



Merck Q1 2023 Earnings

April 27, 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 1Q 2023



Advanced the pipeline to meet patient unmet need



Executed on strategic business development to enhance pipeline

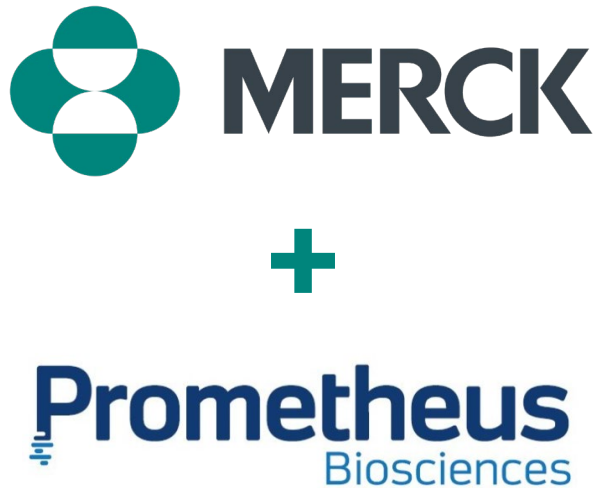


Achieved strong commercial and financial performance



Created long-term value for patients and shareholders

Merck continues to advance science-led strategy through acquisition of Prometheus Biosciences



- Potentially **transformational, first-in-class, late-stage candidate**, in a disease area with **significant unmet medical need**
- Opportunity to potentially **transform standard of care** for certain patients suffering from debilitating autoimmune diseases through **precision medicine** approach
- **Diversifies portfolio** and enhances our **sustainable innovation engine**
- **Multi-billion dollar commercial opportunity** with potential to **drive long-term revenue and earnings growth** well into the next decade

Very significant 1Q sales and underlying earnings growth¹



1Q Worldwide Sales

\$14.5B

-9%

+15% ex-Exchange, ex-LAGEVRIO

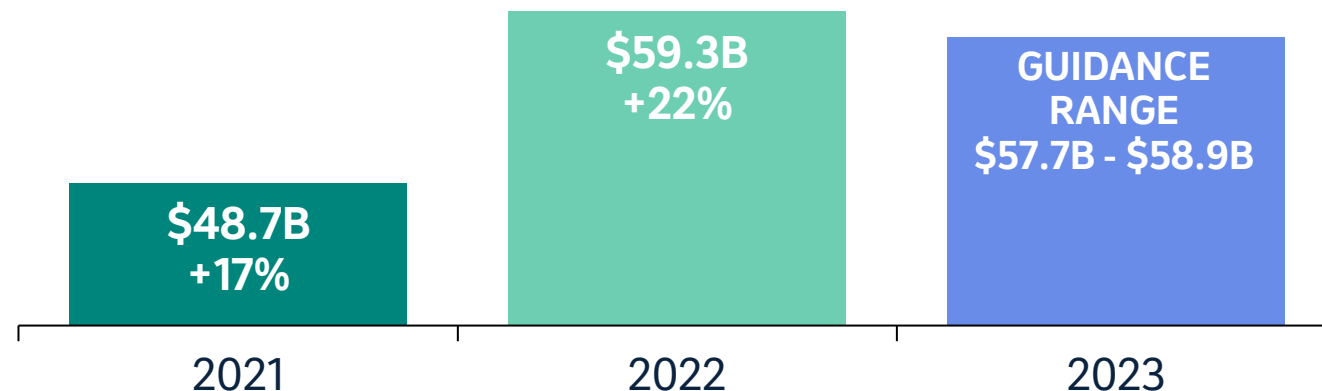


1Q Non-GAAP EPS^{2,3}

\$1.40

-35%

Full Year Sales



Full Year Non-GAAP EPS²



1. Results from continuing operations attributable to Merck & Co., Inc. 2. 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. 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. 1Q23 non-GAAP results include \$1.4 billion or \$0.52 of such charges. For 2023, outlook does not assume the proposed acquisition of Prometheus or any additional significant potential business development transactions. 3. GAAP EPS of \$1.11. 4. 2023 GAAP guidance range of \$5.85 to \$5.97.

Advancing and augmenting deep pipeline in 1Q

Cardiovascular

- Presented positive Phase 3 data from the STELLAR trial evaluating **sotatercept** at ACC.23/WCC
- Presented positive Phase 2 data for **MK-0616** at ACC.23/WCC
- Hosted investor event to discuss data and provide overview of broader research efforts in cardiology

Oncology

- Presented detailed results from Phase 2b trial evaluating KEYTRUDA in combination with **mRNA-4157/V940**, an investigational individualized neoantigen therapy, with partner Moderna, for the adjuvant treatment of patients with stage III/IV melanoma following complete resection at AACR
- Announced positive topline results from Phase 3 **KN-671** trial evaluating KEYTRUDA regimen as neoadjuvant/adjuvant treatment in patients with resectable stage II, IIIA or IIIB NSCLC



Building a sustainable innovation engine

Translating breakthrough science into medicines and vaccines that save and improve lives



