Merck & Co., Inc Q2 2024 Earnings Prepared Remarks

July 30, 2024



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**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.

[SLIDE 5 - Delivered on our key strategic priorities in Q2 2024]

Our business is demonstrating strong momentum as we exit the first half of the year. We remain guided by our Purpose of harnessing the power of leading-edge science to save and improve lives around the world. Our ambitious and dedicated teams are working tirelessly to reach more patients with our broad commercial portfolio and advance our deep pipeline with the goal of delivering future innovations that solve for additional unmet medical needs.

Through excellent scientific, commercial and operational execution, we're achieving significant milestones for our company and for patients. This quarter, we're proud to have successfully launched WINREVAIR, which has introduced a novel mechanism to treat adults suffering with pulmonary arterial hypertension. We're also pleased by the recent FDA approval of CAPVAXIVE, the first approved pneumococcal conjugate vaccine specifically designed for adults, as well as the subsequent ACIP recommendation. Both of these important innovations demonstrate our unwavering commitment to creating value for patients and shareholders.

And we remain committed to the execution of strategic business development to further augment our pipeline. We recently announced and have now closed the acquisition of EyeBio, which expands our effort in ophthalmology and brings to Merck a novel, late-phase candidate for the treatment of retinal diseases. This promising new mechanism adds another substantial potential commercial opportunity to our expanding pipeline in an area of significant unmet

medical need. In addition, our Animal Health business closed the acquisition of Elanco's aqua business, which establishes Merck as a leader in this important production animal category.

[SLIDE 6 - Progress since over the past three years]

Three years ago, I was honored to step into the role of CEO, and it remains my top priority to uphold and build on Merck's legacy as a premier science-driven, patient-focused biopharmaceutical company.

At that time, I affirmed Merck's strategic commitment to the research and development of innovative medicines and vaccines as the source of long-term value creation. I communicated our intention to be appropriately aggressive in making the necessary investments to both advance our broad internal pipeline and augment it with the best external science through business development.

Since then, we've made substantial progress in expanding and evolving our pipeline for the benefit of future patients. We have the potential to bring as many new drugs to market in the next five years as we launched over the last ten years, across a greater number of therapeutic areas and modalities, and with a significant proportion having blockbuster-plus potential.

We've made tremendous progress building on our past successes, enabling the creation of a sustainable engine that will drive future innovations for patients. And we continue to leverage our scientific prowess to identify new therapeutic targets where we can add value through our expertise in clinical development and regulatory affairs, and our global commercial scale.

I'm also proud of the substantial improvements we've made across our sustainability focus areas. We're reaching more people with our medicines and vaccines across a greater number of countries globally than ever before, and doing so with a dedicated, highly talented and diverse employee base.

Finally, we're driving increased innovation and productivity through widespread integration of data, digital and analytics in all areas of our business.

Going forward, I'm committed to ensuring our actions remain aligned with our strategy, and I'm confident that we are well positioned to deliver value to patients and shareholders long into the future.

[SLIDE 7 - Strong Q2 sales and earnings performance]

Turning to our second quarter results, we achieved strong growth, reflecting continued demand across our broad portfolio, which is reflected in our updated full year guidance, which Caroline will speak to in just a moment.

[SLIDE 8 - Advancing our broad pipeline]

Turning to our broader research efforts and new launches. In cardiometabolic, we've seen very favorable reception by physicians, patients and payors to the availability of WINREVAIR. While still early, the U.S. launch has gone very well, in line with our own high expectations. We've deployed a focused, customer-centric rare disease model and are pleased to see an increasing number of prescriptions being written and patients obtaining access. We've also received a positive CHMP opinion and look forward to potential regulatory approval in Europe in the near future. We continue to see a tremendous opportunity to positively impact the lives of patients living with this devastating disease.

In vaccines, we continue to bring forward innovations for both adults and children. We are proud of the recent FDA approval of CAPVAXIVE for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults, and the unanimous ACIP recommendation. Given its compelling clinical profile, we expect that CAPVAXIVE will achieve a majority market share in the adult setting.

We were also pleased to announce positive topline results from the Phase 2b/3 clinical trial of clesrovimab, our investigational monoclonal antibody for the prevention of RSV in infants, and we are moving swiftly to bring this important option to market.

