



Merck Q2 2023 Earnings

August 1, 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 & Business Update

Rob Davis

Chairman and Chief Executive Officer



Delivered on our key strategic priorities in Q2 2023



Advanced the pipeline to meet patient unmet need



Executed on strategic business development to enhance pipeline



Achieved strong commercial and financial performance



Created long-term value for patients and shareholders

Strong underlying Q2 performance¹

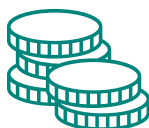


Q2 Worldwide Sales

\$15.0B

+3%

+14% ex-Exchange, ex-LAGEVRIO²



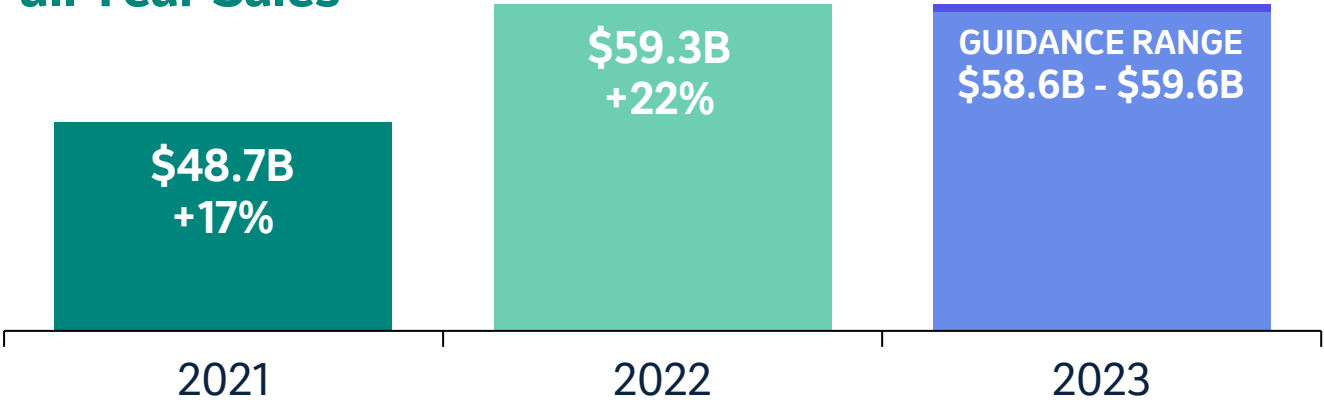
Q2 Non-GAAP LPS³

(\$2.06)

N/M⁴

Includes one-time charge of \$4.02 from Prometheus acquisition

Full Year Sales



Full Year Non-GAAP EPS⁵



1. Results from continuing operations attributable to Merck & Co., Inc. 2. Excludes Lagevrio sales of \$203 million in 2Q23 and \$1.2 billion in 2Q22. 3. GAAP LPS (Loss Per Share) of (\$2.35). Both 2Q23 GAAP and non-GAAP LPS reflect a charge of \$10.2 billion or \$4.02 per share for the acquisition of Prometheus Biosciences, Inc. 4. Not meaningful 5. 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 \$4.53 per share of R&D expenses related to the Prometheus and Imago acquisitions and upfront payment for the license and collaboration agreement with Kelun. 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, outlook does not assume any additional significant potential business development transactions.

Advancing and augmenting our deep pipeline

Oncology

- Highlighted important data at **ASCO**:
 - **KEYNOTE-671** for neoadjuvant and adjuvant for the treatment of **non-small cell lung cancer**
 - KEYTRUDA in combination with **V940¹**, our Individualized Neoantigen Therapy (INT) for the treatment of **adjuvant melanoma**
 - **MK-2870²**, our TROP-2 ADC, for the treatment of **non-small cell lung cancer**

Vaccines and Infectious Disease

- Announced **positive topline results for V116**, our pneumococcal conjugate vaccine candidate specifically designed for adults

General Medicine

Cardiometabolic

- Completed FDA submission of **sotatercept** in **PAH** based on the Phase 3 STELLAR trial
- Presented **Phase 2a data** at EASL for efinopegdutide, our **GLP-1** / glucagon receptor co-agonist, in **NAFLD**