Business/Financial Results and Outlook

Caroline Litchfield
Chief Financial Officer



Strong underlying Q1 sales growth across Human Health and Animal Health



Merck

WORLDWIDE SALES^{1,2}

\$14.5B

-9% growth
+11% ex-LAGEVRIO³
+15% ex-exchange, ex-LAGEVRIO⁴



Human Health

\$12.7B

-10% growth
+14% ex-LAGEVRIO³
+18% ex-exchange, ex-LAGEVRIO⁴



Animal Health

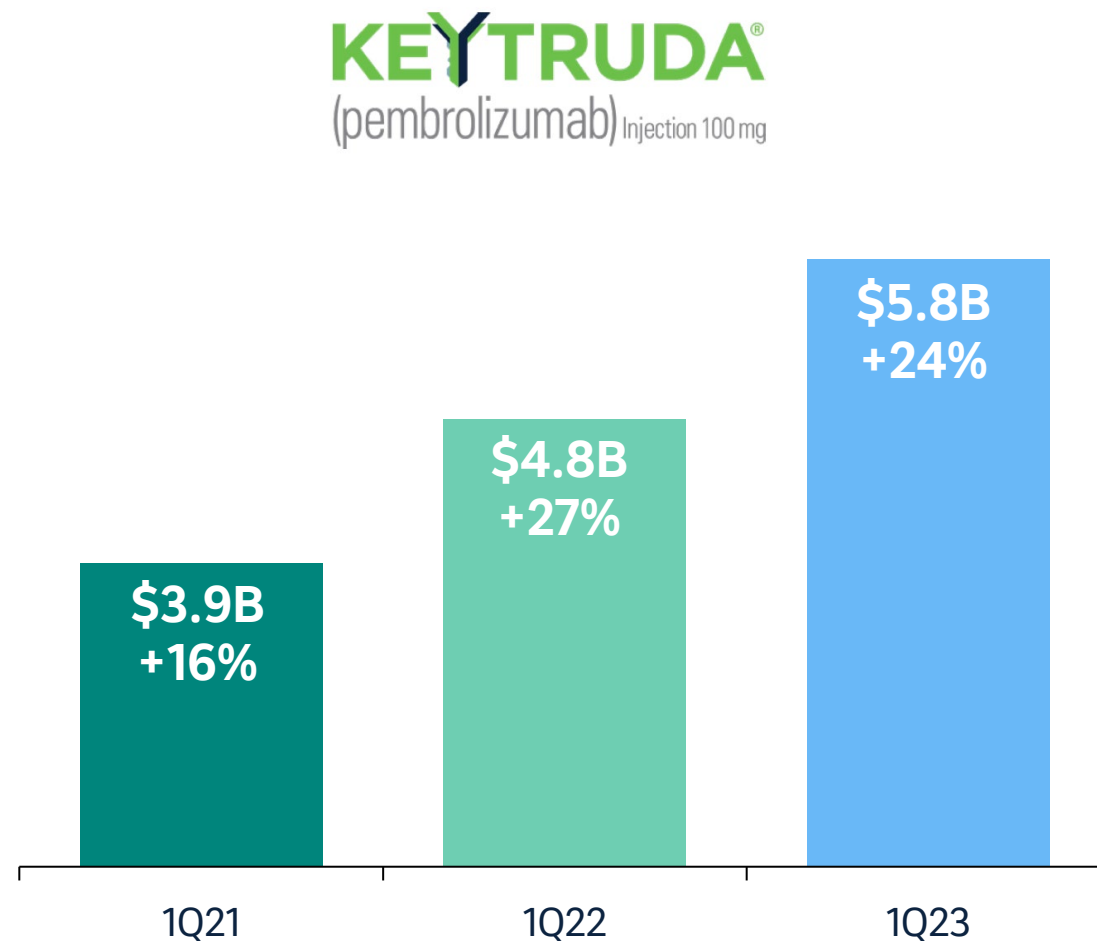
\$1.5B

+1% growth
+5% ex-exchange

1. Results attributable to Merck & Co., Inc. 2. Worldwide Sales includes Other Revenue 3. Excludes Lagevrio sales of \$392 million in 1Q23 and \$3.2 billion in 1Q22.
4. Excludes Lagevrio sales of \$392 million in 1Q23 and \$3.2 billion in 1Q22 and foreign exchange

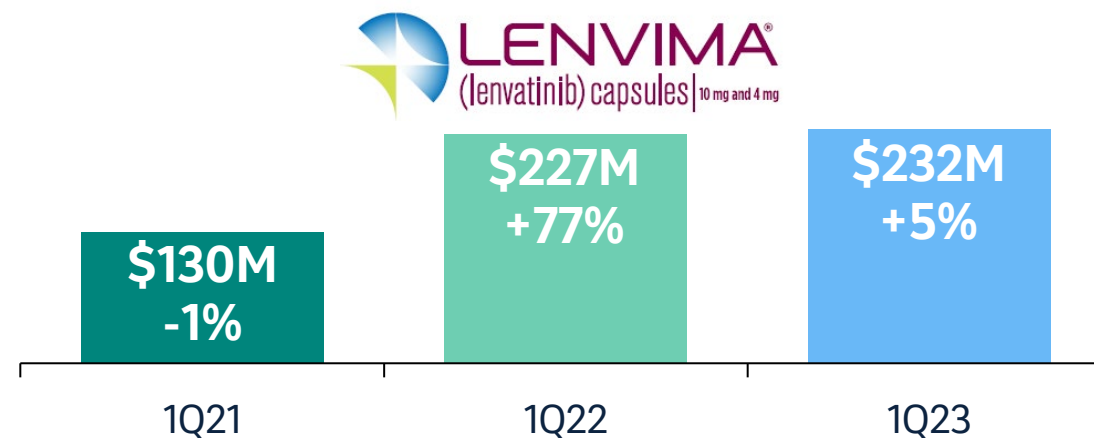
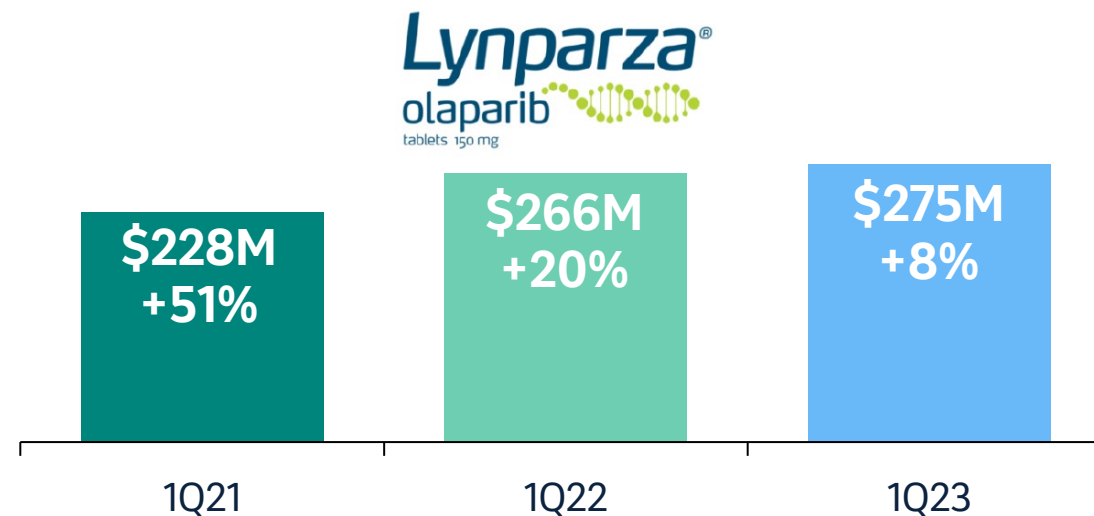
Oncology: KEYTRUDA drives strong growth