Finally, at our ASCO investor event, we highlighted the significant broadening of our oncology pipeline and the progress we've made in building on the success of KEYTRUDA. We presented data for multiple novel candidates, demonstrating our commitment to advancing standards of care and maintaining leadership over the long term.

As a company, we remain highly focused and continue to work with urgency to bring forward these innovations, and others, for the patients we serve.

In summary, I want to again recognize the tremendous efforts of our global team. Together, we've made significant progress across our diverse pipeline and portfolio. As a company, we've been advancing science for the benefit of patients for over 130 years, and I'm confident that Merck is well positioned to deliver value to patients, shareholders and to all of our stakeholders 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 Q2 worldwide sales growth]

As Rob noted, we delivered another excellent quarter, with growth driven by robust global demand across our innovative portfolio. These results are enabled by the excellent execution of our teams and reinforce the conviction we have in our science-led strategy. We remain confident in our ability to continue to deliver strong results in the near-term, and are committed to making disciplined investments in compelling science to drive long-term value for patients, customers and shareholders.

Now, turning to our second quarter results.

Total company revenues were $16.1 billion, an increase of 7%, or 11% excluding the impact of foreign exchange.

The following revenue comments will be on an ex-exchange basis.

Our Human Health business sustained its momentum with double-digit growth of 11% primarily driven by Oncology.

Our Animal Health business also delivered solid performance, with sales increasing 6%, driven by growth in livestock products.

[SLIDE 11 - Oncology: KEYTRUDA continues to drive excellent growth]

Turning to the performance of our key brands.

In Oncology, sales of KEYTRUDA grew 21% to $7.3 billion driven by increased uptake from earlier stage cancers and continued strong global demand from metastatic indications.

In the U.S., KEYTRUDA grew across a broad range of tumors. In the earlier-stage setting, the increase was largely attributable to uptake from KEYNOTE-671 and KEYNOTE-091 in non-small cell lung cancer. KEYTRUDA has now achieved market leadership in the neoadjuvant and adjuvant settings, building on its existing leadership position as adjuvant therapy. In metastatic disease, we saw continued strong uptake in first-line advanced urothelial cancer following the recent launch of KEYNOTE-A39. KEYTRUDA plus Padcev has now surpassed platinum chemotherapy-based regimens in new patient starts.

Outside the U.S., KEYTRUDA growth was driven by increased use in certain earlier stage cancers, including high-risk, early-stage triple negative breast cancer and intermediate-high or high risk renal cell carcinoma as well as continued strong demand from patients with metastatic disease. Inflation-related price increases consistent with market practice in Argentina also contributed to growth.

[SLIDE 12 - Oncology: Strong performance across broad portfolio]

Alliance revenue from Lynparza and Lenvima each grew 4%.

WELIREG sales more than doubled to $126 million driven by increased uptake in certain patients with previously treated advanced renal cell carcinoma.

[SLIDE 13 - Vaccines: Robust growth driven by GARDASIL and VAXNEUVANCE]

Our vaccines portfolio delivered solid growth. GARDASIL sales increased 4% to $2.5 billion. In the U.S., sales benefitted from price as well as demand and favorable CDC purchasing patterns. Outside the U.S., higher demand across many international markets was partially offset by the timing of shipments to China.

In pneumococcal, VAXNEUVANCE sales increased 16% to $189 million. Growth was driven by ongoing launches in international markets.

[SLIDE 14 – Successful initial launch of WINREVAIR]

As Rob noted, we are very excited by the opportunity to positively impact the lives of adult patients with pulmonary arterial hypertension following the recent U.S. launch of WINREVAIR.

Recall, we received FDA approval on March 26th, with the first patients receiving therapy about one month later. Initial patient and physician feedback has been favorable, and we recorded $70 million of sales in the quarter. We estimate

that approximately forty percent of sales were attributable to doses administered to patients, with the remainder due to distributors building inventory in support of increasing demand.

The launch is off to a strong start. As of the end of June, more than 2,000 patients received a prescription for WINREVAIR. Our experience to date with those prescriptions, would suggest that approximately 75 to 80% will receive commercial product. Of those, more than 1,000 patients started treatment in the quarter, largely reflecting prescriptions written in April and May, as it currently takes approximately one month to complete the steps necessary to commence therapy.

