

# Merck & Co., Inc Q2 2023 Earnings Prepared Remarks

August 1, 2023



**MERCK**  
INVENTING FOR LIFE

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

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**Mr. Rob Davis – Merck & Co., Inc., Chairman and Chief Executive Officer**

[SLIDE 4: Strategy & Business Update]

Thanks Peter.

Good morning and thank you for joining today's call. We continue to make great progress in bringing forward compelling science to help address the world's most urgent unmet medical needs. Thanks to the unwavering commitment and discipline of our global teams, we're advancing our innovative pipeline and executing operationally in support of our key growth drivers. Our science-led strategy is generating innovations that save and improve the lives of patients and animals around the world, and is delivering strong underlying growth for our business.

[SLIDE 5: Delivered on our key strategic priorities in Q2 2023]

We're building on our strong track record and advancing our strategic priorities. We're progressing our deep pipeline, including sotatercept for which we have completed our FDA submission, and augmenting it with further strategic business development where we can add value by applying our clinical expertise and leveraging our global scale to accelerate broad access to patients.

An excellent example of this is our acquisition of Prometheus Biosciences, which we completed in June. We're now actively integrating the talented team and are moving with speed toward initiation of a Phase 3 clinical trial. The addition of Prometheus significantly strengthens our presence in immunology, an area with substantial unmet medical need, and builds on the significant scientific insight we have gained in immuno-oncology. It also brings us a potential first-in-class, best-in-class novel TL1A inhibitor, which provides us the opportunity to transform the standard of care in a patient population suffering from debilitating immune-mediated diseases.

With a foundation of great science and a legacy of commercial excellence, we're well-positioned to deliver sustainable value over the long-term.

[SLIDE 6: Strong underlying Q2 performance]

Focusing now on the short-term.

We delivered strong underlying growth, excluding the year-over-year decline in LAGEVRIO sales, led by robust demand across key growth drivers in Oncology and Vaccines. We remain confident in our outlook for the remainder of 2023, which Caroline will address in a moment.

[SLIDE 7: Advancing and augmenting our deep pipeline]

Moving to our research organization, our promising late-stage pipeline continues to demonstrate tangible and impactful benefits for patients across a broad range of diseases.

In oncology, we highlighted data from our expansive pipeline at ASCO, including for KEYTRUDA in earlier stage lung cancer. The strong results of KEYNOTE-671 for the neoadjuvant and adjuvant treatment of patients with non-small cell lung cancer support our aspiration to fundamentally shift the way cancer is managed by developing treatment regimens in the earlier stage setting, where the potential for better outcomes is higher.

Additionally, we're leveraging KEYTRUDA's wide-reaching benefit across a range of cancer types to identify and bring forward promising new candidates.

At ASCO, we shared positive data for KEYTRUDA in combination with V940, our investigational individualized neoantigen therapy in collaboration with Moderna, in the adjuvant treatment of melanoma. And promising data was also presented by our partner Kelun Biotech, for MK-2870, our TROP-2 ADC, in non-small cell lung cancer. Each of these novel candidates offer a glimpse into the future of cancer care and the potential to meaningfully improve outcomes for patients.

We have also made progress outside of oncology. We're advancing our population-specific approach to pneumococcal vaccination and are very pleased to have announced positive topline results for our adult vaccine candidate, V116. If approved, V116 would be the first pneumococcal conjugate vaccine specifically designed for adults. And Dean will speak to our progress in cardiometabolic disease including positive data we recently presented for our GLP-1 / glucagon receptor dual agonist. I commend Dean and his team on the significant work being done to advance our broad pipeline and their commitment to Merck's purpose.

Innovation is the core of who Merck is and it's what our company strives to achieve every day. We're grounded in the relentless pursuit of advancing science and raising the bar of innovation to deliver value for patients. With that in mind, I'd like to speak for a moment about the Inflation Reduction Act. We've consistently communicated our support for elements of the law that improve patient affordability and access, such as the Medicare Part D reform, but which do so without damaging the very promising long-term innovation potential of the biopharmaceutical industry.

Through the complaint we recently filed in U.S. District Court, Merck is taking a principled stand against the negative long-term impacts of the price negotiation provision of the IRA which we believe amounts to unconstitutional price setting that violates several provisions of the U.S. Constitution. This misguided policy does not strike the right balance

between incenting investment in innovation and improving affordability and access. That said, we remain committed to working with the U.S. government to find a better approach to improve affordability and access while protecting further drug breakthroughs that benefit patients facing unmet medical needs.

