



Merck Q3 2022 Earnings

October 27, 2022



Agenda



Strategy and Business Update

Rob Davis
President & 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, 2021 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

President & Chief Executive Officer



Delivered on our key strategic priorities in Q3



Achieved strong commercial and financial performance



Advanced the pipeline to meet patient unmet need



Executed on strategic business development to enhance pipeline



Created long-term value for patients and shareholders

Exceptional Q3 sales and underlying earnings growth¹



Worldwide Sales

\$15.0B

+14%

Ex-LAGEVRIO, +10%

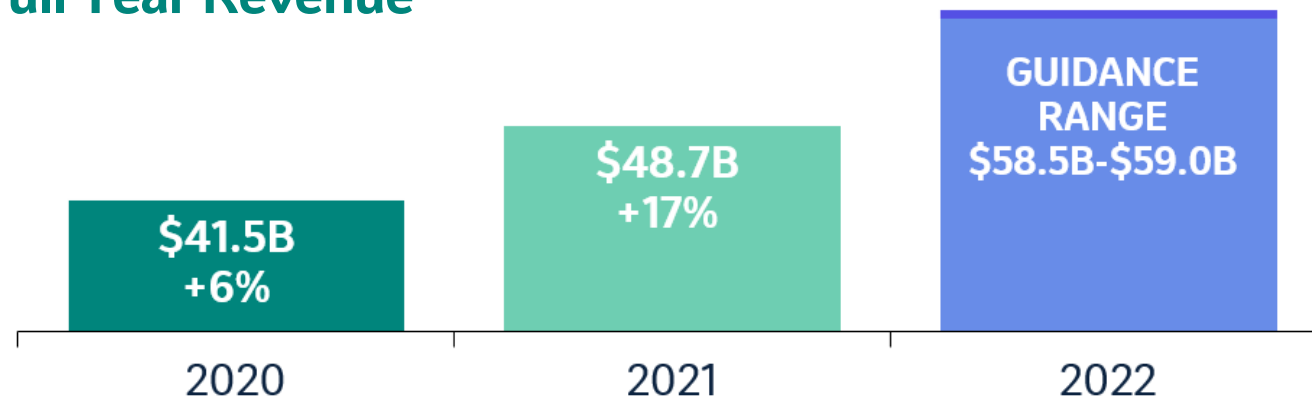


Non-GAAP EPS^{2,3}

\$1.85

+4%

Full Year Revenue



Full Year Non-GAAP EPS²



1. Results from continuing operations attributable to Merck & Co., Inc. 2. Beginning in 2022, Merck no longer excludes 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. For 2020, non-GAAP results have been recast to include \$4.2 billion of incremental R&D expenses, which reduced EPS by \$1.56. For 2021, non-GAAP results have been recast to include \$1.7 billion of incremental R&D expense, which reduced EPS by \$0.65. For 3Q 2022 and full year 2022, non-GAAP results include \$690 million of R&D expense, or an estimated \$0.22 of negative impact to EPS, driven by collaborations and license agreements with Orion, Orna and Moderna recorded in the third quarter of 2022. 3. GAAP EPS of \$1.28.

Advancing deep pipeline across multiple therapeutic areas

Cardiovascular

- Announced positive results for the Phase 3 STELLAR trial evaluating **sotatercept** as an add-on to stable background therapy in patients with pulmonary arterial hypertension
- Received FDA Fast Track Designation for anticoagulant candidate **MK-2060 (Factor XI)** for patients with end-stage renal disease

Oncology

- Presented encouraging results at ESMO across our **broad portfolio** and **promising pipeline**

Vaccines

- Advanced population-specific approach to invasive pneumococcal disease
 - Launched **VAXNEUVANCE** in the pediatric setting in the U.S.
 - Progressing Phase 3 trials evaluating **V116** in adults

HIV

- Announced path forward for **islatravir** for the treatment of HIV
- Committed to helping address unmet needs in HIV treatment and prevention

Making progress on our commitment to deliver value to society, which will in turn, create value for shareholders

Published ESG Progress Report

- Highlighted key initiatives including:
 - Providing **91.5 million doses** of HPV vaccines in Gavi-supported countries
 - Advancing our goal to achieve **carbon neutrality by 2025**
 - Supporting ESG-related projects and partnerships through the use of funds from the issuance of our **\$1 billion sustainability bond**



Appreciation for Ken Frazier as he retires from Merck's Board



“

For decades, Ken has **embodied Merck's core principles** and values, anchored by a singular focus on creating meaningful value for our patients, employees, communities and shareholders.

Ken is a **once-in-a-generation leader**, and his positive impact on our company and patients everywhere will reverberate for decades.

Tom Glocer, lead independent director

”