- KEYTRUDA sales of \$5.8B increased 24% year-over-year, driven by strong global demand in metastatic cancers and increased uptake from earlier-stage indications
 - In the U.S., growth of 25% reflects strong uptake across in earlier-stage cancers such as TNBC, as well as certain types of renal cell carcinoma and melanoma
 - Ex-U.S., 22% increase driven by continued global uptake in metastatic RCC as well as earlier-stage cancers, including high-risk early stage TNBC



Oncology: Solid performance across broad portfolio

- Lynparza¹ sales grew 8% driven primarily by increased demand in key European markets in certain patients with ovarian cancer
- Lenvima² sales grew 5% due to increased uptake in advanced RCC in key European markets

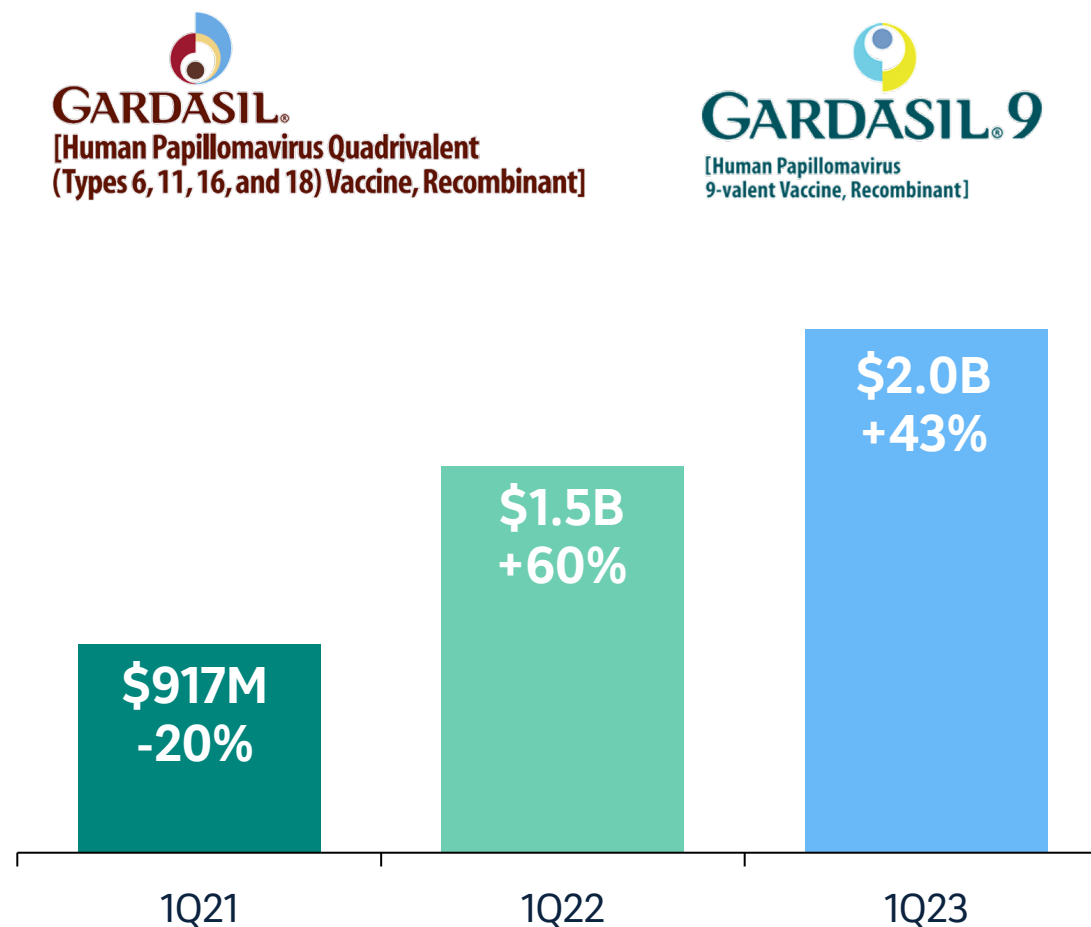


Increase/decrease in sales exclude the impact of foreign exchange.