More than 500 physicians have written at least one prescription, with many looking to gain experience with the product as they prioritize treating the most advanced patients, who are in greatest need of additional therapy. Most prescribers are from either large academic centers or larger private practices.

We are pleased that payors are recognizing the value of WINREVAIR and are already providing access to patients. Many payors have established coverage policies consistent with the label or STELLAR study criteria, while others are in the process of developing their policies. In summary, we are pleased with the strong start and look forward to continued progress in enabling access for appropriate patients over the coming months.

[SLIDE 15 - Animal Health: Growth driven by livestock]

Our Animal Health business delivered another solid quarter, with sales increasing 6%. Livestock sales grew 11% driven by higher demand for poultry and ruminant products as well as price. Companion animal sales grew 1%, reflecting price partially offset by a reduction in distributor inventory. We are also excited to have launched a long-acting BRAVECTO injectable in a number of international markets during June.

[SLIDE 16 – Q2 2024 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 80.9%, an increase of 4.3 percentage points driven by reduced royalty rates for KEYTRUDA and GARDASIL as well as favorable product mix.

Operating expenses decreased to $6.2 billion. There were no significant business development expenses in the quarter, compared with a $10.2 billion charge a year ago. Excluding this charge, operating expenses grew 8%, reflecting strategic investments to realize the promise of our robust early- and late-phase pipeline and support the promotion of our key growth drivers.

Other expense was $108 million.

Our tax rate was 14.1%.

Taken together, earnings per share were $2.28.

[SLIDE 17 - Updated 2024 financial outlook]

Now turning to our 2024 non-GAAP guidance.

The continued operational strength of our business has enabled us to raise and narrow our full year revenue guidance. We now expect revenue to be between $63.4 and $64.4 billion, an increase of approximately $200 million at the midpoint. Our increased guidance range represents strong year over year revenue growth of 5 to 7%, including an approximate 3 percentage point negative impact from foreign exchange using mid-July rates.

Our gross margin assumption remains approximately 81%.

We now expect operating expenses to be between $26.8 and $27.6 billion. This range reflects an incremental $1.5 billion of charges related to the one-time cost to acquire EyeBio and ongoing expenses to advance the assets, as well as investments to progress our innovative pipeline. As a reminder, our guidance does not assume additional significant potential business development transactions.

Other Expense is expected to be approximately $350 million, which now includes financing costs for the acquisitions of EyeBio and Elanco's aqua business.

Our full year tax rate is now expected to be between 15.5% and 16.5%, which includes an unfavorable impact related to the EyeBio acquisition that is not tax-deductible.

We assume approximately 2.54 billion shares outstanding.

Taken together, we expect EPS of $7.94 to $8.04. This range includes a negative impact from foreign exchange of more than 30 cents, using mid-July rates.

Recall our prior guidance range was $8.53 to $8.65. Including the one-time charge of $1.3 billion, or $0.51 per share, related to the acquisition of EyeBio and an estimated 9 cents to advance the assets as well as finance the EyeBio and Elanco aqua business transactions, our prior guidance range would have been $7.93 to $8.05, with a midpoint of $7.99. Our current guidance midpoint remains the same as our higher revenue estimate is being offset by increased investments to support our business.

[SLIDE 18 - Key modeling considerations]

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

We look forward to the opportunity to help protect certain adults from invasive pneumococcal disease and pneumococcal pneumonia following the recent FDA approval and ACIP recommendation of CAPVAXIVE. We are now working toward the achievement of certain milestones that will enable commercial uptake. These milestones include publication in the morbidity and mortality weekly report, which typically lags an ACIP recommendation by a few months, as well as obtaining payor coverage and contracting with customers.

For GARDASIL, over the past few years we've benefitted from extremely strong demand in China, including from the expanded indication for GARDASIL 9 to the 9 to 45 year age cohort in late 2022. In the second quarter however, there was a significant step down in shipments from our distributor and commercialization partner, Zhifei, into the points of vaccination, compared with prior quarters, resulting in above normal inventory levels at Zhifei. We are working closely with them to more fully understand the dynamics that caused this change. As we learn more, we will assess future shipments to our partner and work to bring their inventory back to more normal levels. If shipments from Zhifei into the points of vaccination do not increase it is likely that we will ship less than our full year 2024 contracted doses by the end of this year.