Business/Financial Results and Outlook

Caroline Litchfield
Chief Financial Officer



Excellent Q3 performance led by Human Health



Merck

WORLDWIDE SALES^{1,2}

\$15.0B

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



Human Health³

\$13.0B

+13% growth
+9% ex-LAGEVRIO³
+15% ex-exchange, ex-LAGEVRIO⁴



Animal Health

\$1.4B

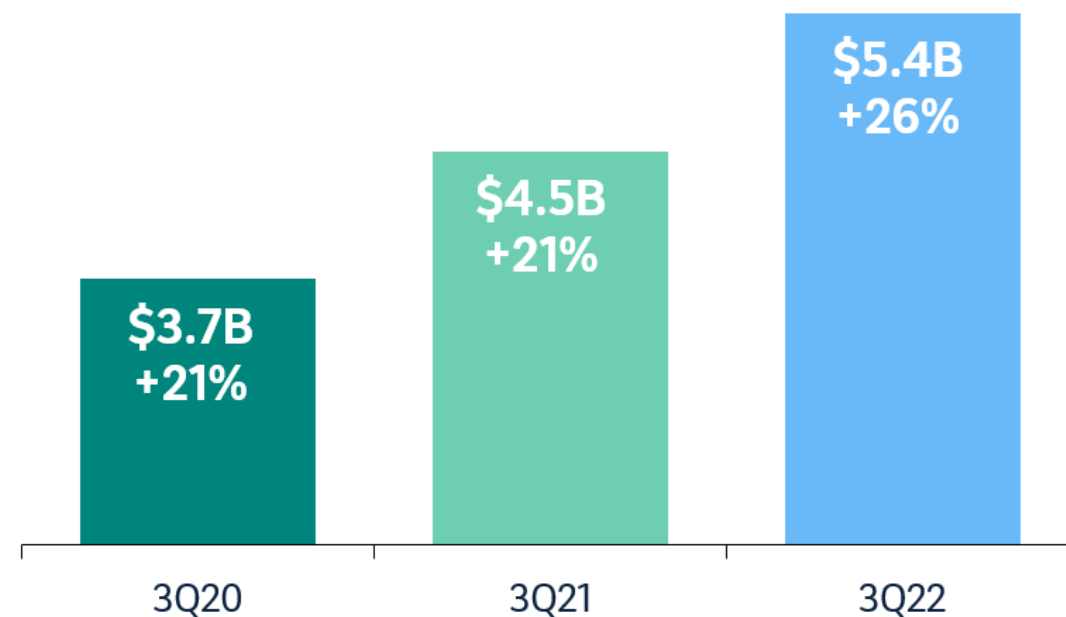
-3% decrease
+4% ex-exchange

1. Results from continuing operations attributable to Merck & Co., Inc. 2. Worldwide Sales includes Other Revenue 3. Excludes LAGEVRIO sales of \$436 million in the quarter
4. Excludes LAGEVRIO sales of \$436 million in the quarter and foreign exchange

Oncology: KEYTRUDA momentum driving strong global growth

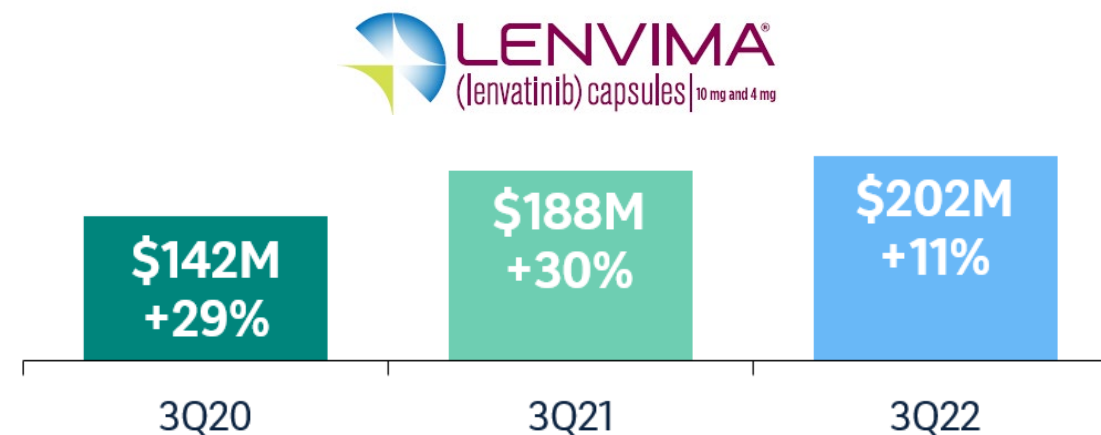
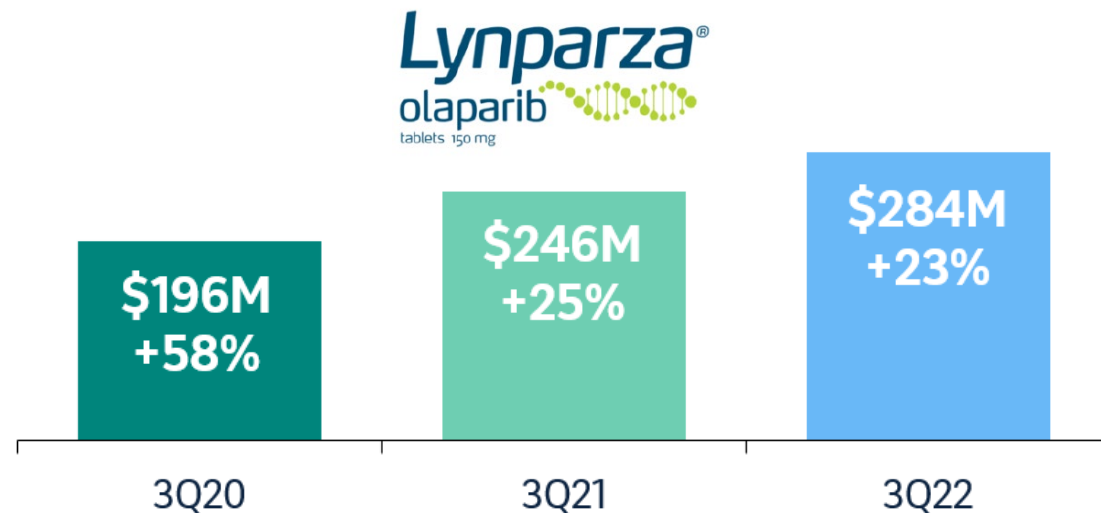
- KEYTRUDA sales of \$5.4B increased 26% year-over-year, driven by strong global demand and uptake in new indications
 - In the U.S., growth of 29% reflects strong momentum in metastatic indications as well as increased uptake in earlier-stage cancer launches including high-risk, early-stage TNBC
 - Ex-U.S., 21% increase driven by global uptake in NSCLC as well as HNSCC and advanced RCC
 - Strong uptake from new launches in high-risk, early-stage TNBC and RCC in key European markets