Immunology

- Completed **acquisition of Prometheus Biosciences**

Putting the patient at the center of everything we do

**Guided by our purpose to
continue advancing
innovative science and
broadening access to
patients around the world**

2022/2023 Impact Report¹ forthcoming



1. Formerly called the ESG report



Business/Financial Results and Outlook

Caroline Litchfield
Chief Financial Officer



Strong underlying Q2 worldwide sales growth



Merck

WORLDWIDE SALES^{1,2}

\$15.0B

+3% growth
+11% ex-LAGEVRIO³
+14% ex-exchange, ex-LAGEVRIO³



Human Health

\$13.5B

+6% growth
+14% ex-LAGEVRIO³
+17% ex-exchange, ex-LAGEVRIO³



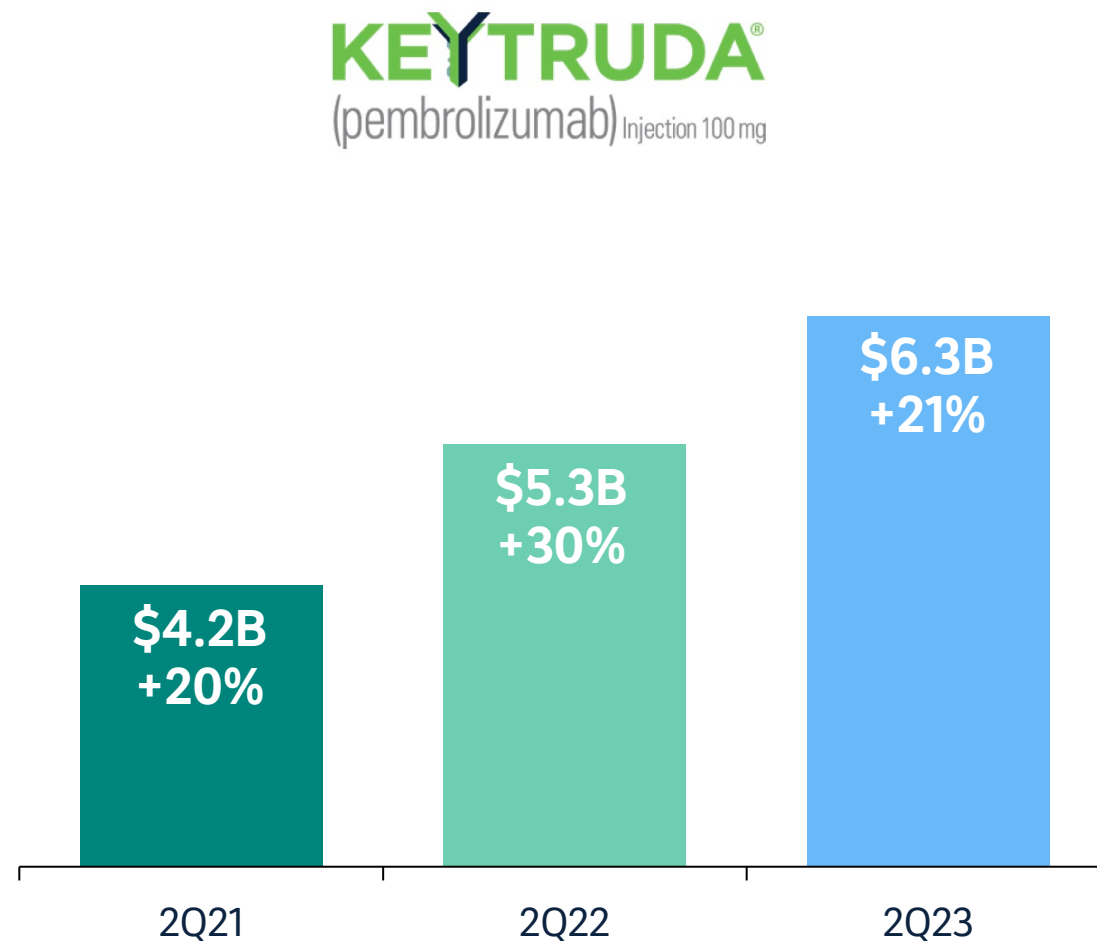
Animal Health

\$1.5B

-1% growth
+2% ex-exchange

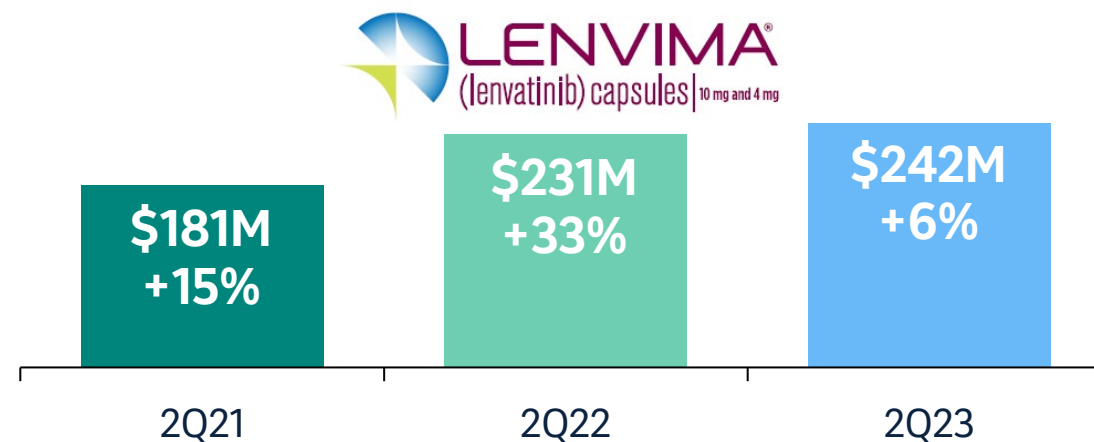
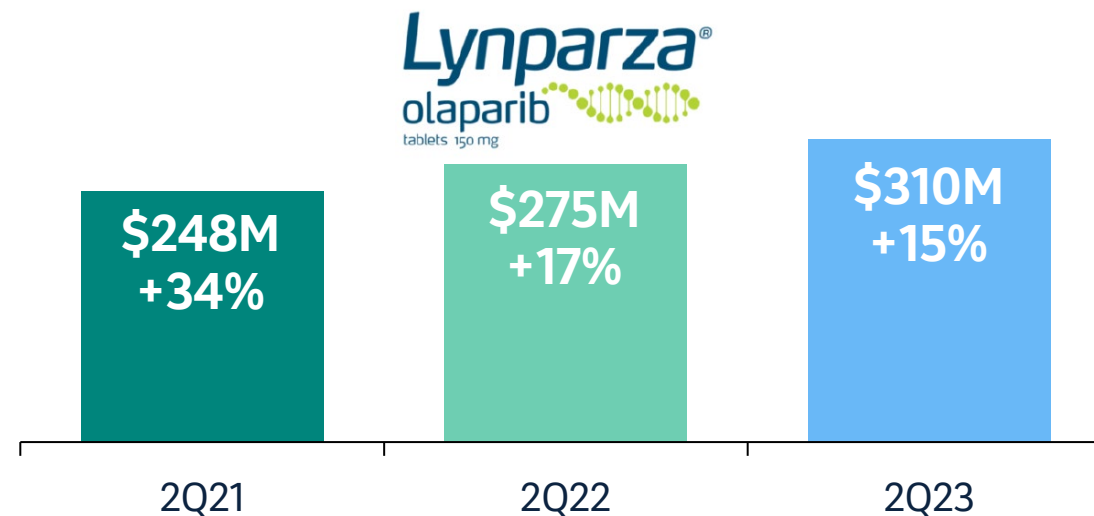
Oncology: KEYTRUDA continues to drive strong growth

- KEYTRUDA sales of \$6.3B increased 21% year-over-year, driven by uptake in earlier stage cancers and continued strong global demand from metastatic indications
 - In the U.S., growth of 21% reflects strong utilization across earlier stage cancers such as TNBC, as well as certain types of RCC and melanoma
 - Ex-U.S., 22% increase driven by demand in metastatic RCC and certain types of H&N cancer, as well as earlier stage cancers, including high-risk early stage TNBC and RCC