We believe the opportunity in China remains very attractive as there are more than 120 million females in the addressable population living in Tier 1 to Tier 5 cities who have not yet received the protection of an HPV vaccine. As we said before, it will take increasing efforts to educate and activate the next wave of patients. Together with Zhifei, we are focused on and committed to investing in additional resources and patient education on the value of GARDASIL given the important benefits it provides. We also look forward to the potential approval for males which we believe represents a meaningful opportunity.

More broadly, we remain confident in the opportunity for GARDASIL globally based on the protection it provides against HPV-related cancers and low immunization levels overall, and continue to believe we will achieve sales of over $11 billion by 2030.

Our initial launch of WINREVAIR is having a positive impact for patients. We are very pleased with its performance and look forward to supporting more patients in the U.S. and across the globe.

Outside the U.S., we are pleased with the positive CHMP opinion and potential near-term launch in Europe. Following EU approval, we will need to obtain reimbursement, which should occur in 2025 in most major markets, but expect that Germany will receive reimbursement and launch this year.

We remain confident in the successful launch of WINREVAIR, consistent with our high expectations, and look forward to providing further updates on our progress.

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

Now turning to capital allocation, where our strategy remains unchanged.

We will prioritize investments in our business to drive near- and long-term growth. We will continue to invest in our expansive pipeline of novel candidates, each of which has significant potential to address important unmet medical needs.

We remain committed to our dividend, and plan to increase it over time.

Business development remains a priority and we are well positioned to pursue additional science-driven, value-enhancing transactions.

We will continue to execute a modest level of share repurchases.

To conclude, as we enter the second half of the year, there is continued strength in our business, driven by global demand and commercial execution. We remain confident in our outlook, driven by our unwavering commitment to leverage leading-edge science to save and improve the lives of patients. With investment in innovation and our ongoing focus on execution, we are well positioned 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.

Momentum continued in the second quarter with several clinical and regulatory milestones, as well as progress in our science-led business development strategy. Today, I will speak first to programs in vaccines, then cover oncology, followed by cardiometabolic disease.

[SLIDE 21 - Important progress across our immunization programs]

As Rob noted, last month the FDA approved CAPVAXIVE our 21-valent pneumococcal conjugate vaccine, and we subsequently received a unanimous recommendation from the CDC's Advisory Committee of Immunization Practices, for its use in certain adult populations.

CAPVAXIVE is the first vaccine specifically designed to help protect adults against pneumococcal pneumonia and invasive pneumococcal disease and, as such, provides an important new public health option. It has been designed to address those serotypes responsible for approximately 85 percent of the incidence of invasive pneumococcal disease in individuals 65 years and older, based on CDC generated surveillance data.

The CAPVAXIVE marketing authorization application is also under review by the European Medicines Agency's Committee for Medicinal Products for Human Use.

We continue to evaluate novel approaches to alleviate the burden of infectious disease. Recently, we announced positive topline results for clesrovimab, our investigational respiratory syncytial virus preventative antibody, a single, fixed-dose option to help protect infants from birth through their first full RSV season. In the Phase 2b / 3 trial, clesrovimab met its primary efficacy and safety endpoints as well as its secondary endpoint regarding RSV-associated

hospitalization. Detailed findings of the study will be presented at an upcoming scientific congress and we plan to file these data with global regulatory authorities.

Globally, RSV infection is a leading cause of hospitalization for otherwise healthy infants under one year of age. The historically high surge in incidence in the 2022-2023 season reinforced the need for more effective preventative measures.

[SLIDE 22 - Executing upon our oncology development strategy]

Now to oncology.

During the investor event at ASCO, we detailed how we have leveraged our foundational position with KEYTRUDA to create a diverse pipeline by executing on our three pillared strategy comprised of immuno-oncology, precision molecular targeting and tissue targeting candidates. This quarter, tangible progress has been made across each of these pillars.