KEYTRUDA[®]
(pembrolizumab) Injection 100 mg



Oncology: Sustained momentum from key products

- Lynparza¹ sales increased 23%, with growth driven by continued demand for the adjuvant treatment of certain patients with gBRCAm, HER2-negative high-risk early-stage breast cancer based on OlympiA
- Lenvima² sales grew 11% driven by demand following recent launches in RCC and endometrial cancer, partially offset by shipment timing in China
- WELIREG experiencing strong uptake in patients with certain VHL-associated tumors

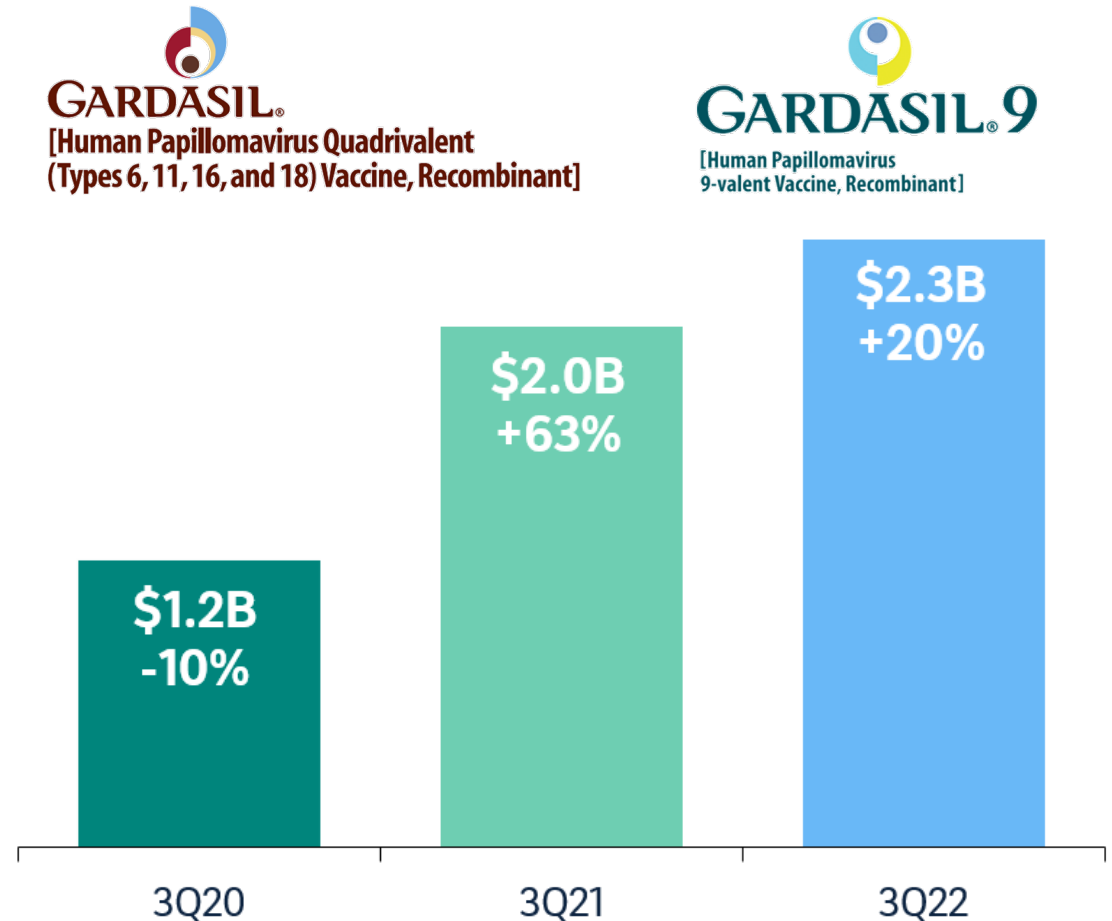


Growth rates exclude the impact of foreign exchange.

¹In collaboration with AstraZeneca. ²In collaboration with Eisai

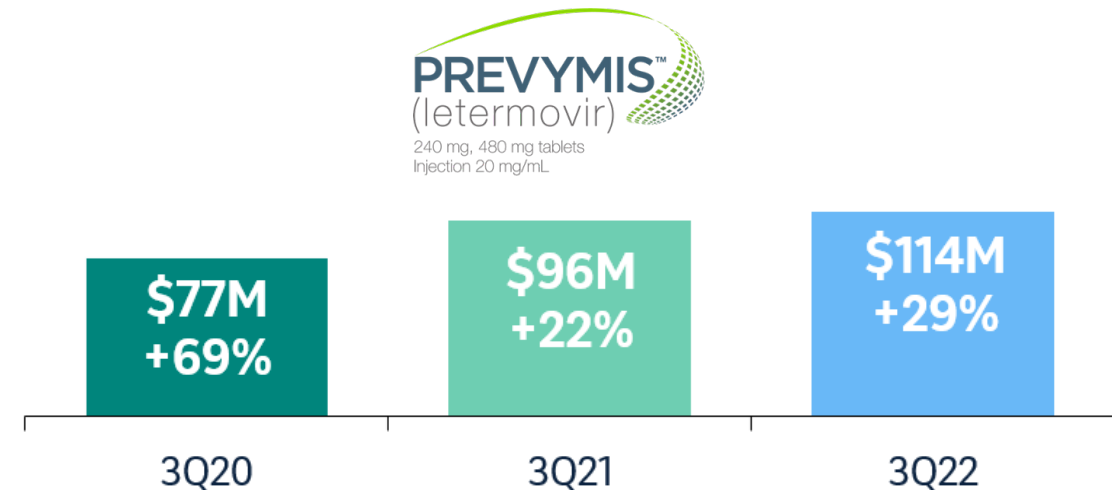
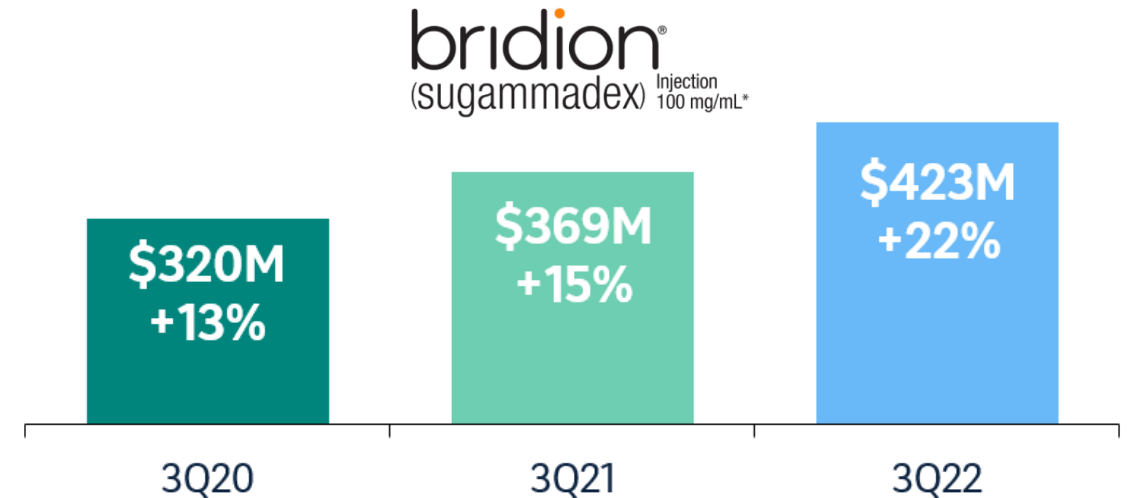
Vaccines: GARDASIL growth remains very strong