Oncology: Solid performance across broad portfolio

- Lynparza¹ sales grew 15% driven primarily by increased demand in certain international markets
- Lenvima² sales grew 6% due to demand in advanced RCC and endometrial cancer in the U.S., partially offset by lower sales in China

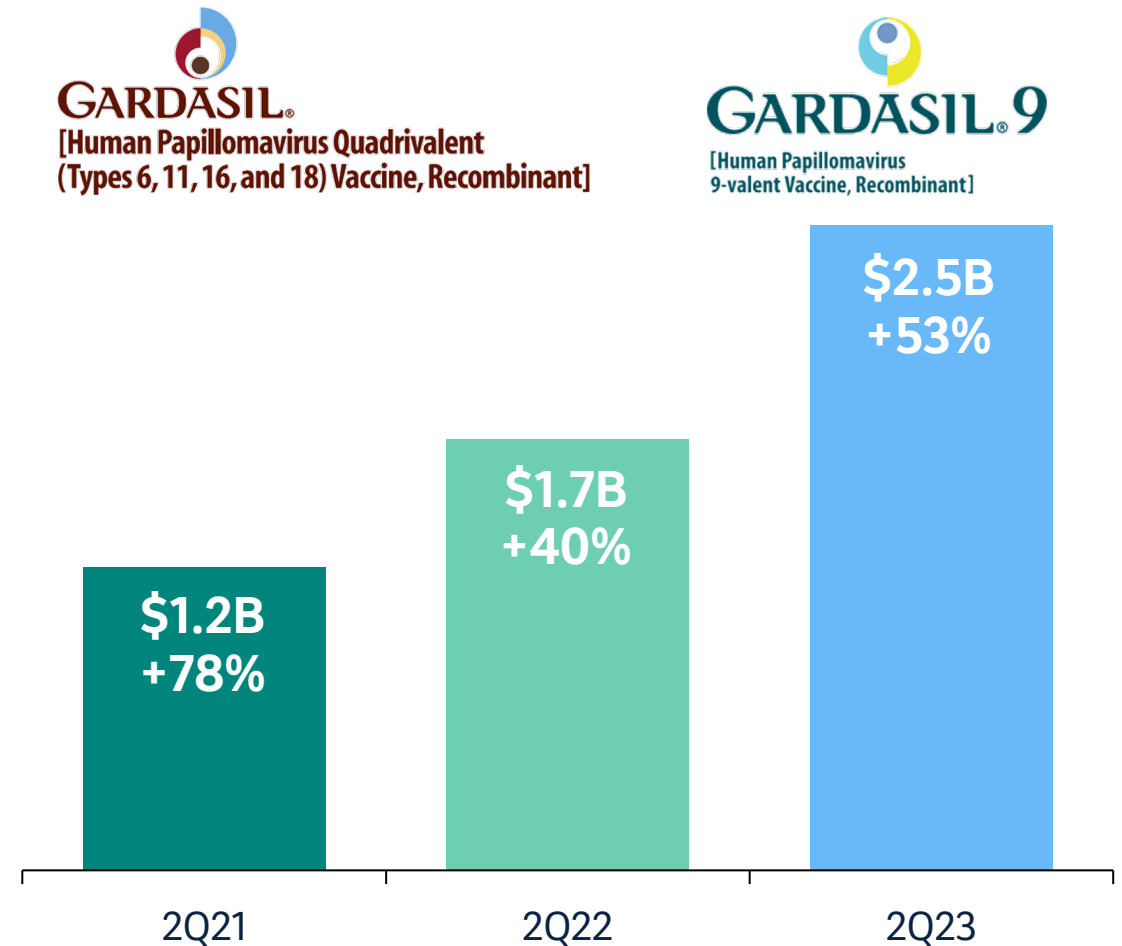


Growth rates exclude the impact of foreign exchange.

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

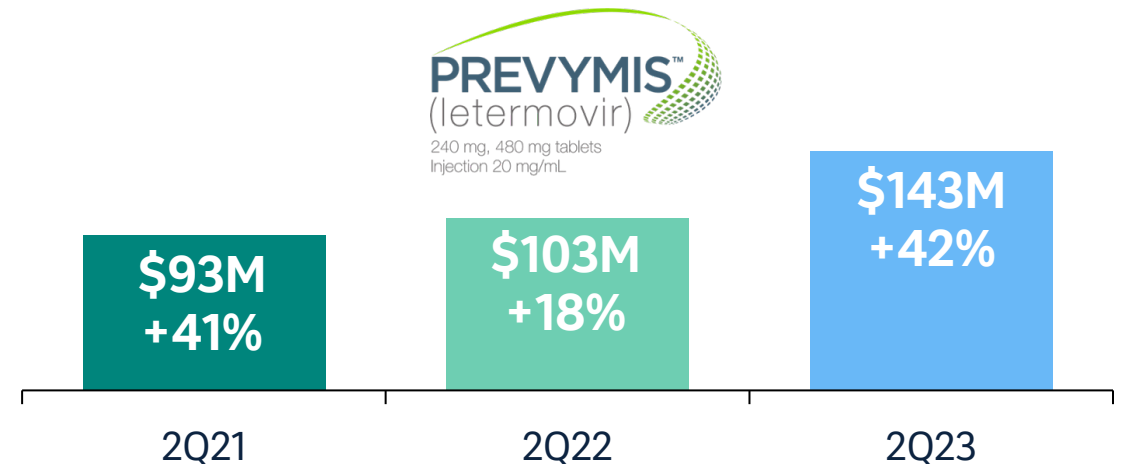
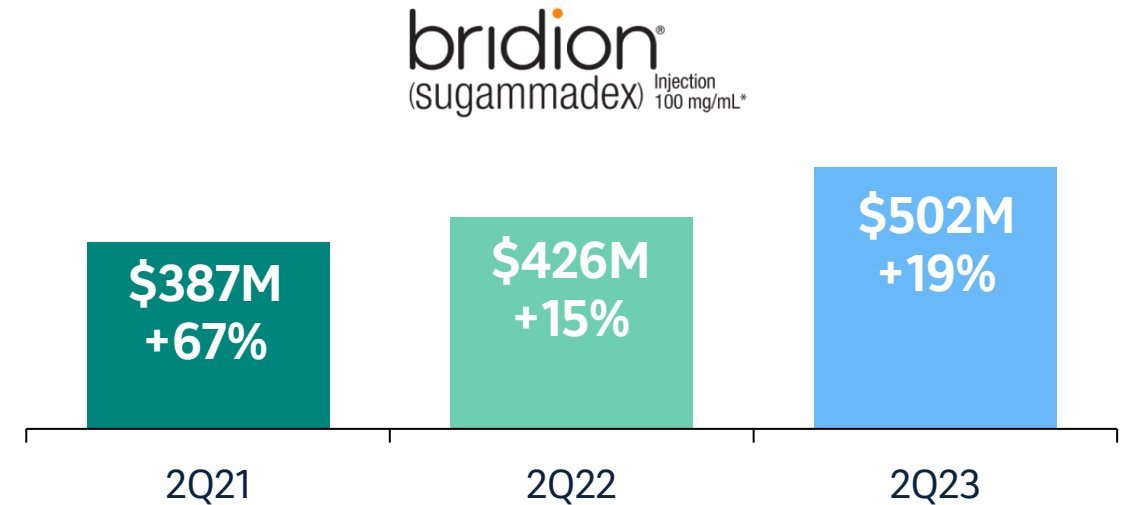
Vaccines: Exceptional growth driven by GARDASIL

