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

October 30, 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 using the power of leading-edge science to save and improve lives around the world.

[SLIDE 5 - Delivering value to patients and customers through innovative portfolio of medicines and vaccines]

We're delivering value to patients and customers today through our innovative portfolio of medicines and vaccines, and we're securing our future by making important investments in our pipeline … the strongest and deepest in recent memory. We now have approximately 80 Phase 3 trials underway across a diverse array of therapeutic areas … with important readouts coming over the next year in Cardio-pulmonary, Immunology, HIV, Ophthalmology and of course, Oncology.

We're investing behind more than 20 compelling launch opportunities, some already underway. These programs will transform our commercial portfolio and fuel future growth, with over $50 billion of revenue opportunity by the mid-2030s and we remain committed to the pursuit of disciplined, science- and value-driven business development to further augment our expansive pipeline.

In the third quarter, we continued to successfully execute on our strategy with important pipeline advancements, significant approvals, and successful new product launches. Additionally, in October, we completed the strategic

acquisition of Verona Pharma. This provides us yet another important growth driver with multi-billion dollar commercial potential into the next decade. We're making strong progress across the business, and I remain confident in our ability to further broaden our impact to patients and deliver long-term growth and value for shareholders.

With respect to U.S. healthcare policy, as I've said before, we share the Administration's goal of decreasing patient out-of-pocket costs for our products in the U.S. while at the same time realizing greater prices for our medicines and vaccines in countries that have not been paying fair value for the innovation we provide. We're actively engaged with the Administration in an effort to find a path forward that achieves these objectives. We also want to preserve our ability to invest in the breakthrough innovations we intend to bring to patients in the future while ensuring the sustainability of our business long-term and we're optimistic about our ability to do so.

We continue to make significant investments in manufacturing in the United States. Last week, we announced a groundbreaking event at our Elkton, Viriginia site as part of a broader plan that will result in the investment of more than $70 billion in expanded domestic manufacturing and R&D. These investments will support our plans to drive long-term growth and will strengthen the U.S. as a global leader in biopharmaceutical innovation.

[SLIDE 6 - Q3 2025 total company performance]

Turning to our third-quarter results, we're pleased to deliver solid performance, with continued strength across Oncology and Animal Health, as well as increasing contributions from our new product launches, WINREVAIR, CAPVAXIVE and most recently, ENFLONSIA.

[SLIDE 7 - Driving value by progressing innovative pipeline]

In research, several notable updates highlight our strong progress. In Cardiovascular, we announced positive topline results from the CORALreef Lipids trial, the third and largest Phase 3 study evaluating enlicitide, our investigational oral PCSK9 inhibitor, in the treatment of hyperlipidemia. We look forward to sharing these results at the American Heart Association meeting next week and submitting these data to regulatory authorities.

In Pulmonary Arterial Hypertension, full results from the HYPERION study in recently diagnosed patients reinforce our confidence in the practice-changing potential of WINREVAIR. Additionally, we secured FDA approval for our supplemental BLA for WINREVAIR based on the strong results of the ZENITH trial.

In Oncology, we're pleased that the FDA approved subcutaneous pembrolizumab, or KEYTRUDA QLEX, and that the CHMP granted a positive opinion. KEYTRUDA QLEX will provide patients and providers an important new option that can be injected in as little as one minute. We're working relentlessly to continue to develop and deliver new treatment options for patients with cancer. At ESMO, we presented data across a broad range of oncology medicines and candidates, including important findings from breakthrough therapy-designated ADCs.

Finally, we continue to expand our efforts in Immunology, including for another of our important late-stage candidates, tulisokibart, where we initiated Phase 2b trials in three immune-mediated inflammatory diseases. These add to the Phase 2 study already underway in SSc-ILD and the ongoing Phase 3s in ulcerative colitis and Crohn's disease.