- GARDASIL sales of \$2.3B increased 20% year-over-year primarily driven by strong underlying demand outside the U.S. and increased supply
 - Ex-U.S., reflects demand driven growth, particularly in China, and increased supply
 - U.S. sales growth was driven by timing of CDC purchases



Hospital: Robust global demand across key products

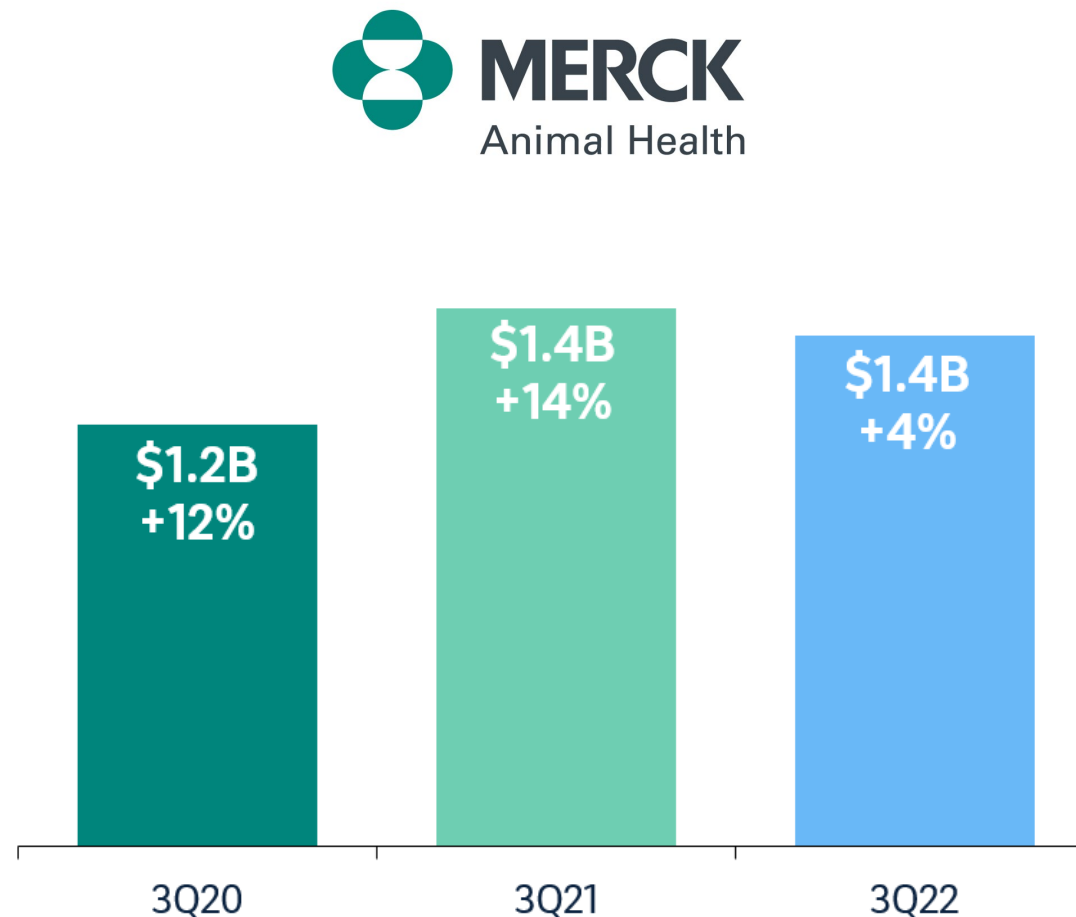
- BRIDION sales of \$423M increased 22% primarily due to greater share among neuromuscular blockage reversal agents and increase in surgical procedures
- PREVYMIS sales grew 29%, driven by continued strong global demand
- ZERBAXA benefiting from completion of global resupply



Growth rates exclude the impact of foreign exchange.

Animal Health: Solid Livestock and Companion Animal performance

- Animal Health sales increased 4% to \$1.4B
 - Livestock sales grew 4% due to poultry products and ruminant technology solutions
 - Companion Animal sales increased 4%, driven by BRAVECTO parasiticide line of products, partially offset by supply challenges for certain vaccines



Q3 2022 continuing operations non-GAAP financial results summary¹: Delivered strong revenue and EPS growth

\$ in billions, except EPS amounts

	Q3 2022	Q3 2021	Change	Change Ex-FX
Sales	\$15.0	\$13.2	+14%	+18%
Non-GAAP Gross Margin	77.0%	76.8%	+0.2pts	-0.4pts
Non-GAAP Operating Expenses²	\$6.0	\$4.7	+28%	+32%
Non-GAAP Tax Rate	13.6%	12.8%	-0.8pts	N/A
Non-GAAP EPS³	\$1.85	\$1.78	+4%	+7%

1. 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 the press release. Non-GAAP results for 2021 have been recast to conform to presentation changes implemented in 2022.