- GARDASIL sales of \$2.5B increased 53% year-over-year primarily driven by strong global demand, particularly in China
 - China growth is benefitting from the expanded indication of GARDASIL 9 to females ages 9 to 45
- Strong ongoing pediatric launch of VAXNEUVANCE



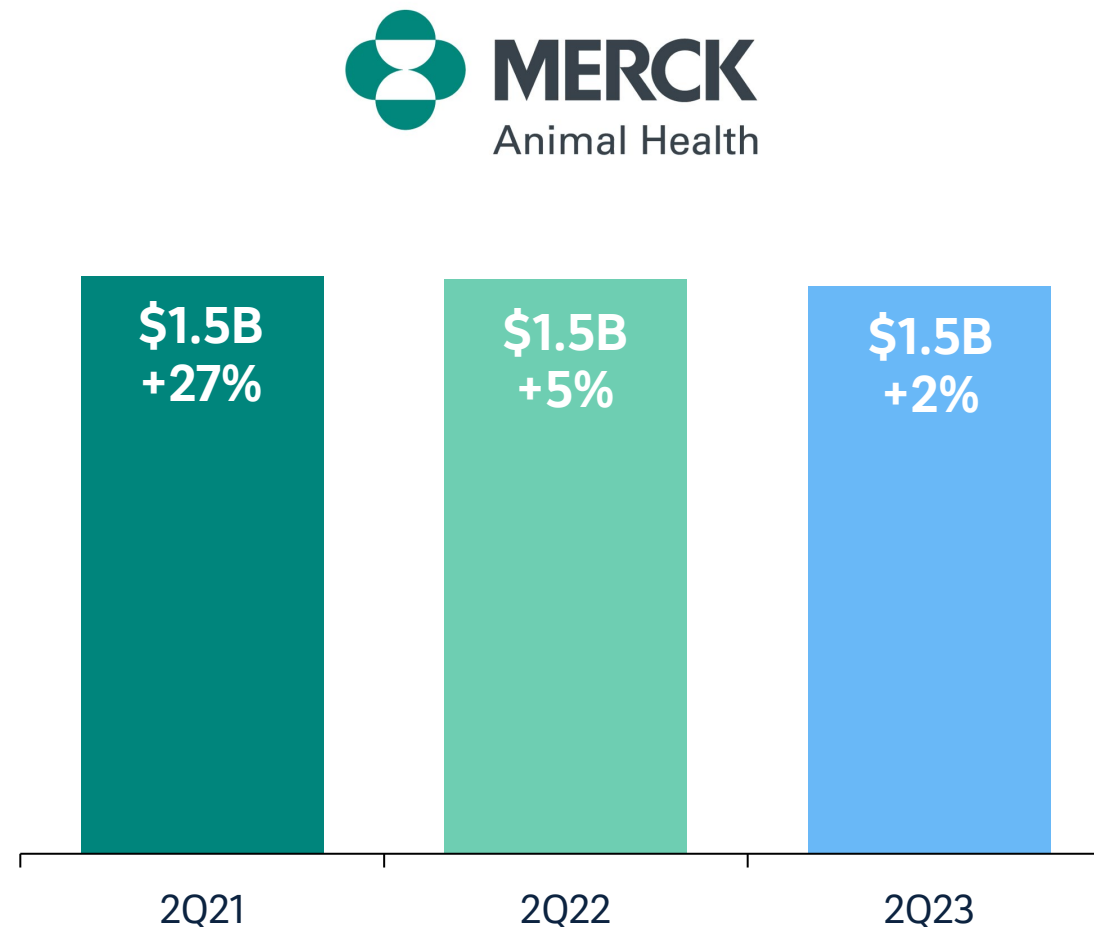
Hospital: Strong demand across key products

- BRIDION sales of \$502M increased 19% primarily due to greater share among neuromuscular blockade reversal agents in the U.S.
- PREVYMIS sales grew 42% driven by continued strong global demand



Animal Health: Growth driven by livestock and companion animal

- Animal Health sales increased 2% to \$1.5B
 - Livestock growth of 2% reflects price actions and increased demand for swine and poultry products, partially offset by lower demand for ruminant products due in part to reduced herd sizes
 - Companion Animal growth of 2% reflects price actions including for BRAVECTO, partially offset by supply challenges for certain vaccines



Q2 2023 non-GAAP financial results summary¹

\$ in billions, except LPS/EPS amounts

	Q2 2023	Q2 2022	Change	Change Ex-FX
Sales	\$15.0	\$14.6	+3%	+7%
Non-GAAP Gross Margin	76.6%	74.7%	+1.9pts	+2.7pts
Non-GAAP Operating Expenses²	\$15.9	\$5.2	N/M	N/M
Non-GAAP Tax Rate³	-18.4%	13.8%	-32.2pts	N/A
Non-GAAP Earnings / (Loss) Per Share⁴	(\$2.06)	\$1.87	N/M	N/M

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. 2Q23 non-GAAP results include \$10.2 billion of R&D expense or \$4.02 of negative impact to EPS, related to the acquisition of Prometheus Biosciences. 3. Q2 2023 provision for Taxes on Income was \$810 million. A pre-tax loss was recorded this quarter due to the Prometheus one-time charge, which was not tax deductible. As a result, the tax rate was negative in the quarter. 4. Q2 2023 GAAP LPS of (\$2.35).

