Merck & Co., Inc, Rahway, N.J. USA Second-Quarter 2025 Sales and Earnings Prepared Remarks

July 29, 2025

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

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Mr. Rob Davis - Merck & Co., Inc., Rahway, N.J., USA, Chairman and Chief Executive Officer

[SLIDE 4 - Strategy and Business Update]

Thank you, Peter. Good morning and thank you for joining today's call.

We continue to make meaningful progress in delivering our important medicines and vaccines to patients and customers, while advancing our innovative pipeline. Over the past few months, we've shared a steady cadence of updates that highlight our strong clinical momentum, and our growth is increasingly benefitting from new product launches now underway with more to come.

We've also taken additional steps to augment our pipeline. Our recently announced acquisition of Verona Pharma is another example of acting decisively when science and value align, and moving with urgency to achieve our business development objectives. I have increasing confidence that our science-driven strategy will continue to generate long-term value for shareholders and for all of our stakeholders.

[SLIDE 5 - Q2 performance in-line with expectations]

Turning to our second quarter results, we delivered performance in-line with our expectations, with revenue of $15.8 billion. Results reflect strength across Oncology and Animal Health, as well as increasing contributions from our new product launches, with WINREVAIR achieving $1 billion of cumulative sales in just over a year since approval. We expect to return to growth in the second half of 2025 and remain confident in our outlook for the remainder of the year.

[SLIDE 6 - Driving value by progressing innovative pipeline]

I'm proud of the tangible progress we're making in expanding and advancing our research program across key therapeutic areas. We're now conducting more than 80 phase 3 studies across a range of therapeutic areas, and we're increasingly seeing the potential we've long spoken about validated with positive clinical trial results, registrational filings, and new product launches. These proof points provide me with growing confidence that we're on track to achieve our ambitions.

Moving to some notable recent news, we announced encouraging topline results from the first two Phase 3 trials evaluating enlicitide, our oral PCSK9 inhibitor for the treatment of hyperlipidemia; and for WINREVAIR based on the HYPERION study for patients recently diagnosed with PAH.

On the regulatory front, the FDA approved, and the ACIP recommended, ENFLONSIA for the prevention of RSV in infants younger than 8 months of age who are born during or entering their first RSV season. We're well-prepared to support families ahead of the upcoming season. Additionally, the FDA has accepted our supplemental BLA for WINREVAIR in PAH and a new drug application for the fixed-dose combination of doravirine and islatravir for the treatment of HIV.

At the IAS conference earlier this month, we highlighted new findings from our promising HIV pipeline, and we're excited about MK-8527, which has the potential to be the first once-monthly pill for HIV prevention. We also hosted an investor event to showcase our HIV programs and the important commercial opportunity they represent.

Our oncology pipeline continues to break new ground. We marked the 10th earlier stage approval for KEYTRUDA and at ASCO, presented encouraging data across multiple novel candidates, further reinforcing the potential of our portfolio to help even more patients with cancer.

[SLIDE 7 - Continuing to advance science-led strategy through pending acquisition of Verona Pharma]

Finally, the acquisition of Verona Pharma brings us Ohtuvayre, a novel, first-in-class treatment for Chronic Obstructive Pulmonary Disease, or COPD, that complements our growing cardio-pulmonary programs and reflects our commitment to transformative science in areas of significant unmet need. Upon closing in the fourth quarter, we'll leverage our commercial capabilities to accelerate Ohtuvayre's successful launch, and we look forward to welcoming the Verona Pharma team to our company.

Overall, we are encouraged by our continued progress. Each of these impactful milestones is an important building block as we move toward a more diversified future.

[SLIDE 8 - Entering period of rapid transformation with expansive late-phase pipeline]

As I've said before, our company is entering a period of rapid transformation which will be marked by meaningful impact on patients and the practice of medicine, and we couldn't be more excited about our future. Over the past several years, we've built the largest and most diverse pipeline in our company's recent history. We have over 20 new and potential future growth drivers, including the successful recent launches of WINREVAIR and CAPVAXIVE.

We also have numerous novel, late-phase compounds with potential for significant patient benefit and blockbuster commercial opportunity. Candidates such as enlicitide, tulisokibart, sac-TMT, and MK-3000, to name a few, represent

potentially profound scientific advances, exactly the types of innovations that Merck is known for. We're committed to fully investing behind our pipeline, given the tremendous opportunities we see, and will continue to do so with sharp focus and discipline for the benefit of the patients we serve.

Today, we announced a multi-year optimization initiative which will redirect investment and resources from more mature areas of our business to our burgeoning array of new growth drivers, further enable the transformation of our portfolio and drive our next chapter of productive, innovation-driven growth. Caroline will provide more detail on this in a moment.