2. Non-GAAP results include \$690 million of R&D expense, recorded in the third quarter of 2022, for collaborations and licensing agreements with Moderna, Orna and Orion, or an estimated \$0.22 of negative impact to EPS 3. Q3 2022 GAAP EPS of \$1.28.

Merck updated full-year 2022 guidance

	Prior Guidance	Updated Guidance	Key Assumptions
Revenue	\$57.5B to \$58.5B +18% to +20% (+21% to +23% ex-FX)	\$58.5B to \$59.0B +20% to +21% (+24% to +25% ex-FX)	<ul style="list-style-type: none"> ~16% growth excluding LAGEVRIO and FX impact Includes \$5.2 to \$5.4B of LAGEVRIO revenue Assumes ~4% negative FX impact (vs. prior ~3% negative FX impact)
Non-GAAP Gross Margin Rate ¹	74.0% - 74.5%	74.0% - 74.5%	
Non-GAAP Operating Expenses ²	\$20.5B to \$21.5B	\$21.3B to \$21.7B	<ul style="list-style-type: none"> Now includes \$250M related to Moderna option exercise; Full-year 2022 includes \$690 million of R&D expense related to collaboration and licensing agreements⁶
Other (Income) / Expense	~\$500M of expense	~\$500M of expense	
Tax Rate ³	~13.5-14.5%	~14%	
Shares Outstanding	~2.54B	~2.54B	
GAAP EPS	\$5.89 to \$5.99	\$5.68 to \$5.73	
Non-GAAP EPS ^{4,5}	\$7.25 to \$7.35	\$7.32 to \$7.37	<ul style="list-style-type: none"> Assumes ~4% negative FX impact (vs. prior ~3% negative FX impact) Full year 2022 includes \$0.22 of R&D expense related to collaboration and licensing agreements⁶

1. GAAP Gross Margin Rate: ~70%. 2. GAAP Operating Expenses: \$22.5 to \$22.9 billion. 3. GAAP Tax Rate: ~11% 4. The GAAP to non-GAAP reconciliation is available in Merck's Q3 2022 earnings release 5. Beginning in 2022, Merck no longer excludes 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. Prior periods have been recast to reflect this change. 6. R&D expense related to collaboration and licensing agreements with Moderna, Orna and Orion recorded in 3Q 2022

Key modeling considerations

FX

- FX continues to be a headwind, particularly for products with a larger portion of ex-US sales, such as in Animal Health

Other Revenue

- Includes ongoing supply sales to Organon, effects from revenue hedging program and out-license receipts