Merck updated full-year 2023 guidance

	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$57.7B to \$58.9B -3% to -1% (-1% to +1% ex-FX)	\$58.6B to \$59.6B -1% to +1% (+1% to +3% ex-FX)	<ul style="list-style-type: none"> Includes approximately \$1B of LAGEVRIO revenue Ex-LAGEVRIO, growth of 8% to 9% (10 to 11% ex-FX) Assumes 2 ppt FX headwind
Non-GAAP Gross Margin Rate	~77.0%	~77.0%	
Non-GAAP Operating Expenses¹	\$23.3B to \$24.1B	\$34.0B to \$34.6B	<ul style="list-style-type: none"> Includes additional \$10.2B related to upfront charge for the acquisition of Prometheus and investment to advance the acquired assets
Other (Income) / Expense	~\$250M of income	~\$100M of expense	<ul style="list-style-type: none"> Includes financing costs related to the acquisition of Prometheus
Tax Rate	~17.0% to 18.0%	~30.5% to 31.5%	<ul style="list-style-type: none"> Includes ~15 ppt negative impact from the acquisition of Prometheus
Shares Outstanding	~2.55B	~2.55B	<ul style="list-style-type: none"> Assumes modest share repurchase
Non-GAAP EPS²	\$6.88 to \$7.00	\$2.95 to \$3.05	<ul style="list-style-type: none"> Includes \$4.02 one-time charge for the Prometheus acquisition and an additional \$0.14 to advance the assets and finance the transaction Assumes 5 ppt FX headwind (additional \$0.02 headwind)

1. Includes an aggregate \$11.6 billion of R&D expenses related to the Prometheus and Imago acquisitions and upfront payment for the license and collaboration agreement with Kelun. Outlook does not assume any additional significant potential business development transactions. 2. Includes \$4.53 of one-time charges related to the Prometheus and Imago acquisitions and upfront payment to Kelun.

Key modeling considerations

KEYTRUDA

- Anticipate strong year-over-year growth, but not quite at the levels experienced in recent quarters
- Continue to expect strong volume growth to be partially offset by pricing headwinds, particularly in key European markets
- In the second quarter, there was a small benefit from wholesaler purchase timing in the U.S. which is expected to reverse in the third quarter

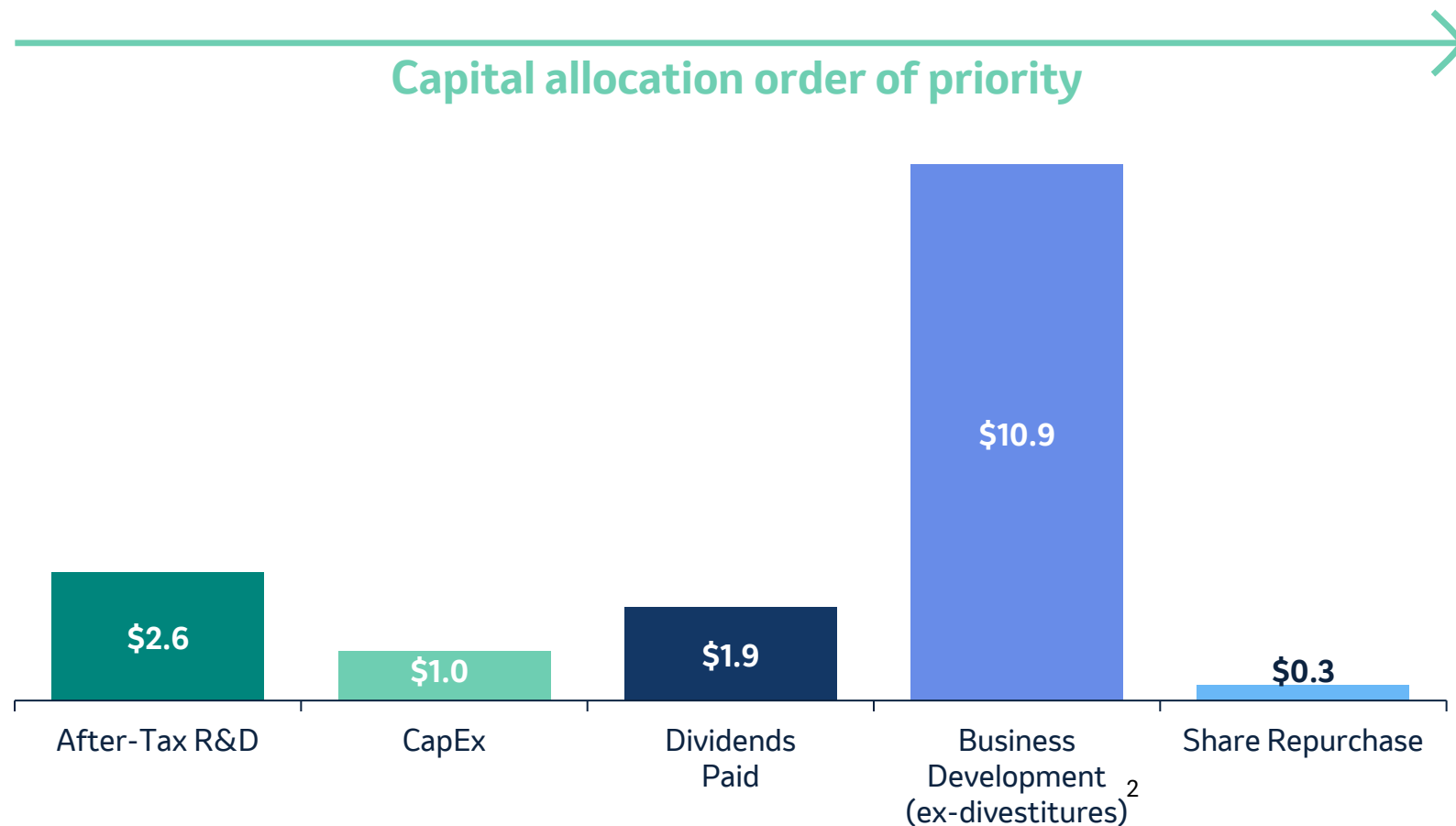
GARDASIL

- Expect the pace of full year growth to be higher in 2023 relative to 2022, with first half growth above that of the second half due in part to the timing of shipments in China



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 Q2 spend. 2. Includes payment for the Prometheus acquisition.