¹In collaboration with AstraZeneca; ²In collaboration with Eisai

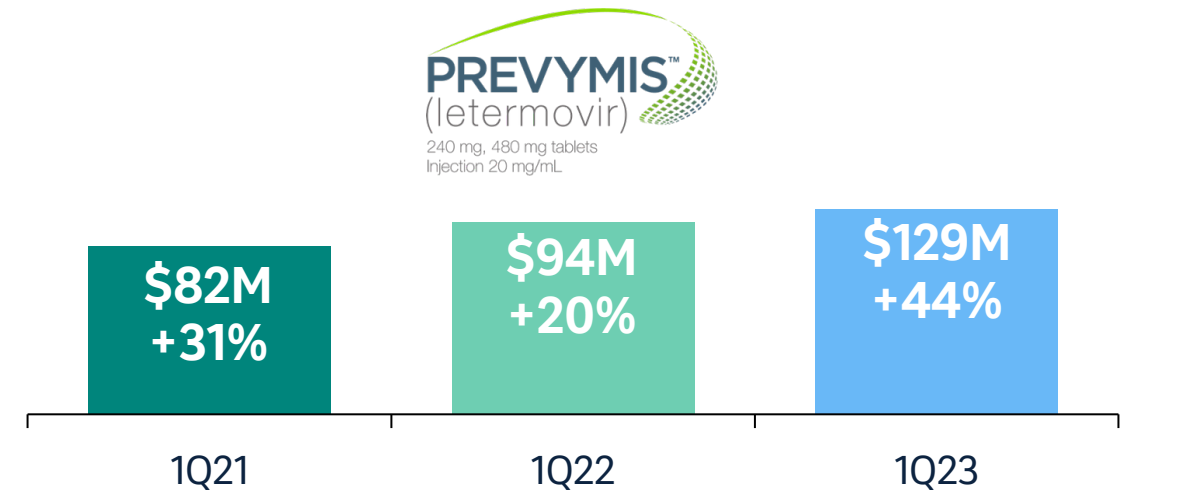
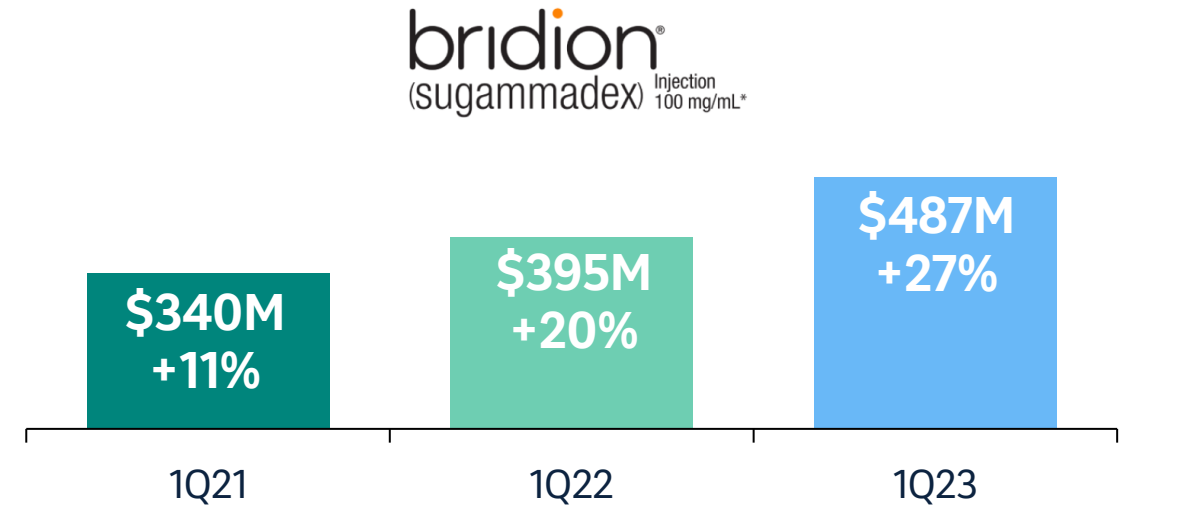
Vaccines: GARDASIL growth driven by strong international demand

- GARDASIL sales of \$2.0B increased 43% year-over-year primarily driven by strong underlying demand outside the U.S., particularly China, as well as increased supply
 - China growth also benefitted from an acceleration of shipments from 2H to 1H to ensure availability of product to meet heightened demand following the approval of the expanded indication of GARDASIL 9 for girls and women 9 to 45 years of age
- Strong ongoing pediatric launch of VAXNEUVANCE is tracking with expectations