[SLIDE 23 - Continuing to harness the power of immuno-oncology]

In immuno-oncology, we received FDA approval for the combination of KEYTRUDA and chemotherapy for the treatment of primary advanced or recurrent endometrial cancer regardless of mismatch repair status, based on the Phase 3 KEYNOTE-868 study.

Data continues to flow from the KEYTRUDA clinical development program including from studies which achieve an overall survival benefit, the gold standard for many oncology trials.

We announced an overall survival benefit in high-risk, early-stage triple negative breast cancer based on the KEYNOTE-522 study. KEYTRUDA is the only PD-1 or PD-L1 to date to receive approval for nine earlier stage

indications, of which four have now demonstrated a statistically significant overall survival benefit including in non-small cell lung cancer, renal cell carcinoma, cervical cancer and most recently, triple negative breast cancer.

We were pleased to announce that KEYNOTE-811 met its overall survival dual primary endpoint for the first line treatment of patients with HER2-positive advanced gastric or gastroesophageal junction adenocarcinoma. These results build on the previously reported positive data that formed the basis for the FDA approval last year. A similar approval was received from the National Medical Products Administration in China this quarter.

Also in immuno-oncology, the FDA granted priority review for KEYTRUDA in combination with chemotherapy for the first-line treatment of patients with unresectable advanced or metastatic malignant pleural mesothelioma based on the overall survival benefit demonstrated in the KEYNOTE-483 trial. The FDA has set a target action date of September 25th.

KEYTRUDA has now received approval for forty distinct indications in the U.S. and has demonstrated statistically significant overall survival in twenty-five trials.

[SLIDE 24 - Updates across precision and tissue targeting]

Next to precision molecular targeting, we exercised the exclusive development option to advance the program for opevesostat, an oral nonsteroidal inhibitor of CYP11A1, through our collaboration with Orion. Two pivotal Phase 3 trials evaluating opevesostat in combination with hormone replacement therapy for the treatment of certain patients with metastatic prostate cancer, OMAHA-1 and OMAHA-2, are ongoing.

Lastly, in the tissue targeting space, The European Medicines Agency's Committee for Medicinal Products for Human Use adopted a positive opinion recommending approval for KEYTRUDA in combination with Padcev for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.

We are also advancing a broad portfolio of diverse antibody-drug conjugates with Kelun-Biotech and Daiichi Sankyo, as well as our own internal programs.

Last month, together with Daiichi Sankyo, we announced receipt of a Complete Response Letter from the FDA for the Biologics License Application for patritumab deruxtecan, for the treatment of certain adult patients with locally advanced or metastatic EGFR-mutated non-small cell lung cancer previously treated with two or more systemic therapies. The letter was issued based on findings from an inspection of a third-party manufacturing site. We are working with Daiichi Sankyo to provide appropriate support as they work with the FDA and the manufacturer to address the feedback in a timely manner. Of note, the findings identified in the CRL have no bearing on either ifinatamab deruxtecan nor raludotatug deruxtecan.

[SLIDE 25 - Important developments across our diverse pipeline]

Turning to cardiometabolic disease, as Caroline indicated there is strong interest from physicians and patients for WINREVAIR in the U.S. Building on this momentum, we were pleased to receive a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use recommending the approval of WINREVAIR as a treatment option for certain patients with pulmonary arterial hypertension. The European Commission's decision on the marketing authorization application is expected in the third quarter.

Finally, we continue to execute on our science-led business development strategy with a focus on seamlessly integrating efforts across our internal pipeline with the best external science through our One Pipeline approach. We recently closed the acquisition of EyeBio that includes Restoret™, MK-3000, an investigational, late phase, potentially first-in-class tetravalent, tri-specific Wnt antibody candidate for diabetic macular edema and neovascular age-related macular degeneration, as well as additional preclinical assets targeting retinal diseases. There remains a significant medical need in this space and our teams are eager to work alongside the talented EyeBio team to advance these promising candidates.

In closing, over the past three-plus years, we have successfully built on the solid foundation established by the previous leadership team to assemble one of the strongest pipelines in recent memory. We have diversified in oncology while strengthening and expanding in other therapeutic areas including cardiometabolic, immunology, infectious diseases, neuroscience and vaccines.

We have strong momentum and I look forward to providing further updates on our progress.

And now I turn the call back to Peter.