[SLIDE 9 - Delivering the next wave of innovation]

In summary, we're leveraging our scientific expertise to deliver the next wave of innovation that can save and improve lives around the world. My confidence in our ability to successfully navigate the KEYTRUDA LOE period increases with each new launch, data readout and business development transaction. I continue to see the LOE as more of a hill than a cliff, and I'm confident in our ability to grow over the long-term. I want to thank our talented and dedicated global team for their hard work and commitment to delivering value for patients, shareholders and for all of our stakeholders. With that, I'll turn the call over to Caroline.

Ms. Caroline Litchfield - Merck & Co., Inc., Rahway, N.J., USA, Chief Financial Officer

[SLIDE 10 - Financial Results and Outlook]

Thank you, Rob. Good morning.

[SLIDE 11 - Q2 performance driven by robust demand for our innovative portfolio]

As Rob noted, second quarter performance was in-line with our expectations. I am pleased to again report that the fundamentals of our business remain strong, with continued robust global demand for our diverse innovative portfolio of human and animal health products. Our commercial and operational execution enables us to generate value in the short-term, while we invest in the next generation of innovations and advance our pipeline for the long-term to deliver value for all stakeholders.

Now, turning to our second quarter results.

Total company revenues were $15.8 billion, a decrease of 2% both nominally and excluding the impact of foreign exchange.

As expected, results were impacted by a decline in sales of GARDASIL in China of approximately $1.3 billion, reducing growth by 9 percentage points. Excluding these sales, global growth was 7%, primarily driven by strength in oncology and Animal Health as well as new products, WINREVAIR and CAPVAXIVE, which are each off to an outstanding start.

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

[SLIDE 12 - Oncology: KEYTRUDA continues to benefit patients and drive growth]

In Oncology, sales of KEYTRUDA increased 9% to $8.0 billion, with growth in both U.S. and international markets driven by robust demand from metastatic indications and increased uptake in earlier-stage cancers. Usage in tumors predominantly affecting women, including those with certain breast, cervical and endometrial cancers, was a key contributor to growth. In addition, we saw increased use of KEYTRUDA in combination with Padcev in first-line, locally advanced urothelial cancer.

We also received positive feedback from healthcare providers following the recent launch of a treatment regimen with KEYTRUDA for certain patients with resectable, locally advanced head and neck cancer, based on KEYNOTE-689. This is the first perioperative anti-PD-1 regimen approved for treatment of patients with this disease.

[SLIDE 13 - Oncology: Strong growth across broad portfolio]

Our broader oncology portfolio achieved another quarter of strong growth. Of note, WELIREG sales increased 29% to $162 million, predominantly driven by increased use in certain patients with previously treated advanced renal cell carcinoma in the U.S.

[SLIDE 14 - Vaccines: GARDASIL protecting lives from HPV-related cancers]

In Vaccines, GARDASIL sales were $1.1 billion, a decrease of 55%, driven primarily by China. Excluding China, sales declined 4% due to lower sales in Japan reflecting the expiration of reimbursement for the catch-up cohort and timing of public sector purchases in certain international markets. Sales growth of 2% in the U.S. was attributable to price and higher demand, partially offset by CDC purchasing patterns.

[SLIDE 15 - Vaccines: Growth across pneumococcal vaccine portfolio]

In pneumococcal, CAPVAXIVE sales were $129 million, driven by demand from both retail pharmacies and non-retail customers, including integrated delivery networks and clinics. We remain well positioned to help protect more adults from invasive pneumococcal disease and drive continued growth moving forward.

VAXNEUVANCE sales increased 20%. In the U.S., growth benefitted by approximately $60 million from CDC stockpile activity, partially offset by competitive pressures. The benefit to VAXNEUVANCE was offset by a drawdown of CDC stockpile inventory for ROTATEQ and VARIVAX, resulting in a net neutral transaction. Outside the U.S., growth in certain international markets was offset by a competitor preferential recommendation in Japan.

[SLIDE 16 – ENFLONSIA: Excited to bring new option for RSV prevention in infants]

Following the recent FDA approval and ACIP recommendation, we are excited to have started taking orders for ENFLONSIA, our monoclonal antibody for the prevention of RSV lower respiratory tract disease in infants entering their first RSV season. ENFLONSIA's compelling clinical data and operational simplicity make it an important option for parents and providers. We have made great progress in achieving the milestones necessary to help ensure a successful launch and are well positioned to help protect infants from RSV lower respiratory tract disease.