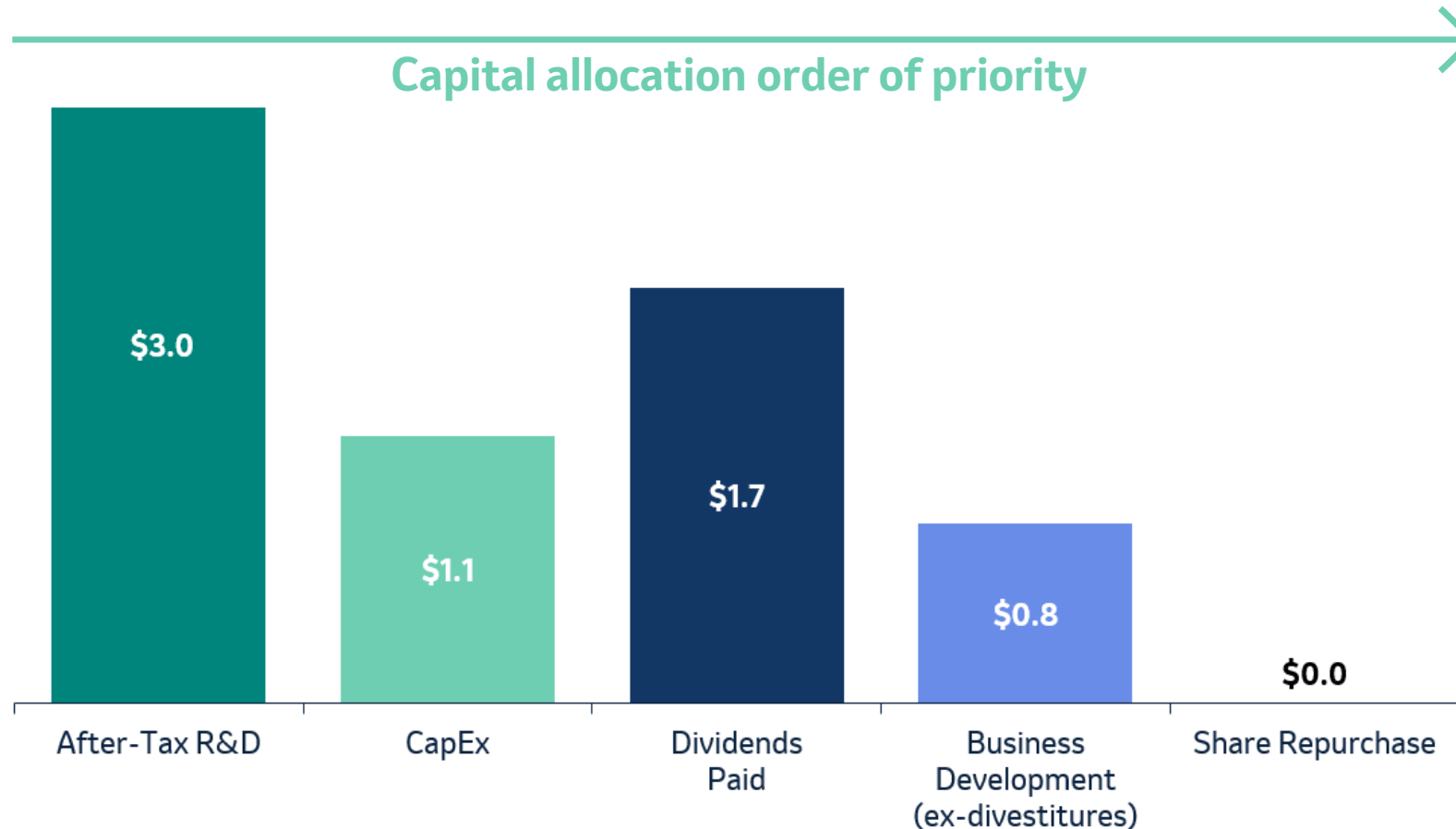
Pneumococcal

- Expect continued negative impact to PNEUMOVAX23 in the U.S. as the market shifts toward newer pneumococcal conjugate vaccines



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 Q3 spend



Research Update

Dr. Dean Li

President, Merck Research Laboratories



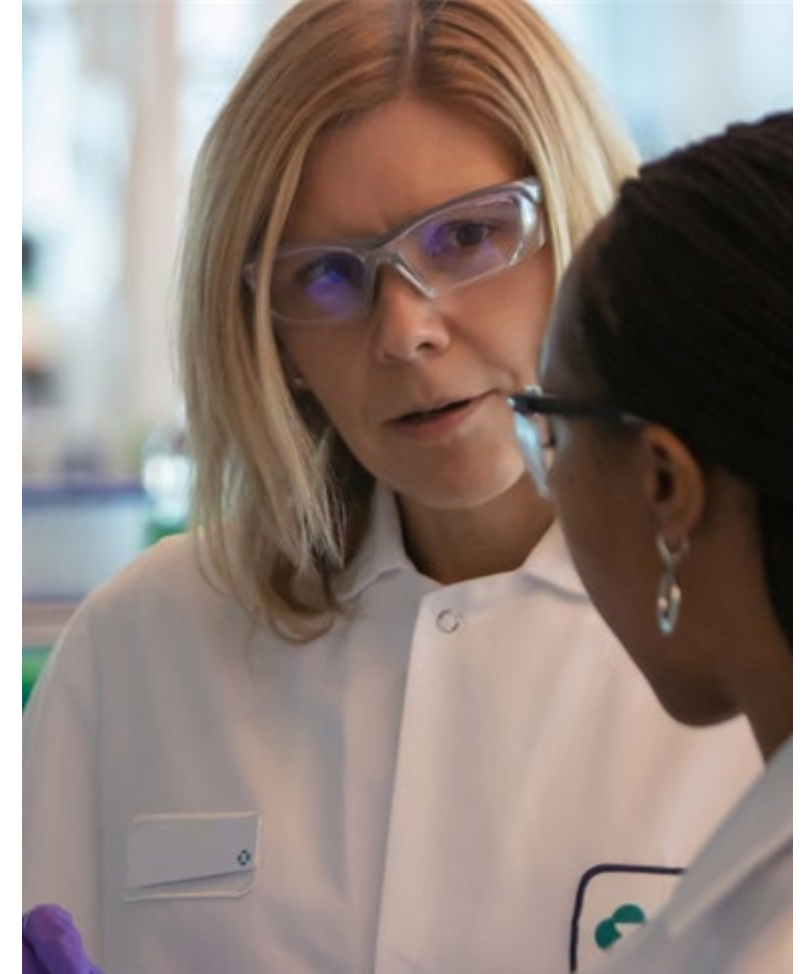
Driving value for patients and shareholders by progressing our pipeline

Key regulatory milestones since the last earnings call:

- In the US:
 - The FDA accepted submission of New Drug Application and granted priority review for Lynparza¹ in combination with abiraterone and prednisone or prednisolone in mCRPC based on PROpel, as well as granted Fast Track designation for investigational anticoagulant MK-2060 in patients with ESRD
- In the EU:
 - Received approval for Lynparza as adjuvant treatment in certain patients with gBRCAm, HER2-negative, high-risk early breast cancer based on OlympiA, as well as for VAXNEUVANCE in pediatrics
- In China:
 - Received approval for KEYTRUDA in 2L HCC based on KN-394, as well as for Lynparza in combination with bevacizumab for maintenance therapy for certain patients with ovarian cancer based on PAOLA-1
- In Japan:
 - Received 4 new approvals for KEYTRUDA (KN-522, KN-564, KN-826 and KN-716) as well as 1 new approval for Lynparza as adjuvant treatment in certain patients with gBRCAm, HER2-negative, high-risk early breast cancer based on OlympiA, 1 new approval for Koselugo¹ in neurofibromatosis type-1 in pediatrics, and 1 new approval for V114 in adults

Key data & clinical advancements since the last earnings call:

- Announced positive top-line results from pivotal Phase 3 STELLAR trial evaluating sotatercept as an add-on to stable background therapy for the treatment of adults with PAH
- Presented data across our broad oncology portfolio at ESMO, including for KEYTRUDA (KN-189 and KN-407), Lynparza (SOLO-1 and PAOLA-1), as well as KEYTRUDA + Padcev (KN-869 / EV-103)²
- Announced path forward for islatravir, including new Phase 3 clinical program with lower dose of daily oral islatravir in combination with doravirine, as well as a new Phase 2 clinical trial studying a once-weekly combination treatment regimen of islatravir and lenacapavir³
- Provided real-world data updates with our partner Ridgeback Biotherapeutics based on the PANORAMIC and Clalit studies



Potential to transform the treatment of adult patients with pulmonary arterial hypertension