[SLIDE 8: Putting the patient at the center of everything we do]

We know it is critical that we provide broad access both to our current portfolio of medicines and vaccines, and to our future innovations, in order to serve the greatest number of patients possible, now and for years to come. Our upcoming annual Impact Report will highlight accomplishments across our four priority areas, including Access to Health, where a portion of employee compensation will now be driven by metrics linked to our progress.

In summary, our science-led strategy is working. We're driving significant scientific, commercial and operational momentum which we expect will enable strong full-year growth. I want to thank our talented, dedicated and diverse global team for their hard work and commitment to delivering value for patients, shareholders and all of our stakeholders. With these efforts, I'm confident we will continue to drive sustainable success well into the future.

With that, I'll turn the call over to Caroline.

**Ms. Caroline Litchfield – Merck & Co., Inc., Chief Financial Officer**

[SLIDE 9: Business/Financial Results and Outlook]

Thank you, Rob. Good morning.

[SLIDE 10: Strong underlying Q2 worldwide sales growth]

As Rob noted, we delivered another very strong quarter, with underlying growth driven by demand across our innovative portfolio. These results reflect the profound impact of our medicines and vaccines globally and reinforce the confidence we have in the health of our business, and in the outlook for continued strong underlying growth.

Now, turning to our second quarter results.

Total company revenues were \$15.0 billion. Excluding the impact from LAGEVRIO and foreign exchange, the business delivered very strong growth of 14%.

The remainder of my revenue comments will be on an ex-exchange basis.

Our Human Health business sustained its strong momentum. Excluding LAGEVRIO, growth was 17%, driven by Oncology and Vaccines.

Sales in our Animal Health business increased 2% across both companion animal and livestock products.

[SLIDE 11: Oncology: KEYTRUDA continues to drive strong growth]

Now, turning to the second quarter performance of our key brands.

In Oncology, KEYTRUDA grew 21% to \$6.3 billion driven by increased utilization from approvals in earlier stage cancers and continued strong global demand from metastatic indications.

In the U.S., KEYTRUDA grew across all key tumor types and continues to benefit from usage in earlier-stage cancers including triple negative breast cancer, as well as in certain types of renal cell carcinoma and melanoma. We are encouraged by the positive feedback from healthcare providers and initial uptake of KEYNOTE-091, reflecting the significant impact KEYTRUDA is having on patients with earlier stage non-small cell lung cancer.

Outside the U.S., KEYTRUDA is maintaining its leadership in non-small cell lung cancer. Growth was driven by demand in metastatic renal cell carcinoma and certain types of head and neck cancer, as well as in earlier-stage cancers, including high-risk, early-stage triple negative breast cancer and renal cell carcinoma, which saw continued uptake in recently launched markets.

[SLIDE 12: Oncology: Solid performance across broad portfolio]

Lynparza remains the market leading PARP inhibitor. Alliance revenue grew 15% driven by increased demand in certain international markets.



Lenvima alliance revenue grew 6% due to increased demand for the treatment of certain patients with advanced renal cell carcinoma and endometrial cancer in the U.S., partially offset by lower sales in China.

[SLIDE 13: Vaccines: Exceptional growth driven by GARDASIL]

Our vaccines portfolio delivered exceptional growth, led by GARDASIL, which grew 53% to \$2.5 billion. Performance was driven by strong global demand, especially in China, where we are benefitting from the expanded indication of GARDASIL 9 for girls and women 9 to 45 years of age. Vaccine sales also benefited from increased uptake of VAXNEUVANCE following the ongoing pediatric launch, particularly in the U.S.

[SLIDE 14: Hospital: Strong global demand across key products]

In our Hospital Acute Care portfolio, BRIDION sales grew 19%, driven by increased market share among neuromuscular blockade reversal agents in the U.S.

[SLIDE 15: Animal Health: Growth driven by livestock and companion animal]

Sales in our Animal Health business grew 2%. Livestock sales growth reflects price actions as well as higher demand for swine and poultry products, partially offset by lower demand for ruminant products, due in part, to reduced herd sizes. Companion animal growth reflects price actions, including for the BRAVECTO line of products partially offset by supply challenges for certain vaccines.