Research Update

Dr. Dean Li

President, Merck Research Laboratories



Driving value for patients and shareholders by progressing our pipeline

Key regulatory milestones since the last earnings call:

- **In the U.S., the FDA:**
 - Granted approval of Lynparza¹ in combination with abiraterone and prednisone in patients with deleterious or suspected deleterious BRCAm metastatic castration-resistant prostate cancer
 - Accepted sBLA for KEYTRUDA in combination with chemotherapy in patients with locally advanced unresectable or metastatic biliary tract cancer
 - Approved a new indication for PREVYMIS for prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk
 - Accepted the re-submission of NDA for gefapixant in patients with refractory or unexplained chronic cough
- **In the EU, the EMA:**
 - Accepted sMAA for KEYTRUDA in combination with trastuzumab and chemotherapy in patients with locally advanced unresectable or metastatic HER2- positive gastric or gastroesophageal junction adenocarcinoma
 - Received positive CHMP opinion for gefapixant in patients with refractory or unexplained chronic cough
- **In Japan, the PMDA:**
 - Granted approval of KEYTRUDA in patients with relapsed or refractory primary mediastinal B-cell lymphoma
 - Accepted sJNDA for KEYTRUDA in combination with chemotherapy in 1L treatment of locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, as well as in patients with locally advanced unresectable or metastatic biliary tract cancer
 - Granted approval of VAXNEUVANCE in pediatrics
- **In China, the CDE:**
 - Granted approval of Koselugo¹ for the treatment of symptomatic, inoperable plexiform neurofibromas in pediatric patients with neurofibromatosis type I ages 3 years and older

Key data & clinical advancements since the last earnings call:

- Presented data across broad oncology portfolio at ASCO, including for KEYTRUDA (KN-671, KN-483, KN-581, KN-716, KN-826), Lenvima², Lynparza¹, WELIREG, mRNA-4157/V940³ (INT) and MK-2870/SKB264⁴ (TROP2 ADC)
- Announced positive topline results for KN-811 evaluating KEYTRUDA in combination with trastuzumab as 1L treatment in patients with HER2-positive advanced gastric or gastroesophageal junction adenocarcinoma in PD-L1 positive patients
- Announced Phase 3 KN-A18 trial met primary endpoint of progression-free survival in patients with newly diagnosed high-risk locally advanced cervical cancer
- Announced Phase 3 KN-756 trial met one of its dual primary endpoints of pathological complete response rate in patients with high-risk, early-stage ER+/HER2- breast cancer
- Presented Phase 2a data at EASL for efinopegdutide (MK-6024), an investigational GLP-1/glucagon receptor co-agonist, in patients with nonalcoholic fatty liver disease (NAFLD), which has advanced to Phase 2b in nonalcoholic steatohepatitis (NASH)
- Completed BLA submission of sotatercept for pulmonary arterial hypertension (PAH) to the FDA
- Announced positive topline results from two Phase 3 trials evaluating V116 in vaccine-naïve and previously vaccinated individuals

Continuing to advance our broader oncology program

Clinical progress

- **KEYNOTE-756:** Phase 3 trial met one of its dual primary endpoints of pCR for treatment of patients with high-risk early-stage ER+/HER2- breast cancer
- **KEYNOTE-A18:** Phase 3 trial met one of its primary endpoints of PFS for treatment of patients with high-risk locally advanced cervical cancer
- Promising data presented at **ASCO:**
 - **KEYNOTE-671:** KEYTRUDA perioperative regimen reduced risk of disease recurrence, progression, or death by 42% in patients with resectable stage II, IIIA or IIIB NSCLC
 - **KEYNOTE-942:** V940¹ (INT) and KEYTRUDA reduced risk of distant metastasis or death by 65% in patients with stage III/IV melanoma following complete resection
 - Initiated Phase 3 trial for adjuvant treatment of high risk, stage II to IV melanoma
 - **MK-2870²:** Showed encouraging anti-tumor activity in patients with locally advanced or metastatic NSCLC

Regulatory updates

- **PROpel:** received FDA approval for Lynparza³ in combination with abiraterone and prednisone in patients with deleterious or suspected deleterious BRCA-mutated mCRPC
- **KEYNOTE-966:** sBLA for KEYTRUDA in combination with chemotherapy in patients with locally advanced unresectable or metastatic biliary tract cancer accepted for FDA review
- **KEYNOTE-811:**
 - KEYTRUDA in combination with trastuzumab and chemotherapy showed significant improvement in PFS in 1L treatment of HER2-positive advanced gastric or GEJ adenocarcinoma in patients whose tumors were PD-L1 positive
 - Received positive EMA opinion

Progressing our broader pipeline

Vaccines and Infectious Disease

VACCINES

- **V116**, our investigational **pneumococcal conjugate vaccine** specifically designed for adults:
 - protects against serotypes that are responsible for ~85% of invasive pneumococcal disease in adults ages ≥65¹
 - includes 8 serotypes that are currently not covered by approved vaccines, and are responsible for ~30% of invasive pneumococcal disease in adults ages ≥65¹
- Announced positive topline data for V116 for two Phase 3 trials (**STRIDE-3** and **STRIDE-6**)

ID

- Received FDA approval for **PREVYMIS** for **prophylaxis of CMV disease** for adult recipients of kidney transplant who are at high-risk of infection