[SLIDE 8 - Completed strategic acquisition of Verona Pharma in October]

We're pleased to welcome our new colleagues from Verona Pharma and look forward to adding our commercial

capabilities and scale to accelerate the launch of OHTUVAYRE, a novel, first-in-class maintenance treatment for Chronic Obstructive Pulmonary Disease.

Strategic business development remains a top priority. We're assessing potential targets with urgency given our desire to make additional compelling investments when both science and value align.

[SLIDE 9 - Delivering the next wave of innovation to transform our portfolio]

In summary, we remain highly focused on building on the strong clinical and commercial progress we made in the quarter. The investments we're making to advance and expand our pipeline are increasingly translating into positive clinical results and successful new product launches. This is giving us improved line of sight toward the transformation of our portfolio to one with a far more diversified set of growth drivers. With each milestone we achieve, including compelling strategic business development, my conviction that we're well positioned to drive the next chapter of success for our company increases. I want to recognize the commitment and efforts of our teams across the world. Together, I'm confident we'll achieve long-term growth and create sustainable value for both patients and shareholders. 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 - Q3 performance driven by demand for our innovative portfolio]

As Rob noted, we delivered solid performance in the quarter with growth driven by continued strength in Oncology and Animal Health as well as increasing contributions from our many new product launches. These results reinforce the conviction we have in our science-led strategy and in our outlook for continued growth. We remain confident in our ability 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 third quarter results.

Total company revenues were $17.3 billion, an increase of 4%, or 3% excluding the impact of foreign exchange.

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 8% to $8.1 billion, with global growth driven by strong demand from metastatic indications and robust uptake in earlier-stage cancers. Usage in tumors that primarily affect women, including cervical, breast 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 or metastatic urothelial cancer. In the U.S., growth benefitted by approximately $100 million from an extra Tuesday of shipments partially offset by other channel movements.

We are also excited by the recent FDA approval and launch of KEYTRUDA QLEX, which occurred at the end of the quarter.

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

Our broader oncology portfolio achieved another quarter of strong growth driven by WELIREG with sales increasing 41% to $196 million predominantly driven by increased use in certain patients with previously treated advanced renal cell carcinoma in the U.S. as well as continued uptake from ongoing launches in certain international markets.

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

In Vaccines, GARDASIL sales were $1.7 billion, a decrease of 25%. Excluding China, sales declined 3% primarily due to lower sales in Japan reflecting the expiration of reimbursement for the catch-up cohort partially offset by sales growth of 13% in the U.S. which was attributable to price and CDC purchasing patterns.

[SLIDE 15 - Vaccines & Infectious Disease: Broad portfolio driving impact for patients]

In pneumococcal, CAPVAXIVE sales were $244 million, driven by demand from both retail pharmacies and non-retail customers as well as the expected seasonal inventory build. We look forward to helping protect more adults from invasive pneumococcal disease and to driving continued growth of this important product.

VAXNEUVANCE sales decreased 7% due to a competitor preferential recommendation in Japan, which more than offset growth in certain international markets. In the U.S., sales were roughly flat as competitive pressures were largely offset by favorable CDC stockpile activity.

In RSV, ENFLONSIA sales of $79 million reflect initial stocking ahead of expected demand. We look forward to helping protect infants born during or entering their first RSV season.

[SLIDE 16 - WINREVAIR: Continuing to benefit more patients with PAH]

In Cardiovascular, WINREVAIR continued its strong momentum with global sales of $360 million.

In the U.S., approximately fifteen hundred new patients received a prescription and over twenty four thousand total prescriptions were dispensed in the quarter, a testament to the continued strong demand for this important treatment option. There was also an approximate $40 million negative impact from the timing of distributor purchases, which fully reversed in October.

Compelling additional data from ongoing studies, which Dean will speak to in a moment, further support our outlook for steady new patient starts. Over time, we expect an increasing proportion of use in patients whose background therapies do not include a prostacyclin.

Outside the U.S., we continue to make progress with securing approvals and reimbursement, including the recent launch in Japan, which is off to a good start.