[SLIDE 16: Q2 2023 non-GAAP financial results summary]

I will now walk you through the remainder of our P&L, and my comments will be on a non-GAAP basis.

Gross margin was 76.6%, an increase of 1.9 percentage points due to favorable product mix, including a benefit from the lower sales of LAGEVRIO.

Operating expenses increased to \$15.9 billion, including a \$10.2 billion one-time charge related to the acquisition of Prometheus. Excluding this charge, operating expenses grew 10%. This growth reflects increased investments in support of near-term opportunities for our in-line portfolio and disciplined investments for the future as we advance our exciting early- and late-phase pipeline.

Other income was \$19 million.

Our tax provision was approximately \$800 million. As a result of the Prometheus one-time charge, we had a pre-tax loss this quarter. This one-time charge is not tax deductible. Our tax rate is therefore a negative 18.4%.

Taken together, we reported a loss of \$2.06 per share, which includes a negative impact of \$4.02 per share from the one-time charge related to the Prometheus transaction.

[SLIDE 17: Merck updated full-year 2023 guidance]

Turning now to our 2023 non-GAAP guidance.

The underlying strength of our business has enabled us to raise and narrow our full year revenue guidance. We now expect revenue to be between \$58.6 and \$59.6 billion, an increase of \$800 million at the midpoint. This range reflects strong underlying year over year revenue growth of 10% to 11%, offset by the expected lower sales of LAGEVRIO, which we continue to estimate to be approximately \$1 billion this year, and an approximate 2 percentage point negative impact from foreign exchange using mid-July rates.

Our gross margin assumption is unchanged at approximately 77%.

We now estimate operating expenses to be between \$34.0 and \$34.6 billion. This range includes \$11.6 billion of acquisition and upfront collaboration research and development expenses associated with Prometheus, Imago and Kelun. Our guidance does not assume additional significant potential business development transactions.

We now assume Other Expense of approximately \$100 million, which includes incremental financing costs related to Prometheus.

Our full year tax rate is expected to be between 30.5% and 31.5%, reflecting an increase due to the Prometheus transaction of approximately 15 percentage points.

We continue to assume approximately 2.55 billion shares outstanding.

Taken together, we expect EPS of \$2.95 to \$3.05, which includes the one-time charge for Prometheus and a negative impact from foreign exchange of approximately 5 percentage points versus 2022, using mid-July rates.

Recall our prior guidance range was \$6.88 to \$7.00, which we noted at the time excluded Prometheus. Had we included the \$4.02 one-time charge and an estimated 14 cents to advance the assets and financing costs, our prior guidance range would have been \$2.72 to \$2.84 with a midpoint of \$2.78. Our current guidance midpoint of \$3.00 represents an increase resulting from the strength in our business of approximately \$0.24, partially offset by an incremental headwind from foreign exchange of approximately 2 cents.

[\[SLIDE 18: Key modeling considerations\]](#)

Our guidance reflects our continued confidence in the strength of our business driven by our key pillars, enabling us to deliver robust underlying growth while investing in our promising pipeline.

As you consider your models, there are a couple of items to keep in mind.

KEYTRUDA growth has been exceptional in recent quarters, outperforming our expectations, driven in part by robust uptake of recently launched earlier stage indications. We continue to expect strong year-over-year growth of KEYTRUDA, but not quite at the levels experienced in recent quarters, as a result of lapping launches and the impact of continued pricing headwinds, particularly as we launch new indications in key European markets. In addition, there was a small benefit from wholesaler purchase timing in the U.S. in the second quarter, which we expect to reverse in the third quarter. As we look out to 2024 and beyond, we continue to expect strong growth including the impact of additional approvals.

And as a reminder, while we expect the pace of growth of GARDASIL to be higher in 2023 than 2022, the rate of second half growth is anticipated to be below the first-half, due in part to the timing of shipments to China.

[SLIDE 19: Remain committed to balanced capital allocation strategy]

Now turning to capital allocation. We will continue to prioritize investments in our business and growing pipeline to drive near and long-term growth across our portfolio.

We remain committed to our dividend, with the goal of increasing it over time.

Business development remains a priority. We remain well positioned to pursue the most compelling external science through value-enhancing business development to augment our pipeline.

We continue to expect to execute a modest level of share repurchases this year.