Hospital: Strong global demand across key products

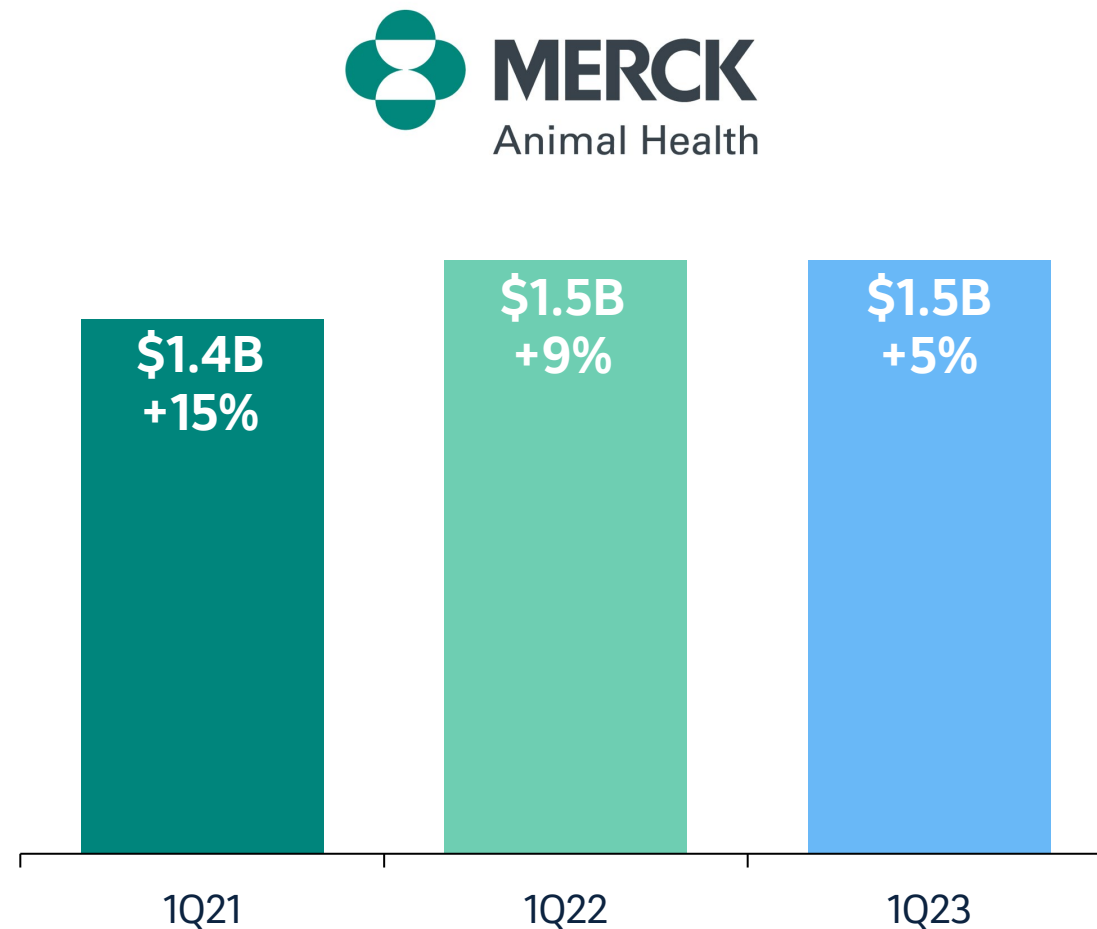
- BRIDION sales of \$487M increased 27% primarily due to greater share among neuromuscular blockade reversal agents
- PREVYMIS sales grew 44% driven by continued strong global demand



Growth rates exclude the impact of foreign exchange.

Animal Health: Solid growth driven by livestock

- Animal Health sales increased 5% to \$1.5B, reflecting strong demand across livestock portfolio, as well as strategic price actions
 - Livestock growth of 8% due to strong performance in ruminants and poultry products
 - Companion Animal results reflect increased sales of Bravecto, partially offset by supply challenges for certain vaccines



Q1 2023 continuing operations non-GAAP financial results summary¹

\$ in billions, except EPS amounts

	Q1 2023	Q1 2022	Change	Change Ex-FX
Sales	\$14.5	\$15.9	-9%	-5%
Non-GAAP Gross Margin	76.9%	70.7%	+6.1pts	+5.9pts
Non-GAAP Operating Expenses²	\$6.7	\$4.8	+40%	+42%
Non-GAAP Tax Rate	20.4%	14.0%	+6.4pts	N/A
Non-GAAP EPS³	\$1.40	\$2.14	-35%	-30%

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 this release. 2. For Q1 Non-GAAP results include \$1.4 billion of R&D expense, or an estimated \$0.52 of negative impact to EPS, related to an asset acquisition, and collaboration and licensing agreement. 3. Q1 2023 GAAP EPS of \$1.11.

Merck updated full-year 2023 guidance

	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$57.2B to \$58.7B -4% to -1% (-2% to +1% ex-FX)	\$57.7B to \$58.9B -3% to -1% (-1% to +1% ex-FX)	<ul style="list-style-type: none"> Includes approximately \$1B of LAGEVRIO revenue Ex-LAGEVRIO, growth of 6% to 8% (8 to 10% ex-FX) Assumes ~2% FX headwind
Non-GAAP Gross Margin Rate¹	~77.0%	~77.0%	
Non-GAAP Operating Expenses^{2,5,6}	\$23.1B to \$24.1B	\$23.3B to \$24.1B	<ul style="list-style-type: none"> Includes \$1.4B of upfront R&D expense related to acquisition of Imago Biosciences and expansion of collaboration with Kelun Biotech Does not include the proposed acquisition of Prometheus Biosciences⁶
Other (Income) / Expense	~\$250M of income	~\$250M of income	
Tax Rate³	~17.0%-18.0%	~17.0%-18.0%	
Shares Outstanding	~2.55B	~2.55B	<ul style="list-style-type: none"> Assumes modest share repurchase
GAAP EPS	\$5.86 to \$6.01	\$5.85 to \$5.97	
Non-GAAP EPS^{4,5,6}	\$6.80 to \$6.95	\$6.88 to \$7.00	<ul style="list-style-type: none"> Includes \$0.52 of charges related to an acquisition, and significant collaborations and licensing agreement Assumes ~4% FX headwind

1. GAAP Gross Margin Rate: ~73% 2. GAAP Operating Expenses: \$23.5 to \$24.3 billion 3. GAAP Tax Rate: ~17-18% 4. The GAAP to non-GAAP reconciliation is available in Merck's Q1 2023 earnings release 5. Merck includes expenses for upfront and milestone payments related to collaborations and licensing agreements, as well as charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions from its non-GAAP results 6. The proposed Prometheus Biosciences acquisition is anticipated to result in a one-time charge of approximately \$10.3 billion recorded to both GAAP and non-GAAP R&D expenses in 2023 or approximately \$4.00 per share, as well as an approximate \$0.25 negative impact on EPS in the first 12 months following close.