Overall, we look forward to positively impacting the lives of more patients with PAH.

[SLIDE 17 - Animal Health: Strong growth driven by livestock portfolio]

Our Animal Health business again delivered strong growth, with sales increasing 7%. Livestock sales grew 14% driven by higher demand across all species as well as a benefit from timing of sales. Companion animal sales declined 3% due to a reduction in vet visits and competition in parasiticides, partially offset by price, improved supply and new product launches.

[SLIDE 18 - Q3 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 81.9%, an increase of 1.4 percentage points driven by favorable product mix.

Operating expenses decreased to $6.6 billion. There were $300 million in business development charges in the quarter, compared with $2.2 billion in charges a year ago. Excluding these charges, operating expenses were flat, reflecting an increase in investments in support of our robust early- and late-phase pipeline as well as key growth drivers, offset by the timing of expenses.

Other expense was $106 million.

Our tax rate of 13.4% benefited from certain discrete items.

Taken together, earnings per share were $2.58.

[SLIDE 19 - Updated 2025 financial outlook]

Now turning to our 2025 non-GAAP guidance, which now includes the acquisition of Verona Pharma, as well as the restructured agreement for Koselugo. We expect full year revenue to be between $64.5 and $65.0 billion. This range represents growth of 1 to 2%, excluding a negative impact from foreign exchange of approximately 0.5% using mid-October rates.

Our gross margin assumption remains approximately 82.0%, including an updated estimate of less than $100 million in costs related to the impact of tariffs.

Operating expenses are now assumed to be between $25.9 and $26.4 billion. This guidance does not assume additional significant potential business development transactions.

Other Expense is now expected to be between $400 and $500 million.

We now assume a full year tax rate between 14.0% and 15.0%.

We assume approximately 2.51 billion shares outstanding.

Taken together, our EPS guidance is $8.93 to $8.98. Relative to 2024, this range includes a negative impact from foreign exchange of approximately 15 cents, using mid-October rates. Recall, our prior guidance midpoint was $8.92. Our current guidance midpoint of $8.96 reflects a benefit from the restructured agreement for Koselugo of $0.09, partially offset by an estimated negative impact related to the acquisition of Verona of $0.04.

[SLIDE 20 - Key modeling considerations]

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

For KEYTRUDA, as previously communicated, year over year growth in the U.S. in the fourth quarter is expected to be negatively impacted by approximately $200 million due to the timing of wholesaler purchases.

For ENFLONSIA, we are pleased with the initial purchases in the U.S. Keep in mind that most of this was stocking ahead of expected usage in this RSV season.

Lastly, as Rob noted, we have one of the most robust pipelines in our recent history. Importantly, all of our major programs are advancing and we are excited about the additional opportunities in front of us. As we have said before, we intend to fully invest behind these opportunities, and as we look to 2026, we expect an acceleration in underlying operating expense growth driven by investment in both R&D and SG&A to fuel our pipeline and new launches, including more than half a billion dollars of investment to maximize the potential of OHTUVAYRE. This will enable us to continue to bring forward innovative medicines and vaccines to make a difference in the lives of patients and drive growth for our company.

[SLIDE 21 - 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 key growth drivers and expansive pipeline of novel candidates, each of which has significant potential to 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 and we are well positioned to pursue additional science-driven, value-enhancing transactions.

We are maintaining our increased pace of share repurchases and expect approximately $5 billion for the full year.

To conclude, as we finish the year, we are confident in the outlook of our business driven by global demand for our innovative in-line portfolio, the exciting progress we are seeing with our many product launches, and our exceptional pipeline. With continued investment in innovation and our ongoing focus on execution, we remain 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 Y. Li – Merck & Co., Inc., Rahway, N.J., USA, President, Research Laboratories

[SLIDE 22 – Research Update]

Thank you, Caroline.