To conclude, as we enter the second half of the year, we remain very confident in both, the strength of our underlying business, driven by global demand for our innovative medicines and vaccines, and the excellent execution of our dedicated teams across all areas of our business, which will enable us to continue to deliver value to patients, customers and shareholders now and well into the future.

With that, I'd now like to turn the call over to Dean.

**Dr. Dean Li – Merck & Co., Inc., President, Merck Research Laboratories**

[SLIDE 20: Research Update]

Thank you, Caroline. Good morning, everyone.

[SLIDE 21: Driving value for patients and shareholders by progressing our pipeline]

It's my pleasure to provide an overview of the significant pipeline progress across multiple therapeutic areas since the first quarter call. Today I will start with oncology, followed by vaccines and infectious diseases and finally onto our broader pipeline.

[SLIDE 22: Continuing to advance our broader oncology program]

Starting with oncology. The development of meaningful treatment options for patients with earlier stage disease, where there is greater prospect to improve outcomes, continues to be an area of significant progress.

Last week we announced, the Phase 3 KEYNOTE-756 trial evaluating KEYTRUDA in combination with chemotherapy, in patients with high-risk, early-stage estrogen receptor-positive, HR positive, HER2 negative breast cancer, met one of its dual primary endpoints of pathological complete response following the neoadjuvant part of the neoadjuvant / adjuvant study. This is the first Phase 3 study to demonstrate a positive result for an immunotherapy-based regimen in early-stage breast cancer for this patient population.

Further, in women's cancer and building on our progress in earlier-stages of disease, we announced that the Phase 3 KEYNOTE-A18 trial met one of its primary endpoints of progression-free survival for treatment of newly diagnosed patients with high-risk locally advanced cervical cancer. This is the first study of KEYTRUDA plus chemo-radiotherapy or radiotherapy to show statistically significant and clinically meaningful improvement in progression-free survival.

At ASCO, as part of our investor event, we provided an overview of our clinical development pipeline and highlighted relevant data presentations. We have strong momentum as we evaluate the opportunity for KEYTRUDA in earlier stages of disease.

Detailed results were presented from the ongoing KEYNOTE-671 study, evaluating KEYTRUDA in combination with platinum doublet chemotherapy as neoadjuvant therapy, followed by adjuvant KEYTRUDA in patients with resectable stage II, IIIA and IIIB non-small cell lung cancer.

Treatment with KEYTRUDA and chemotherapy before surgery, followed by KEYTRUDA monotherapy after surgery, reduced the risk of disease recurrence, progression, or death by 42 percent versus preoperative chemotherapy alone. Subgroup analysis showed a consistent response regardless of PD-L1 expression, histology, and stage of disease. The PDUFA target action date is October 16<sup>th</sup>.

With the approval of KEYNOTE-091, as treatment after surgery and adjuvant chemotherapy, along with the potential approval for KEYNOTE-671 as treatment before and after surgery, KEYTRUDA will provide the optionality to benefit more patients with earlier-stage non-small cell lung cancer.

Further data were also presented for KEYNOTE-942 from our Phase 2b study of KEYTRUDA in combination with V940, an investigational individualized neoantigen therapy in collaboration with Moderna. The study showed a 65

percent reduction in risk of distant metastasis or death in patients with resected stage III / IV melanoma compared to KEYTRUDA alone. We are eager to build upon these findings and have started enrolling patients into the registrational Phase 3 trial for adjuvant treatment of high risk, stage IIB to IV melanoma, with plans to expand the program to additional tumor types, including non-small cell lung cancer.

Finally, data presented for MK-2870, our investigational anti-TROP-2 antibody drug conjugate, licensed from Kelun Biotech showed encouraging anti-tumor activity in patients with relapsed or refractory locally advanced or metastatic non-small cell lung cancer, regardless of TROP-2 expression level. We are advancing a broad clinical development program for this candidate with global Phase 3 trials scheduled in lung cancer and additional tumor types.

On the regulatory front. Lynparza in combination with abiraterone and prednisone, was approved by the FDA for the treatment of adult patients with BRCA-mutated metastatic castration-resistant prostate cancer, an important area of unmet need.

In addition, our supplemental Biologics License Application for KEYTRUDA in combination with chemotherapy for patients with locally advanced unresectable or metastatic biliary tract cancer, based on findings from KEYNOTE-966, was accepted by the FDA for review. The PDUFA target action date is February 7<sup>th</sup>, 2024.