[SLIDE 17 – WINREVAIR: Strong launch execution demonstrates ability to maximize value of pipeline]

In Cardiovascular, WINREVAIR continued its strong momentum with global sales of $336 million. As Rob noted, in just 15 months since launch, cumulative net sales of WINREVAIR have already exceeded $1 billion. This achievement is a testament to both the impact WINREVAIR has for patients with pulmonary arterial hypertension and our ability to pair leading edge science with execution excellence, even in disease areas that are new to us.

In the U.S., more than 1,600 new patients received a prescription during the quarter. We are continuing to see a steady increase in the percentage of new prescriptions for patients whose background therapies do not include a prostacyclin.

Outside the U.S., we continue to progress with approvals and reimbursement, including in Japan where we expect a launch later in the third quarter.

Overall, the ongoing launch of WINREVAIR continues to meet our high expectations, and we look forward to positively impacting the lives of more patients with PAH.

[SLIDE 18 – Animal Health: Growth across livestock and companion animal]

Our Animal Health business delivered very strong growth, with sales increasing 11%. Livestock growth reflects higher demand across all species as well as sales from the aqua portfolio acquired from Elanco. Companion animal sales growth reflects price. Growth in both segments also benefitted from improved supply.

[SLIDE 19 – Q2 2025 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 82.2%, an increase of 1.3 percentage points driven by favorable product mix.

Operating expenses increased to $6.6 billion, including a $200 million charge related to the license agreement with Hengrui. Excluding this charge, operating expenses grew 4%, reflecting disciplined investments in support of our robust early- and late-phase pipeline as well as key growth drivers.

Other expense was $54 million.

Our tax rate was 15.0%.

Taken together, earnings per share were $2.13.

[SLIDE 20 – Updated 2025 financial outlook]

Turning to our outlook. As Rob noted, our company is rapidly moving to a future with a diversified set of growth drivers, each with the potential to address important unmet patient needs. We have a compelling array of novel pipeline candidates as a result of our steadfast commitment to innovation and our longstanding efforts to invest with discipline.

To ensure we are well positioned to maximize the many opportunities in front of us, we have announced a multi-year optimization program. This portfolio management program will enable us to fully reinvest $3 billion of cost savings from lower-growth areas of our business to higher-potential areas in order to have maximum impact. It will also allow us to leverage technological advancements to enable productivity and streamline our operations. Taken together, our overall investment will continue to increase, a reflection of the many compelling opportunities we have. We are confident these actions will position us to deliver value for patients, customers and shareholders, as well as drive long-term growth.

Now turning to our 2025 non-GAAP guidance. We expect full year revenue to be between $64.3 and $65.3 billion. This range represents growth of 1 to 2%, excluding a negative impact from foreign exchange of approximately 0.5 percent using mid-July rates.

Our gross margin assumption remains approximately 82.0%. Our guidance of $200 million of costs related to the impact of tariffs is unchanged pending the outcome of additional potential government actions.

Operating expenses are now assumed to be between $25.6 and $26.4 billion. This range continues to include the $300 million milestone to LaNova for the tech transfer that was completed earlier this month. This guidance does not assume the proposed acquisition of Verona or additional significant potential business development transactions.

Other Expense is expected to be between $300 and $400 million.

We now assume a full year tax rate between 15.0% and 16.0%.

We assume approximately 2.51 billion shares outstanding.

Taken together, our EPS guidance is $8.87 to $8.97. This range includes a negative impact from foreign exchange of approximately 15 cents, using mid-July rates.

[SLIDE 21 – Key modeling considerations]

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

We remain confident in the outlook for our launch products and continued growth across oncology and Animal Health as well as our return to growth in the second half of the year. In China, GARDASIL channel inventories remain elevated and demand continues to be soft. As a result, we will not resume shipments to China through at least the end of this year. As we look to the balance of the year for GARDASIL, Japan will be a more significant headwind to growth in the second half of the year as we lap the increase in vaccinations from the catch-up cohort in 2024. Overall, we expect full year growth for GARDASIL excluding China.

Next, we expect Other Revenue to be significantly lower in the second half of the year. While we actively manage the impact from foreign exchange through our revenue hedging program, based on mid-July rates, we expect to see a negative impact from our hedges, which is reflected in Other Revenue.

Finally, we expect operating expenses to be roughly evenly split between the third and fourth quarters, excluding business development expenses.

[SLIDE 22 – 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 innovative pipeline, including the initiation of many new late-stage clinical trials across multiple novel candidates, each of which has the potential to meaningfully address important unmet medical needs.