Good morning, everyone,

The third quarter was marked by several notable clinical and regulatory milestones. I will start with updates in oncology, followed by vaccines and infectious disease, immunology, ophthalmology and then cover advancements in our cardiovascular and pulmonary programs. I will close by highlighting key upcoming events through the first half of 2026.

[SLIDE 23 - KEYTRUDA continues to expand benefits, including for earlier-stage patients]

Progress continues across our diverse oncology portfolio.

Last month we received FDA approval for KEYTRUDA QLEX injection for subcutaneous administration of pembrolizumab.

KEYTRUDA QLEX offers a substantially quicker administration time than intravenous infusion of KEYTRUDA and can be administered subcutaneously by a health care provider in as little as one minute when given every three weeks. It has the potential to provide flexibility in the site of care while helping to increase efficiency in and access to health care systems. We also see opportunity for use in certain patients with earlier stage disease. To date, KEYTRUDA-based regimens have received FDA approval for ten indications in the earlier setting.

Last month, the European Medicines Agency's Committee for Medicinal Products for Human Use granted a positive opinion for subcutaneous administration of KEYTRUDA.

The European Commission has approved KEYTRUDA as part of a perioperative regimen for the treatment of certain adult patients with resectable, locally advanced head and neck squamous cell carcinoma based on the Phase 3 KEYNOTE-689 trial.

[SLIDE 24 - Continued momentum across diversified oncology portfolio in multiple tumor types]

We continue to build upon the extensive body of evidence for KEYTRUDA in multiple indications spanning both earlier and metastatic stages of disease.

At the European Society for Medical Oncology Congress, data from the KEYTRUDA program were showcased in two Presidential Symposium sessions. These include progression-free and overall survival results from KEYNOTE B96 in

certain patients with platinum-resistant recurrent ovarian cancer. The FDA has accepted our sBLA for priority review and set a PDUFA date of February 20th.

Also at ESMO, event-free and overall survival data from KEYNOTE-905 in patients with muscle-invasive bladder cancer who were ineligible for cisplatin-based chemotherapy, conducted in collaboration with Astellas and Pfizer, were presented. The FDA has also accepted this sBLA for priority review with a PDUFA date of April 7th.

The success of KEYTRUDA has enabled us to build a diversified oncology pipeline.

At ESMO, data from our growing portfolio of antibody drug conjugate candidates were also presented, including:

- results for sac-TMT, our TROP-2 targeting ADC, from the Phase 3 OptiTROP-Lung04 study in patients with EGFR-mutated non-small cell lung cancer conducted by our collaborator Kelun,
- findings from Kelun's Phase 3 OptiTROP-Breast02 study evaluating sac-TMT in locally advanced or metastatic HR-positive, HER2-negative breast cancer, as well as
- results from the Phase 2/3 REJOICE-Ovarian01 study evaluating R-DXd our CDH6 targeting ADC, in certain patients with platinum resistant ovarian, primary peritoneal or fallopian tube cancer in collaboration with Daiichi Sankyo.

Also, earlier this week we were pleased to announce positive results for WELIREG, our first-in-class oral HIF-2 alpha inhibitor, across adjuvant and advanced renal cell carcinoma based on two Phase 3 trials:

- LITESPARK-022 in combination with KEYTRUDA and
- LITESPARK-011 in combination with Lenvima, in collaboration with Eisai.

[SLIDE 25 - Clinical progress across vaccines and infectious diseases]

Next to vaccines and infectious disease, starting with CAPVAXIVE, our 21 valent pneumococcal conjugate vaccine. Following the approval in the U.S. and EU, in August the Japanese Ministry of Health, Labor and Welfare granted approval for CAPVAXIVE for the prevention of pneumococcal infections in the elderly and adults at high risk.

We are also evaluating the potential of CAPVAXIVE in additional patient types. At the European Society of Clinical Microbiology and Infectious Diseases Conference on Vaccines, results of the Phase 3 STRIDE-13 trial, examining the safety, tolerability and immunogenicity in children and adolescents aged 2 to 17 years who are at increased risk of pneumococcal disease, were presented. The FDA has accepted for review the sBLA and set a PDUFA date of June 18th.