General Medicine

CARDIOMETABOLIC

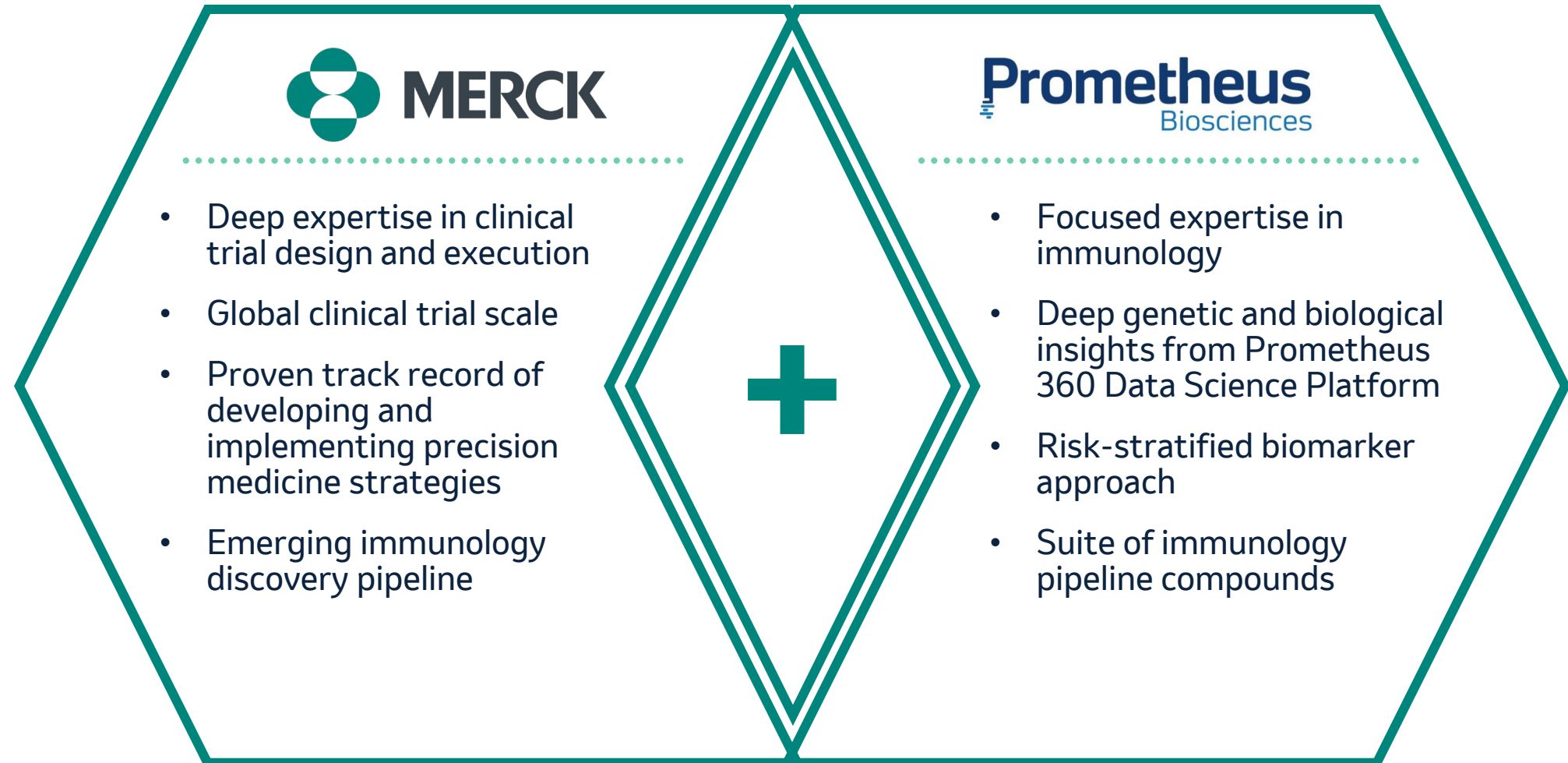
- Completed FDA submission of **sotatercept** for the treatment of adults with **PAH** based on the Phase 3 STELLAR trial
- Presented positive data at EASL from the Phase 2a trial evaluating efinopegdutide, our investigational **GLP-1 / glucagon receptor co-agonist**, in patients with **NAFLD** and initiated Phase 2b trial in **pre-cirrhotic NASH**

COUGH

- FDA accepted re-submission of the NDA for **gefapixant** in patients with **refractory or unexplained chronic cough**

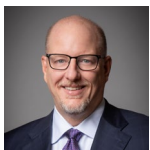
1. Centers for Disease Control and Prevention, IPD serotype data 2019, as compiled from data provided through Active Bacterial Coresurveillance (ABCs).

Accelerating our presence in immunology





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

Q2 2023 GAAP financial results summary

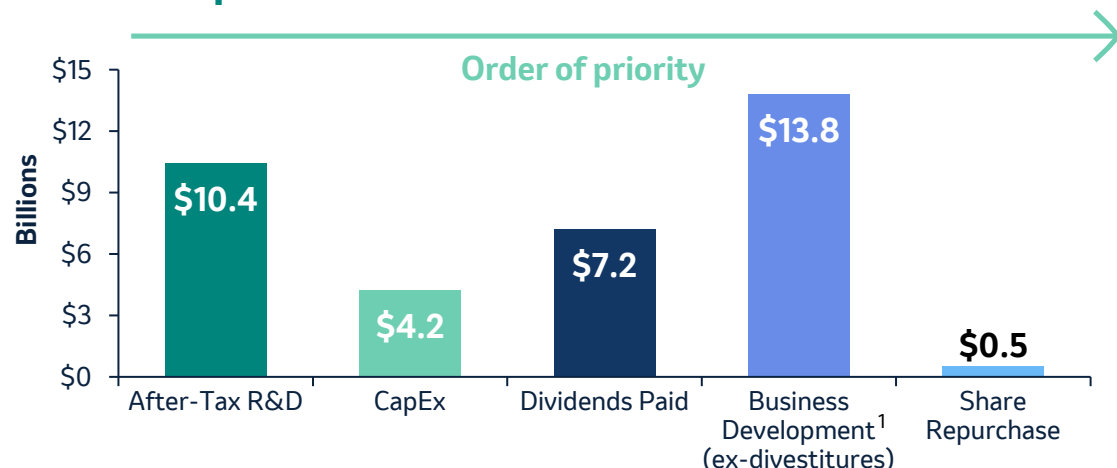
\$ in billions, except LPS/EPS amounts

	Q2 2023 ¹	Q2 2022	Change	Change Ex-FX
Sales	\$15.0	\$14.6	+3%	+7%
Operating Expenses	\$16.0	\$5.3	N/M	N/M
Tax Rate	-11.9%	12.0%	-23.9pts	N/A
GAAP Earnings / (Loss) per Share	(\$2.35)	\$1.55	N/M	N/M

1. Q223 GAAP results include \$10.2 billion or \$4.02 of such charges related to the acquisition of Prometheus Biosciences.