Key modeling considerations

KEYTRUDA

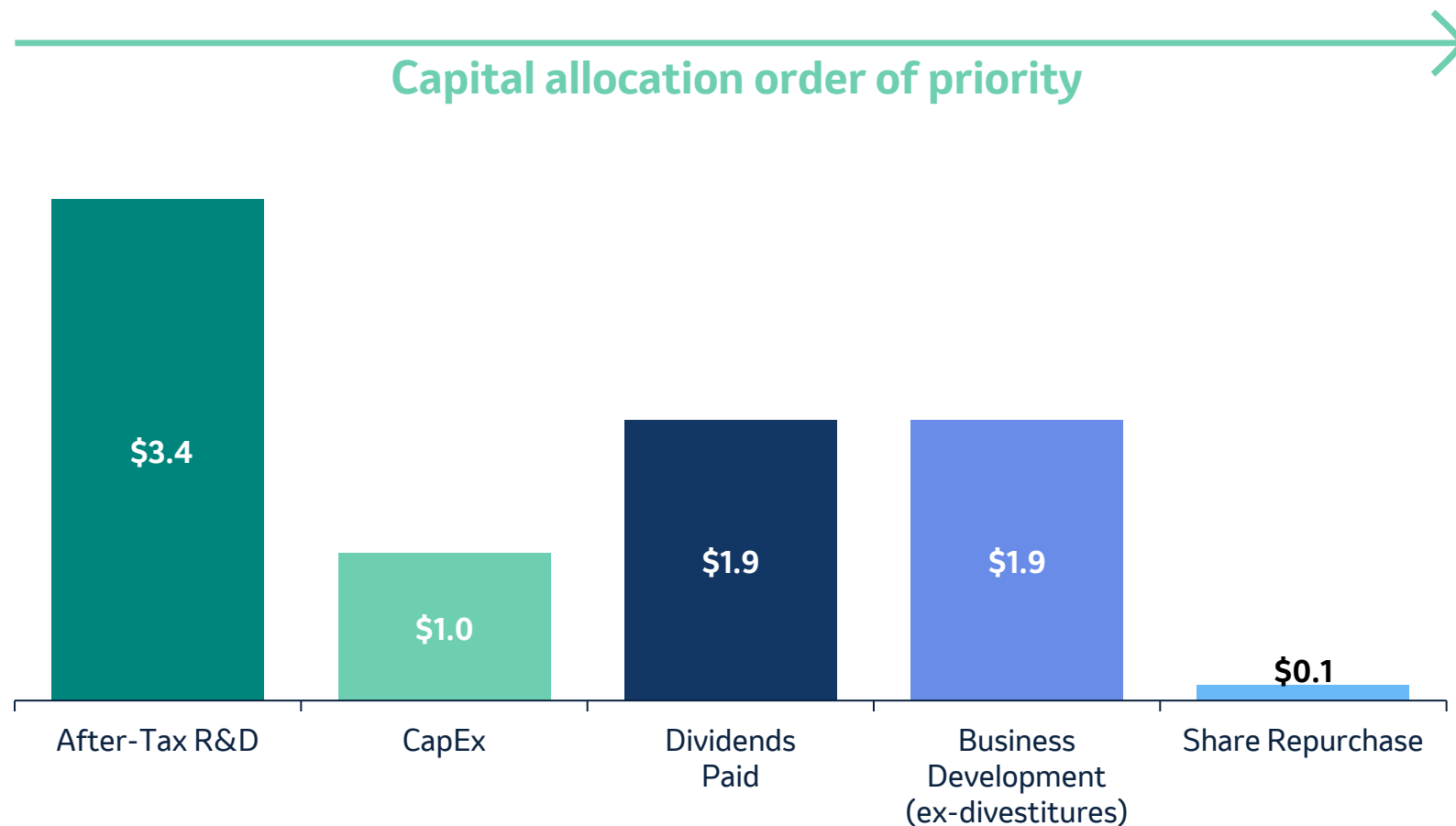
- In the U.S., exceptional growth in prior quarters is expected to moderate as strong uptake from recently launched indications, particularly in earlier-stage cancers, is annualized
- Ex-U.S., expect strong volume growth to be partially offset by pricing headwinds, particularly in key European markets

GARDASIL

- Expect strong growth driven by robust global demand, particularly in ex-U.S. markets
- Expect an acceleration of full year growth in 2023 relative to 2022, though not at the same rate of growth as in Q1 2023

Remain committed to balanced capital allocation strategy

\$ Billions¹



Continue to prioritize investments in our **pipeline** and **business** to realize value of near- and long-term opportunities

1. Reflects Q1 spend

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:**
 - Converted from accelerated to full approval indication for KEYTRUDA in patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment option
 - Granted accelerated approval of KEYTRUDA in combination with enfortumab vedotin, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy based on **KEYNOTE-869**
 - Accepted sBLA for KEYTRUDA in combination with chemotherapy for the treatment of HER2-negative locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma regardless of PD-L1 expression based on **KEYNOTE-859**
 - Granted Breakthrough Therapy Designation for mRNA-4157/V940 in combination with KEYTRUDA the adjuvant treatment of high-risk melanoma following complete resection
 - Approved expanded administration option for intramuscular route of administration for the MMRV family of vaccines, M-M-RII, VARIVAX and ProQuad
 - Accepted priority review for the sNDA for PREVYMIS for prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk
- **In Europe, the EMA:**
 - Granted Priority Medicines scheme designation for mRNA-4157/V940 in combination with KEYTRUDA for the treatment of high-risk adjuvant melanoma following complete resection
- **In Japan, the MHLW:**
 - Approved LAGEVRIO for the treatment of COVID-19

Key data & clinical advancements since the last earnings call:

- Presented results of the Phase 3 **STELLAR** trial evaluating sotatercept, a novel investigational activin signaling inhibitor biologic, in combination with stable background therapy for the treatment of adult patients with pulmonary arterial hypertension and the Phase 2b clinical trial evaluating MK-0616, an investigational oral PCSK9 candidate, for adult patients with hypercholesterolemia at ACC.23/WCC
- Presented final results of key secondary overall survival endpoint from Phase 3 **PROpel** trial evaluating Lynparza¹ in combination with abiraterone and prednisone or prednisolone at 2023 ASCO Genitourinary Cancers Symposium
- Announced Phase 3 **KEYNOTE-671** trial evaluating KEYTRUDA in combination with chemotherapy as a perioperative treatment regimen for patients with resectable stage II, IIIA or IIIB non-small cell lung cancer met one of its dual primary endpoints of event-free survival
- Announced results of Phase 3 **NRG-GY018** trial evaluating KEYTRUDA in combination with chemotherapy then continued as a single agent for the treatment of patients with stage III-IV or recurrent endometrial carcinoma whose cancer was either mismatch repair proficient or mismatch repair deficient
- Announced results of Phase 2/3 **KEYNOTE-483** trial evaluating KEYTRUDA in combination with chemotherapy as first-line treatment for patients with unresectable advanced or metastatic malignant pleural mesothelioma met its primary endpoint of overall survival
- Announced results of Phase 2 **KEYNOTE-942** trial evaluating KEYTRUDA in combination with mRNA-4157/V940² for the treatment of high-risk adjuvant melanoma following complete resection at AACR
- Opened enrollment for new Phase 3 clinical trials with investigational once-daily islatravir in combination with doravirine and Phase 2 clinical trial with once-weekly islatravir in combination with lenacapavir³ for treatment of HIV-1 infection

Making tangible advancements in our cardiovascular pipeline

Sotatercept

- Presented **Phase 3** results from the STELLAR trial
 - Substantial **improvement of 40.8 meters in 6MWD** at Week 24
 - Met **8 out of 9 secondary endpoints** including:
 - **84% reduction** in **risk of death or clinical worsening** events¹
- **Advancing broad program**, including Phase 3 HYPERION, ZENITH, SOTERIA and Phase 2 CADENCE studies

MK-0616

- Presented **Phase 2b** results
 - Reduction of LDL-cholesterol levels from **41.2 up to 60.9 %** vs placebo, across 4 doses in study
 - **Eighty to 90%** of patients receiving MK-0616 were able to **reach their LDL-C goals**
- Defined path toward providing a therapy that could achieve **broad global access**
- Initiating **multiple Phase 3 studies** including a **cardiovascular outcomes trial**

1. TTCW is time to clinical worsening or death (defined by death of any cause or specified non-fatal clinical worsening events); sotatercept plus stable background therapy reduced the risk of clinical worsening or death by 84% compared to placebo plus background therapy with a median follow-up of 32.7 weeks (HR=0.16 [95% CI, 0.08-0.35]; p<0.001)

Developing treatments for earlier stages of cancer remains a key area of focus and execution

Making progress in the treatment of earlier stage NSCLC through multiple clinical trials

APPROVED

KEYNOTE-091: Received FDA approval for KEYTRUDA for adjuvant treatment of adult patients with stage IB (T2a \geq 4 cm), II or IIIA NSCLC following resection and platinum-based chemotherapy

FILED

KEYNOTE-671: Announced positive top line results for KEYTRUDA with platinum doublet chemotherapy as neoadjuvant followed by adjuvant therapy for patients with resectable stage II, IIIA and IIIB NSCLC

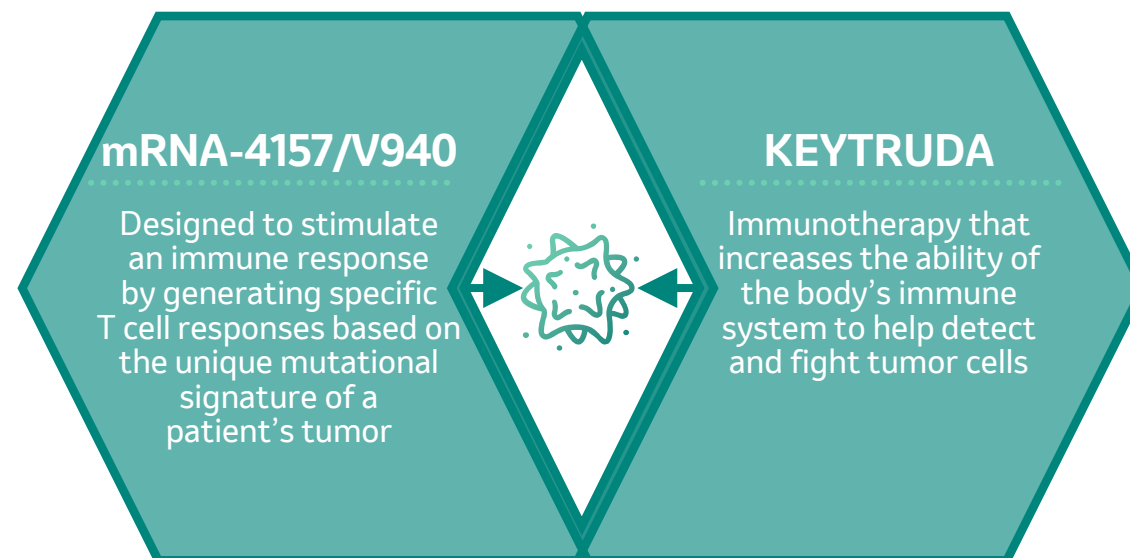
PHASE III

KEYNOTE-867: Evaluating KEYTRUDA in patients undergoing stereotactic body radiotherapy with unresected stage I or II NSCLC

KEYLYNK-012: Evaluating KEYTRUDA in combination with Lynparza¹ in stage III disease

At AACR, in collaboration with Moderna, announced detailed results from Phase 2b KEYNOTE-942 investigating the combination of KEYTRUDA and mRNA-4157/V490, an individualized neoantigen therapy

