biologics License Application with target action date of March 26th
 - **Completed submission to EMA** in the European Union
- **MK-0616:**
 - Initiated Phase 3 **CORALreef Lipids** study in broad patient population with **hypercholesterolemia**
 - Initiated Phase 3 **CORALreef HeFH** study for patients with **heterozygous familial hypercholesterolemia**
 - Enrollment has begun for **CORALreef Outcomes** study measuring time to first occurrence of **major atherosclerotic cardiovascular events** in high risk patients



Q&A



Rob Davis
Chairman & Chief Executive Officer



Caroline Litchfield
Chief Financial Officer



Dr. Dean Li
President, Merck Research Laboratories



Peter Dannenbaum
Vice President, Investor Relations



Appendix

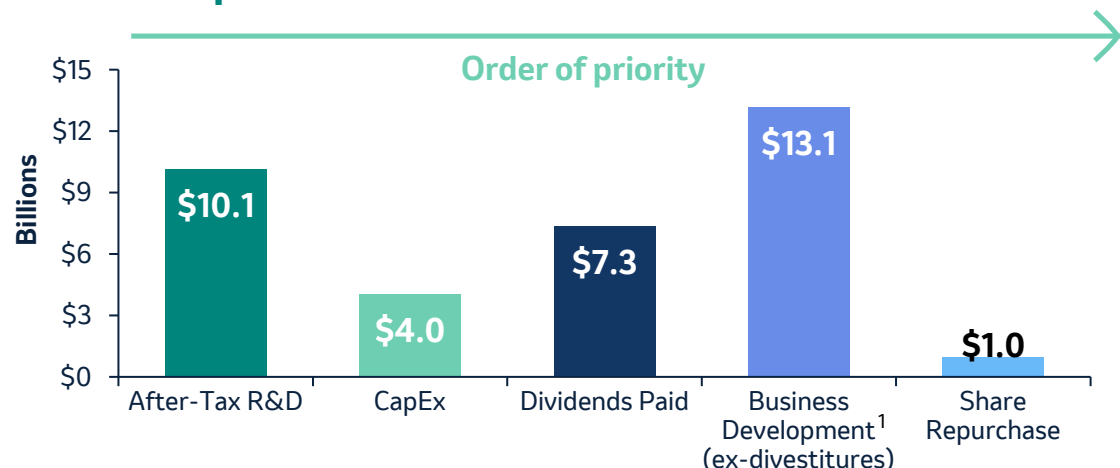
Q3 2023 GAAP financial results summary

\$ in billions, EPS amounts

	Q3 2023	Q3 2022	Change	Change Ex-FX
Sales	\$16.0	\$15.0	+7%	+9%
Operating Expenses	\$5.8	\$6.9	-16%	-16%
Tax Rate	15.5%	9.2%	+6.3pts	N/A
GAAP EPS	\$1.86	\$1.28	+45%	+55%

Capital allocation: Trailing twelve months

Over the past 12 months



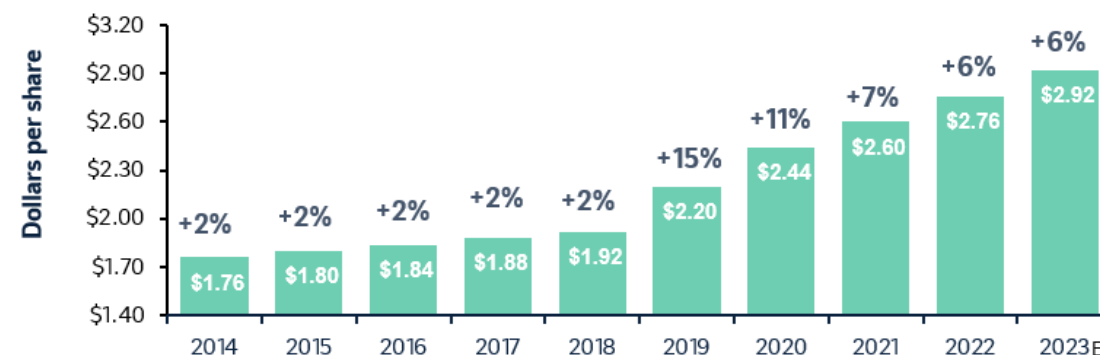
Capital investments 2023 to 2027

~\$18B

Over 5 years, including expanding manufacturing capacity for Oncology, Vaccines, and Animal Health. Includes >\$10B in the U.S.

Well positioned balance sheet
with capacity to fund
**additional value-enhancing
business development
opportunities**

Commitment to the dividend



1. Includes payments reflected in operating cash flow

Driving value for patients and shareholders by progressing our pipeline

Key regulatory milestones since the last earnings call:

- **In the U.S.:**
 - FDA accepted for priority review the sNDA for WELIREG for the treatment of patients with advanced RCC immune checkpoint and anti-angiogenic therapies based on LITESPARK-005
 - FDA accepted for priority review the sBLA for KEYTRUDA in combination with concurrent chemoradiotherapy for the treatment of patients with newly diagnosed high-risk locally advanced cervical cancer based on KN-A18
 - Received FDA approval for KEYTRUDA in the perioperative setting for the treatment of certain patients with resectable NSCLC based on KN-671
 - FDA approved KEYTRUDA for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell cancer based on KN-017 and KN-913
 - FDA accepted for priority review the BLA for sotatercept for the treatment of patients with PAH based on STELLAR
 - FDA approved an expanded indication for ERVEBO for the prevention of disease caused by Zaire ebolavirus in individuals 12 months of age and older
- **In the EU:**
 - Received EMA approval for KEYTRUDA in combination with trastuzumab and chemotherapy as 1L treatment in patients with HER2-positive advanced gastric or gastroesophageal junction adenocarcinoma in PD-L1 positive patients based on KN-811
 - Received EMA approval for KEYTRUDA in patients with adjuvant NSCLC based on KN-091
 - Received positive CHMP opinion for KEYTRUDA in combination with chemotherapy for 1L treatment of certain patients with locally advanced unresectable or metastatic HER2- gastric or GEJ adenocarcinoma based on KN-859
 - Received EMA approval for an expanded indication for ERVEBO for active immunization of individuals 12 months of age and older to protect against Ebola Virus Disease (EVD) caused by Zaire ebolavirus
- **In Japan:**
 - Received approval of Lynparza¹ in certain patients with BRCA-mutated castration-resistant prostate cancer
 - Accepted for review the sNDA for KEYTRUDA in the perioperative setting for the treatment of patients with resectable NSCLC based on KN-671

Key data & clinical advancements since the last earnings call:

- Presented data across broad oncology portfolio at ESMO, including for KEYTRUDA (KN-A39², KN-671, KN-A18, KN-522, KN-756, KN-811), Lenvima³, Lynparza¹, WELIREG (LITESPARK-005), V940/mRNA-4157⁴ (INT), MK-2870/SKB264⁵ (TROP2 ADC) and MK-1084⁶ (KRAS G12C)
- Announced Phase 3 KN-123 trial met one of its dual primary endpoints of disease-free survival for the adjuvant treatment of patients with localized muscle-invasive urothelial carcinoma and locally advanced urothelial carcinoma after surgery
- Presented new analyses from studies of sotatercept at ERS, including post-hoc analysis of right heart catheterization and echocardiography data from the STELLAR study and interim analysis of the Phase 3 SOTERIA open-label extension study
- Advanced broad pipeline, including:
 - Initiated Phase 3 clinical program for MK-0616, an oral PCSK9 inhibitor
 - Poised to initiate Phase 3 trials for V940⁴ in NSCLC, MK-2870⁵ in NSCLC and MK-7240 in UC

1. In collaboration with AstraZeneca 2. Trial conducted in collaboration with Seagen and Astellas 3. In collaboration with Eisai

4. In collaboration with Moderna 5. In collaboration with Kelun-Biotech 6. In collaboration with Taiho and Astex

Broad and innovative pipeline to address significant unmet medical needs

Phase 2				Phase 3		Under regulatory review
Oncology				Oncology		Oncology
MK-0482 NSCLC	KEYTRUDA (MK-3475) Advanced Solid Tumors Prostate	MK-4830 CRC Esophageal Melanoma NSCLC Ovarian RCC SCLC	WELIREG (MK-6482) Biliary Certain VHL tumors (EU) CRC Endometrial Esophageal HCC Pancreatic Rare Cancers	MK-7684A (vibostolimab +pembrolizumab) Biliary Bladder Breast Cervical CRC Endometrial Esophageal Gastric HCC HNSCC Ovarian Prostate	LENVIMA (MK-7902) Esophageal Gastric	KEYTRUDA (MK-3475) 2L HCC (US) LA Cervical (US) Resectable NSCLC (EU, JPN) 1L HER2- Gastric (US, EU, JPN) 1L Biliary (US, EU, JPN)
MK-1308 (quavonlimab) NSCLC	MK-3543 (bomedemstat) Myeloproliferative Disorders				LYNPARZA (MK-7339) NSCLC SCLC	
MK-1308A (quavonlimab +pembrolizumab) CRC SCLC	MK-4280 (favezelimab) NSCLC	MK-5684 Prostate	TUKYSA (MK-7119) Advanced Solid Tumors Bladder Biliary Cervical Endometrial Gastric NSCLC		WELIREG (MK-6482) RCC (EU)	WELIREG (MK-6482) Advanced RCC (US)
MK-2140 (zilovertamab vedotin) Bladder Breast Gastric Hematological Malignancies NSCLC Ovarian Pancreas	MK-4280A (favezelimab+ pembrolizumab) Bladder cSCC Esophageal Melanoma RCC SCLC	MK-5890 (boseralimab) NSCLC SCLC			TUKYSA (MK-7119) Breast CRC	
MK-2870 Neoplasm Malignant		LYNPARZA (MK-7339) Advanced Solid Tumors			MK-3475A (pembrolizumab +hyaluronidase) NSCLC	
		LENVIMA (MK-7902) Biliary HNSCC Pancreas Prostate SCLC			V940 Melanoma	
Vaccines				Infectious diseases		General medicine
V181 Dengue Virus	Cardiovascular		General medicine			Gefapixant (MK-7264) Cough (US)
Infectious diseases	MK-2060 Thrombosis		MK-6024 (efinopegdutide) NASH			PREVYMIS (MK-8228) Prophylaxis of CMV in kidney transplant patients (EU)
MK-8591B (islatravir+MK-8507) ¹ HIV-1 Infection	MK-5475 Pulmonary Arterial Hypertension		Neuroscience			
MK-8591D (islatravir+lenacapavir) ² HIV-1 Infection	MK-7962 (sotatercept) Pulmonary Hypertension due to Left Heart Disease		MK-8189 ⁴ Schizophrenia			

¹On FDA clinical hold ²On FDA partial clinical hold for higher doses than those used in current clinical trials

³Available in the US under EUA ⁴Development is co-funded by Royalty Pharma

Note: Pipeline does not include the three DXd ADCs from the collaboration with Daiichi Sankyo