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

Business development remains a high priority, as evidenced by our acquisition of Verona Pharma, which we expect to finance through a combination of cash on hand, commercial paper and new debt issuance. We maintain the ability within our strong investment grade credit rating to pursue additional, science driven, value enhancing transactions going forward.

We continued our pace of share repurchases with approximately $1.3 billion in the quarter. We expect to maintain a similar level of repurchases in each of the third and fourth quarters of 2025 given our strong balance sheet.

To conclude, we are confident in the outlook of our business driven by global demand for our innovative in-line portfolio and launches. We maintain our steadfast commitment to bringing forward medically significant innovations that will enable us to deliver value to patients, customers and shareholders well into the future.

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

Dr. Dean Y. Li – Merck & Co., Inc., Rahway, N.J., USA, President, Research Laboratories

[SLIDE 23 – Research Update]

Thank you, Caroline. Good morning, everyone.

In the second quarter, we continued to see strong momentum across the pipeline. Today, I will cover updates from our cardiopulmonary, infectious diseases, HIV and oncology programs.

[SLIDE 24 – Ohtuvayre is the first inhaled COPD maintenance treatment that combines bronchodilatory and non-steroidal anti-inflammatory activity]

First, on the proposed acquisition of Verona Pharma. Building on what Rob noted earlier, we have been following the strong progress of the Verona team for a number of years.

Ohtuvayre is the first novel mechanism for the inhaled maintenance treatment of COPD in more than two decades. It is a dual inhibitor of phosphodiesterase 3 and 4 with bronchodilatory and non-steroidal anti-inflammatory properties. As such, it is an important maintenance therapy option for patients who are persistently symptomatic. Ohtuvayre is used to improve symptoms of COPD for better breathing and to reduce the number of flare-ups.

Phase 3 trials that evaluated Ohtuvayre as monotherapy or with background therapies in patients with moderate-to-severe symptomatic COPD demonstrated clinically meaningful improvement in lung function. These results provided strong validation that culminated in an FDA approval in June of 2024.

We are eager to complete the acquisition and work with the Verona team to advance the ongoing work in bronchiectasis and evaluate utility in additional indications, combination therapies and alternative formulations.

[SLIDE 25 – Important updates across cardiopulmonary portfolio]

Now to focus on WINREVAIR, evidence continues to accumulate for WINREVAIR's strong clinical benefit across a broad spectrum of patients with pulmonary arterial hypertension.

The Phase 3 HYPERION trial evaluating WINREVAIR in adults recently diagnosed with PAH was stopped early based on review of available data from the program. Despite the early stoppage, positive topline results announced last month showed that adding WINREVAIR on top of background therapy significantly reduced the risk of clinical worsening events compared to background therapy alone. Detailed findings will be presented at a scientific congress later this year.

Additionally, the FDA granted priority review for a supplemental Biologics License Application to update the label for WINREVAIR based on data from the Phase 3 ZENITH trial and set a PDUFA date of October 25th. As a reminder, ZENITH was the first positive trial in PAH with a primary endpoint comprised entirely of major outcome measures and the first Phase 3 study in PAH to be stopped early for overwhelming efficacy.

As Caroline mentioned, the Ministry of Health, Labor and Welfare in Japan has recently granted approval for WINREVAIR.

Moving to enlicitide, positive topline results were announced from the Phase 3 CORALreef HeFH and CORALreef AddOn clinical trials for enlicitide, our investigational once daily oral PCSK9 inhibitor, for the treatment of adults with hyperlipidemia on lipid-lowering therapies, including at least a statin. Of note, the CDC estimates that in the United

States more than a million people have heterozygous familial hypercholesterolemia and approximately 86 million adults older than 20 have high cholesterol.

Both trials met their primary and all key secondary endpoints, demonstrating statistically significant and clinically meaningful reductions in LDL-cholesterol for patients receiving enlicitide versus placebo. Detailed findings will be presented at future medical meetings.

Finally, we are eagerly awaiting results from the CORALreef Lipids Phase 3 trial in the broader hyperlipidemia population, and I am pleased to report that we recently completed enrollment for the Phase 3 CORALreef Outcomes trial.

[SLIDE 26 – Building on our progress in infectious diseases]

Next to infectious disease, last month, the FDA approved ENFLONSIA, our long-acting monoclonal antibody for the prevention of respiratory syncytial virus lower respiratory tract disease in infants born during or entering their first RSV season. ENFLONSIA is the first and only option designed to protect infants with the same dose regardless of weight. The CDC's Advisory Committee on Immunization Practices subsequently voted to recommend ENFLONSIA for use in infants younger than eight months of age for their first RSV season and include this new option in the Vaccines for Children Program, an important step in ensuring access. This vote is provisional, and we await confirmation.