We also announced new data from KEYNOTE-811, which demonstrated KEYTRUDA in combination with trastuzumab and chemotherapy showed a significant improvement in progression-free survival for the first-line treatment of HER2-positive advanced gastric or gastroesophageal junction adenocarcinoma in patients whose tumors were PD-L1 positive. Merck has discussed these findings with the FDA and is working to update the current indication for KEYTRUDA.



In addition, based on the data from the KEYNOTE-811 study, we received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use.

[\[SLIDE 23: Progressing our broader pipeline\]](#)

Turning to vaccines and infectious diseases.

We have taken a thoughtful and evidence-based approach to establishing a pipeline of pneumococcal vaccine candidates to address the specific needs of different populations, including infants and children, healthy adults and at-risk subgroups, starting with VAXNEUVANCE and now continuing with V116, our investigational 21-valent pneumococcal conjugate vaccine for adults.

V116 has potential to expand disease coverage to help protect against serotypes responsible for 85% of invasive pneumococcal disease in individuals 65 and older, based on 2019 pre-pandemic CDC data. V116 includes eight serotypes not currently covered by approved pneumococcal vaccines, which are responsible for approximately 30% of invasive pneumococcal disease in individuals 65 and older based on the same data.

Last week, we announced positive topline results from two Phase 3 trials evaluating V116. The STRIDE-003 trial demonstrated statistically significant immune responses in vaccine-naïve adults compared to PCV20 for serotypes common to both vaccines, and the STRIDE-006 trial demonstrated that V116 was immunogenic for all 21 pneumococcal serotypes in the vaccine among adults who previously received a pneumococcal vaccine at least 1 year prior to the study.

We are eager to share these findings and plan to present detailed data at an upcoming medical conference.

As Rob noted, if approved, V116 would be the first pneumococcal conjugate vaccine specifically designed to address the serotypes that represent adult pneumococcal disease.

In Infectious Diseases, we received FDA approval for PREVYMIS for prophylaxis of cytomegalovirus disease for adult recipients of kidney transplant who are at high-risk of CMV infection. Since 2017, PREVYMIS has been an important preventive option for CMV infection and disease in adult seropositive recipients of an allogeneic hematopoietic stem cell transplant and we are pleased to build on the benefits it provides with this new approval.

Progress continues in the cardiometabolic space. As Rob mentioned, following the remarkable results from the STELLAR trial, we have completed the submission to the FDA of the biologics license application for sotatercept, for the treatment of adults with pulmonary arterial hypertension. Sotatercept has been granted Breakthrough Therapy designation by the FDA, and we look forward to working with the Agency on its review.

We are advancing our broad cardiovascular program. Enrollment in Phase 3 trials for MK-0616, our oral PCSK9 inhibitor, is anticipated to start later this month.

In June, at the European Association for the Study of the Liver meeting, positive results were presented from the Phase 2a randomized, active-comparator-controlled, open-label study of efinopegdutide, our investigational GLP-1 / glucagon receptor dual agonist, in patients with non-alcoholic fatty liver disease. Based on the findings from this study, efinopegdutide was granted Fast Track Designation by the FDA. We have now started a Phase 2b study to evaluate efficacy and safety in adult patients with pre-cirrhotic NASH.

Lastly, the FDA has accepted our resubmission of the New Drug Application for gefapixant, our P2X3 receptor antagonist, for the treatment of refractory or unexplained chronic cough in adults. The PDUFA target action date is December 27<sup>th</sup>, 2023.

This follows, the positive opinion from the CHMP in the European Union.

[SLIDE 24: Accelerating our presence in immunology]

And finally, as Rob mentioned, this past quarter we are were delighted to welcome our new colleagues from Prometheus to Merck. The team is focused on advancing the clinical development program for MK-7240, formerly PRA-023, and leveraging our combined strengths and expertise to better serve patients with immune-mediated diseases.

In closing, we have established a regular cadence of late-phase pipeline progress and are proceeding with speed and rigor to advance a promising portfolio of diverse candidates, guided by science and focused on patient needs.

Moving forward, we are well positioned to build on this momentum with further regulatory milestones, data readouts and clinical catalysts across therapeutic areas.

And now I turn the call back to Peter.