The 18-month RFS rate was 78.6% (95% CI, 69.0-85.6) and 62.2% (95% CI, 46.9-74.3) in the combination and control arms, respectively



Advancing our broader oncology portfolio

Antibody Drug Conjugates

- **KEYNOTE-869:** Announced accelerated approval of KEYTRUDA, in combination with enfortumab vedotin, an anti-body drug conjugate, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy
- **Kelun-Biotech:** Planning to initiate multiple Phase 3 trials for MK-2870, a TROP-2 targeting ADC, as monotherapy and in combination with KEYTRUDA

Adenocarcinoma

- **KEYNOTE-859:** FDA accepted application for KEYTRUDA in combination with chemotherapy in HER2- negative locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma

Women's Cancers

- **NRG-GY018:** Announced positive data for KEYTRUDA in combination with chemotherapy for 1L treatment of patients with stage III to IV of recurrent endometrial carcinoma
- Building upon approvals based on KEYNOTE-146, KEYNOTE-775 and KEYNOTE-158 in endometrial cancer

Prostate

- Remain committed to addressing this area of significant unmet patient need
- Planning to initiate Phase 3 trials for MK-5684¹, a novel oral non-steroidal inhibitor of CYP-11A1, by the end of 2023

Expanding our broader pipeline and portfolio

Infectious Disease

- **HIV**
 - Enrolling multiple new Phase 3 studies for once-daily islatravir in combination with doravirine
 - Resumed the Phase 2 study of an oral once-weekly combination treatment regimen of islatravir and Gilead's lenacapavir
- **COVID-19**
 - Received full approval for LAGEVRIO for the treatment of COVID-19 by the Ministry of Health Labor and Welfare in Japan

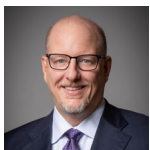
Immunology

- Proposed acquisition of Prometheus Biosciences augments and accelerates ongoing research efforts in immunology
- PRA023 is a potential first-in-class late-stage clinical candidate with positive Phase 2 results in ulcerative colitis and Crohn's Disease
- Suite of immunology pipeline compounds including PRA052
- Deep genetic and biological insights from Prometheus 360 Data Science Platform





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

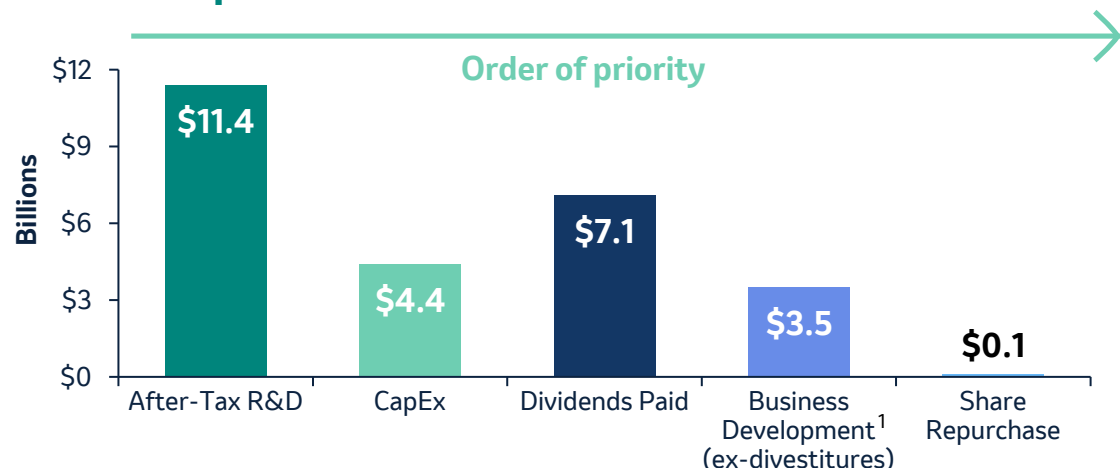
Q1 2023 GAAP financial results summary

\$ in billions, except EPS amounts

	Q1 2023	Q1 2022	Change	Change Ex-FX
Sales	\$14.5	\$15.9	-9%	-5%
Operating Expenses	\$6.8	\$4.9	+38%	+40%
Tax Rate	22.6%	11.4%	+11.2pts	N/A
GAAP EPS	\$1.11	\$1.70	-35%	-30%

Capital allocation: Trailing twelve months

Over the past 12 months



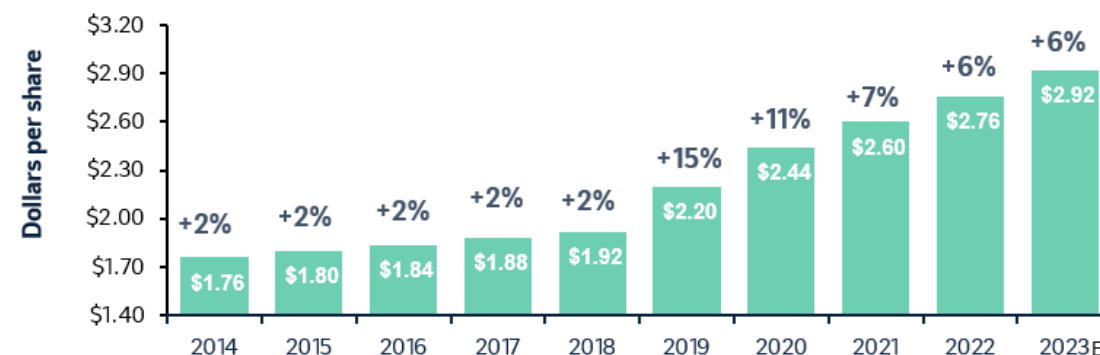
Capital investments 2022 to 2026

~\$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

Broad and innovative pipeline to solve significant unmet medical needs

[illegible]