In vaccines, we initiated the first Phase 3 clinical trial for our investigational quadrivalent dengue vaccine, V181. The MOBILIZE-1 study will evaluate the safety, immunogenicity and efficacy of a single dose of V181 for the prevention of dengue disease caused by any of the four dengue virus serotypes, regardless of prior exposure. According to the

World Health Organization, about half of the world's population is now at risk of dengue with an estimated 100 to 400 million infections occurring each year.

Turning to HIV, earlier this month, we hosted an investor event coinciding with the International AIDS Society Conference on HIV Science. At the conference, we presented findings from a Phase 2 study of MK-8527, a novel NRTTI candidate being evaluated as an oral option for HIV pre-exposure prophylaxis. The data support the targeted monthly dosing schedule of MK-8527, which has the potential to enable rapid onset of protection within one hour of intake without the need for a loading dose.

These findings support the initiation of two Phase 3 studies: one to evaluate the safety and efficacy of MK-8527 among people at greater likelihood of HIV-1 exposure, EXPrESSIVE-11, and a separate study in women and adolescent girls, EXPrESSIVE-10, in collaboration with the Gates Foundation. We believe MK-8527 has the potential to be an important new option for people at high risk for HIV.

At IAS, we also presented data for the combination of islatravir, an investigational NRTTI anchor therapy and ulonivirine, an investigational NNRTI, being evaluated as a potential once-weekly regimen for the treatment of adults living with HIV. The Phase 2 study in adults with suppressed HIV is ongoing.

Finally, the FDA accepted for review the New Drug Application for the fixed dose combination of doravirine and islatravir, an investigational once-daily, oral two-drug regimen for the treatment of adults living with HIV-1 that is virologically suppressed on antiretroviral therapy. The target action date is April 28, 2026.

[SLIDE 27 – Continuing to advance cancer care with a broad, differentiated portfolio and pipeline]

Moving to oncology, during last month's investor event at ASCO, we showcased how we have leveraged our foundational position with KEYTRUDA to create a diverse pipeline by successfully executing on our oncology strategy and advancing key pipeline candidates. We are uniquely positioned to advance cancer care with a broad, differentiated portfolio and pipeline spanning immuno-oncology, precision medicine and tissue targeting.

The strategic ambition is to develop leading assets in all three segments so that in a world of combination therapies our pipeline will be optimally positioned to continue to change the practice of clinical oncology.

With regards to tissue targeting, through our collaboration with Daiichi Sankyo, we now have three Phase 3 trials evaluating ifinatamab deruxtecan:

- IDeate-Esophageal01 in unresectable advanced or metastatic esophageal squamous cell carcinoma,
- IDeate-Prostate01 in metastatic castration-resistant prostate cancer, and
- IDeate-Lung02 in relapsed small cell lung cancer.

KEYTRUDA continues to generate compelling data and regulatory approvals.

We recently received FDA approval for its use as part of a perioperative treatment regimen for certain patients with resectable, locally advanced head and neck squamous cell carcinoma based on the KEYNOTE-689 study. This marks the 42nd indication and the 10th earlier stage approval for a KEYTRUDA-based regimen. Earlier intervention has the potential to improve outcomes and reduce the burden of disease in this patient population.

In ovarian cancer, positive progression free survival and overall survival results for KEYTRUDA plus chemotherapy with or without bevacizumab were announced in certain patients based on the Phase 3 KEYNOTE-B96 study. This is the first immune checkpoint inhibitor-based regimen to demonstrate a statistically significant overall survival benefit in ovarian cancer. We plan to present the results at an upcoming medical meeting.

And finally, the Ministry of Health, Labor and Welfare in Japan granted approval for WELIREG for certain patients with advanced renal cell carcinoma.

[SLIDE 28 – Key second half dates and milestones]

As we look to the second half of this year we anticipate multiple important milestones.

- In oncology, the upcoming PDUFA date for subcutaneous pembrolizumab on September 23rd.
- In the cardio-pulmonary space,
  - For WINREVAIR:
    - The October 25th PDUFA date for the FDA label update based on the Phase 3 ZENITH trial,
    - presentation of detailed findings from the HYPERION study,
    - and the primary completion date in September of the Phase 2 CADENCE study in pulmonary hypertension due to left heart disease.
  - For enlicitide:
    - Begin presenting the detailed results of Phase 3 trials from the CORALreef development program at major cardiovascular conferences.
  - And finally, the closing of the Verona Pharma acquisition in the fourth quarter.

I look forward to providing further updates on our progress.

And now I turn the call back to Peter.