Capital allocation: Trailing twelve months

Over the past 12 months



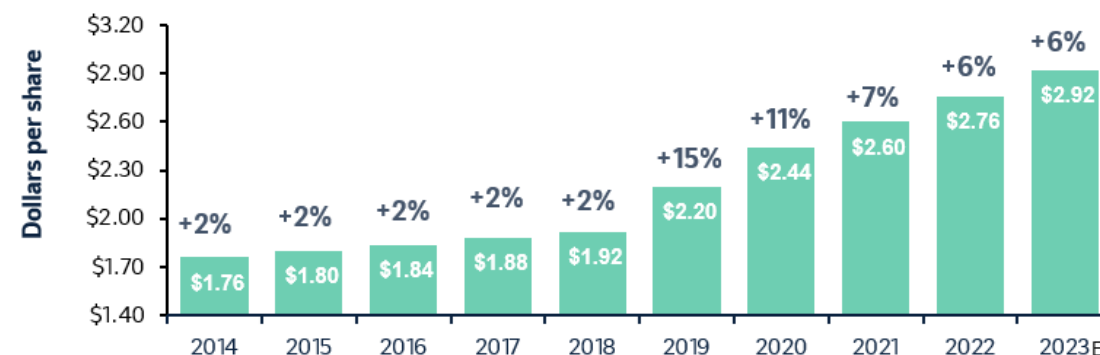
Capital investments 2023 to 2027

~\$15B

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

Broad and innovative pipeline to solve significant unmet medical needs

Phase 2

Oncology

MK-0482
NSCLC

MK-1308 (quavonlimab)
NSCLC

MK-1308A (quavonlimab + pembrolizumab)
CRC
HCC
Melanoma
SCLC

MK-2140 (zilovetamab vedotin)
Bladder
Breast
Gastric
Hematological Malignancies
NSCLC
Ovarian
Pancreas

MK-2870
Neoplasm Malignant

KEYTRUDA (MK-3475)
Advanced Solid Tumors
Prostate

MK-3543 (bomedemstat)
Myeloproliferative Disorders

MK-4280 (favezelimab)
NSCLC

MK-4280A (favezelimab + pembrolizumab)
Bladder
Esophageal
Melanoma
RCC
SCLC

MK-4830
CRC
Esophageal
Melanoma
NSCLC
Ovarian
RCC
SCLC

MK-5684
Prostate

MK-5890 (boserolimab)
NSCLC
SCLC

LYNPARZA (MK-7339)
Advanced Solid Tumors

LENVIMA (MK-7902)
Biliary
Pancreas
Prostate

WELIREG (MK-6482)
Biliary
Certain VHL tumors (EU)
CRC
Endometrial
Esophageal
HCC
Pancreatic
Rare Cancers

TUKYSA (MK-7119)
Advanced Solid Tumors
Bladder
Biliary
Cervical
Endometrial
Gastric
NSCLC
SCLC

MK-7684A (vibostolimab + pembrolizumab)
Biliary
Bladder
Breast
Cervical
CRC
Endometrial
Esophageal
Gastric
HCC
HNSCC
Hematological Malignancies
Ovarian
Prostate

Vaccines

V181
Dengue Virus

Infectious diseases

MK-8591B (islatravir + MK-8507)¹
HIV-1 Infection

MK-8591D (islatravir + lenacapavir)²
HIV-1 Infection

Cardiovascular

MK-0616
Hypercholesterolemia

MK-2060
Thrombosis

MK-5475
Pulmonary Arterial Hypertension

MK-7962 (sotatercept)
Pulmonary Hypertension due to Left Heart Disease

General medicine

MK-1942
Treatment Resistant Depression

MK-6024 (efinopegdutide)
NASH

Neuroscience

MK-8189⁴
Schizophrenia

Immunology

MK-7240
Ulcerative Colitis

Phase 3

Oncology

KEYTRUDA (MK-3475)
CSCC (EU)
Hepatocellular (EU)
Mesothelioma
Ovarian
SCLC

LENVIMA (MK-7902)
Esophageal
Gastric
HNSCC
NSCLC

LYNPARZA (MK-7339)
NSCLC
SCLC

WELIREG (MK-6482)
RCC

TUKYSA (MK-7119)
Breast
CRC

MK-3475A (pembrolizumab + hyaluronidase)
NSCLC

V940
Melanoma

MK-1026 (nemtabrutinib)
Hematological Malignancies

MK-1308A (quavonlimab + pembrolizumab)
RCC

MK-7684A (vibostolimab + pembrolizumab)
Melanoma
NSCLC
SCLC

MK-4280A (favezelimab + pembrolizumab)
CRC
Hematological Malignancies

Infectious diseases

MK-8591A (doravirine + islatravir)²
HIV-1 Infection

LAGEVRIO (MK-4482)³
COVID-19 antiviral

Vaccines

MK-1654 (clesrovimab)
Respiratory Syncytial Virus (RSV)

V116
Pneumococcal vaccine, adult

Cardiovascular

MK-7962 (sotatercept)
Pulmonary Arterial Hypertension

Under regulatory review

Oncology

KEYTRUDA (MK-3475)
2L HCC (US)
LA Merkel Cell (US)
Adjuvant NSCLC (EU)
HER2+ Gastric (EU)
Resectable NSCLC (US, EU)
1L HER2- Gastric (US, EU, JPN)
1L Biliary (US, EU, JPN)

LYNPARZA (MK-7339)
Metastatic 1L Prostate (JPN)

General medicine

Gefapixant (MK-7264)
Cough (US, EU)

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

⁵Requested re-examination of EUMAA following CHMP major objection of data to support market authorization

As of August 2, 2023