- **Positive** topline results from Phase 3 **STELLAR** trial evaluating sotatercept added to currently approved background therapy in Pulmonary Arterial Hypertension
 - **Profound effect** on primary efficacy outcome measure of improvement in 6MWD from baseline at 24 weeks
 - **8 out of 9 secondary efficacy outcome measures** achieved statistical significance
- Additional Phase 3 trials evaluating sotatercept in patients with Pulmonary Arterial Hypertension include **ZENITH** and **HYPERION**
- Sotatercept is also being evaluated in the Phase 2 **CADENCE** trial, in patients with Cpc-PH due to HFpEF
- Ongoing Phase 2/3 trials studying **MK-5475** an investigational, **inhaled sGC stimulator** in PAH



Real-world evidence (RWE) supports the role of LAGEVRIO as an important option in treating adults at high risk for severe COVID-19

- Approximately **2.5 million people globally** have received LAGEVRIO for the treatment of COVID-19
- Data from recent **RWE studies** conducted across **different geographies** provide insight into patient experience with LAGEVRIO, suggesting:
 - faster time to recovery and to initial alleviation of symptoms, among highly-vaccinated adults at risk for severe COVID-19, vs. usual care alone¹
 - reduced risk for hospitalization and mortality among patients aged 65 years and older²
- LAGEVRIO remains an **important treatment option** as the pandemic continues to evolve with new variants and varying degrees of vaccine effectiveness across the globe
- **Initiated** Phase 2 trial for the treatment of Respiratory Syncytial Virus based on the **promising clinical profile** of LAGEVRIO



1. Butler et al. Preprint, 4 Oct 2022. Available at SSRN: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4237902. In the preliminary analysis of the PANORAMIC study, a UK-based clinical trial sponsored by the University of Oxford, the primary endpoint of reduction of hospitalizations and deaths within 28 days of randomization, compared to usual care, was not met.

2. The Clalit trial, an observational, retrospective cohort study, evaluated data obtained from the electronic medical records of members of Clalit Health Services. The study assessed the real-world effectiveness of LAGEVRIO in preventing severe COVID-19 outcomes in patients 40 years of age and older estimated to be at high risk of progression to severe disease, who were infected by the Omicron variant and were not eligible for ritonavir-boosted nirmatrelvir therapy due to drug-drug interactions or impaired kidney function. No evidence of benefit was found in younger adults ages 40 to 64 years

Significant advancements across our broader pipeline and portfolio

HIV

- Initiated **new Phase 3 clinical program** evaluating a once-daily oral combination of doravirine and a lower dose of islatravir for the treatment of people with HIV-1 infection
- Announced plans to **resume Phase 2 study** with Gilead, evaluating **a weekly oral combination treatment** regimen of islatravir and lenacapavir in adults with HIV-1 infection who are virologically suppressed is resuming with a lower dose of islatravir
- Prioritizing an **internal novel NRTTI compound** for development in the PrEP setting

Vaccines

- In China, received **broadened approval** based on age from the National Medical Products Administration for GARDASIL-9 for use in girls and women ages 9 to 45
- In the EU, received **approval** for VAXNEUVANCE in infants, children and adolescents 6 weeks to less than 18 years of age for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae*

RNA Technologies

- **Executing** on business development and licensing strategy
 - Collaboration with Orna Therapeutics on its circular RNA technology

Continuing to build on strong momentum in oncology

Quarterly highlights

- Important data at ESMO:
 - Showcased **long-term survival benefit** for KEYTRUDA in NSCLC, melanoma and head and neck cancers as well as LYNPARZA in ovarian cancer
 - Presented data in **earlier stage settings**, building on our expansive efforts
 - Presented first time **positive data** in collaboration with Seagen and Astellas for KEYTRUDA plus enfortumab vedotin-ejfv in locally advanced / metastatic urothelial cancer
- Received **priority review** from FDA for Lynparza with abiraterone and prednisone or prednisolone for certain patients with metastatic castration-resistant prostate cancer

Global highlights

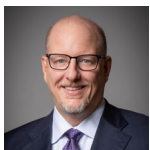
- **Four approvals in Japan** for KEYTRUDA in neoadjuvant / adjuvant high-risk early-stage TNBC, adjuvant RCC, stage IIB and IIC melanoma and cervical cancer
- **Approval in EU and Japan** for Lynparza for adjuvant treatment of certain patients with gBRCAm, HER2-negative, high-risk early breast cancer
- **Approval in China** for Lynparza for first line maintenance treatment with bevacizumab of HRD-positive of advanced ovarian cancer

Personalized Cancer Vaccines

- Exercised option to **jointly develop** mRNA-4157 / V940 with Moderna in melanoma
- **Complements** broad oncology and vaccine development programs



Q&A



Rob Davis
President & Chief Executive Officer



Caroline Litchfield
Chief Financial Officer



Dr. Dean Li
President, Merck Research Laboratories



Peter Dannenbaum
Vice President, Investor Relations



Appendix

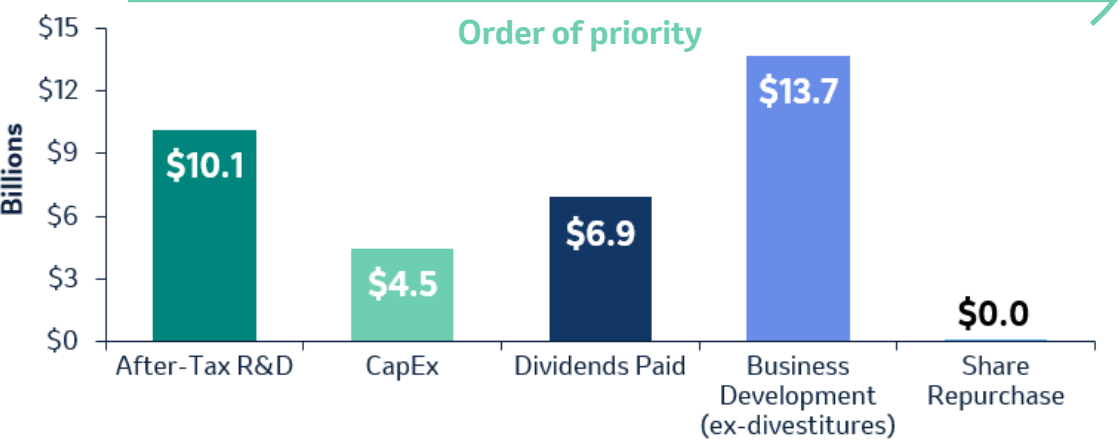
Q3 2022 continuing operations GAAP financial results summary

\$ in billions, except EPS amounts

	Q3 2022	Q3 2021	Change	Change Ex-FX
Sales	\$15.0	\$13.2	+14%	+18%
Operating Expenses	\$6.9	\$4.8	+45%	+49%
Tax Rate	9.2%	13.2%	-4.0pts	N/A
GAAP EPS	\$1.28	\$1.80	-29%	-25%

Capital allocation: Trailing twelve months

Over the past 12 months



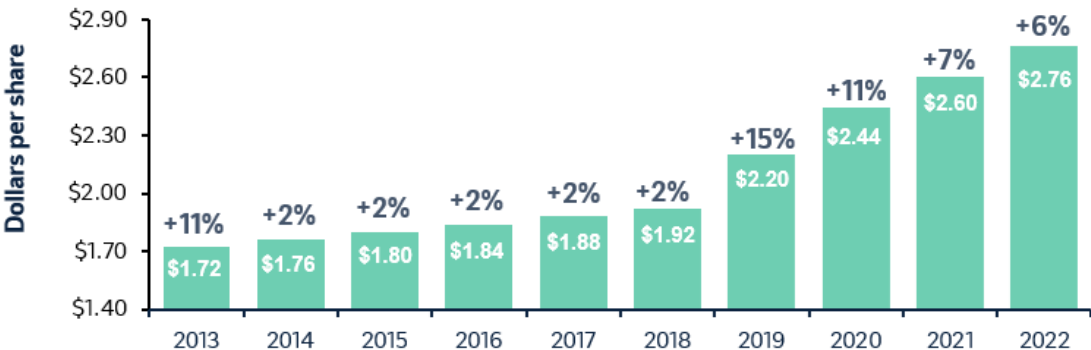
Well positioned balance sheet
with capacity to fund
**additional value-enhancing
business development
opportunities**

Capital investments 2022 to 2026

~\$17B

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

Commitment to the dividend



Broad and innovative pipeline to solve significant unmet medical needs

Phase 2			Phase 3	Under regulatory review
Oncology			Oncology	Oncology
MK-0482 NSCLC	MK-2870 Neoplasm Malignant	MK-5684 Prostate	KEYTRUDA (MK-3475) Biliary Tract CSCC (EU) Gastric (EU) Hepatocellular (EU) Mesothelioma Ovarian Prostate SCLC	KEYTRUDA (MK-3475) 2L HCC (US) Adjuvant NSCLC (US, EU)
MK-1026 (nemtabrutinib) Hematological Malignancies	KEYTRUDA (MK-3475) Advanced Solid Tumors	MK-5890 (bosertolimab) NSCLC SCLC	LENVIMA (MK-7902) HNSCC Melanoma CRC Esophageal NSCLC Gastric	LYNPARZA (MK-7339) Metastatic 1L Prostate (US, EU, JPN)
MK-1308 (quavonlimab) NSCLC	MK-4280 (favezelimab) NSCLC	MK-6440 (ladiratuzumab vedotin) Breast NSCLC SCLC HNSCC Esophageal Gastric Prostate Melanoma	MK-1308A (quavonlimab + pembrolizumab) HCC CRC SCLC Melanoma	V114 Pneumococcal Vaccine, pediatric (JPN)
MK-1308A (quavonlimab + pembrolizumab) HCC CRC SCLC Melanoma	MK-4280A (favezelimab + pembrolizumab) Esophageal RCC SCLC	LYNPARZA (MK-7339) Advanced Solid Tumors	MK-7684A (vibostolimab + pembrolizumab) NSCLC SCLC	General medicine
MK-2140 (zilovetamab vedotin) Breast Gastric Ovarian Pancreas NSCLC Hematological Malignancies	MK-4830 Esophageal Ovarian NSCLC SCLC RCC CRC Melanoma	LENVIMA (MK-7902) Biliary Glioblastoma Prostate SCLC Pancreas	TUKYSA (MK-7119) Advanced Solid Tumors Gastric Endometrial NSCLC Bladder Biliary Cervical mRNA-4157/V940 Melanoma	Gefapixant (MK-7264) Cough (US, EU)
Vaccines			Infectious diseases	Infectious diseases
V184 Chikungunya Virus	Cardiovascular	General medicine	MK-8591A (doravirine + islatravir) ² HIV-1 Infection	Molnupiravir (MK-4482) COVID-19 antiviral (EU)
V181 Dengue Fever Virus	MK-0616 Hypercholesterolemia	MK-1942 Treatment Resistant Depression	Molnupiravir (MK-4482) ³ COVID-19 antiviral	
Infectious diseases	MK-2060 Cardiovascular Thrombosis	MK-3655 NASH	Vaccines	
MK-8591B (islatravir + MK-8507) ¹ HIV-1 Infection	MK-5475 Pulmonary Arterial Hypertension	MK-6024 NASH	MK-1654 (clesrovimab) Respiratory Syncytial Virus	V116 Pneumococcal vaccine, adult
MK-8591D (islatravir + lenacapavir) ² HIV-1 Infection	MK-7962 Pulmonary Hypertension due to Left Heart Disease	MK-7075 (miransertib) Overgrowth Syndrome	Cardiovascular	
Neuroscience			Sotatercept (MK-7962) Pulmonary Arterial Hypertension	
MK-8189 ⁴ Schizophrenia				

¹On FDA clinical hold ²On FDA partial clinical hold ³Available in the US under EUA ⁴Development is co-funded by Royalty Pharma