Regarding RSV, following approval in June, ENFLONSIA, our long-acting monoclonal antibody for the prevention of RSV disease in infants entering or during their first RSV season, is now available. Earlier this month we received a positive CHMP opinion from the European Medicines Agency.

Turning to HIV, we have development programs spanning both treatment and PrEP settings anchored by our investigational NRTTIs islatravir and MK-8527. Earlier this month, new findings were presented at the European AIDS Conference including:

- 48-week Phase 3 data for doravirine and islatravir as a once-daily, oral two-drug regimen for the treatment of adults with virologically suppressed HIV-1 infection on antiretroviral therapy, and
- 96-week Phase 2 outcomes data for the investigational once-weekly oral combination of islatravir with lenacapavir for adults with virologically suppressed HIV-1 infection, in collaboration with Gilead.

[SLIDE 26 - Expanding and advancing late-stage programs in immunology and ophthalmology]

Moving to immunology then ophthalmology, tulisokibart is a humanized monoclonal antibody that targets tumor necrosis factor like cytokine 1A, that is associated with inflammation and fibrosis. The Phase 3 ATLAS trial, in ulcerative colitis recently completed enrollment and the Phase 3 ARES trial in Crohn's disease remains on track. Building on these studies we recently announced an expansion of the development program evaluating tulisokibart in dermatology and rheumatology indications with the initiation of three Phase 2b trials.

Since the acquisition of EyeBio last year we have made significant progress advancing the Phase 3 clinical development program for MK-3000, our novel candidate targeting the Wnt pathway for certain retinal diseases. Enrollment in the Phase 3 BRUNELLO study in patients with diabetic macular edema is complete and the study's primary completion date has been accelerated to September 2026. SUPER TUSCAN, a Phase 2 study evaluating MK-3000 in patients with neovascular age-related macular degeneration as well as retinal vein occlusion is currently enrolling.

In addition, earlier this month at the Eyecelerator event hosted by the American Academy of Ophthalmology, we presented promising first-time Phase 1 data from the RIOJA study evaluating MK-8748, our tetravalent bi-specific antibody targeting Tie2 and VEGF, in patients with macular edema secondary to branch retinal vein occlusion and neovascular age-related macular degeneration. Based on these data, we plan to initiate late-stage trials in 2026.

[SLIDE 27 - Committed to alleviating burden of cardiopulmonary diseases]

Next to our cardiovascular and pulmonary programs. WINREVAIR, the first and only activin signaling inhibitor for the treatment of adults with pulmonary arterial hypertension, continues to generate evidence for benefit across a broad spectrum of patients with PAH.

Results from the Phase 3 HYPERION trial in recently diagnosed adults with PAH were presented at the European Respiratory Society meeting. Adding WINREVAIR on top of background therapy showed a significant 76% reduction in risk of clinical worsening events compared to background therapy alone, despite early termination of the study due to loss of clinical equipoise. The findings were also published in the New England Journal of Medicine.

The FDA also recently approved an update to the WINREVAIR product label based on the results of the Phase 3 ZENITH trial. With the expanded indication, WINREVAIR is the first PAH therapy to have an indication that includes components of the clinical worsening events: hospitalization for PAH, lung transplantation and death.

With the closing of the Verona Pharma acquisition, we welcomed new colleagues to the team. Together, we are well positioned to build upon the success of OHTUVAYRE, a first-in-class dual phosphodiesterase 3 and 4 inhibitor for the maintenance treatment of chronic obstructive pulmonary disease. We plan to advance the ongoing work in bronchiectasis and evaluate utility in additional indications, combination therapies and alternative formulations.

Despite advances in the screening and treatment there continues to be a cardiovascular disease epidemic with ASCVD as the leading cause of death globally.

In September, we announced that enlicitide, our investigational oral PCSK9 inhibitor, met all primary and key secondary endpoints in the CORALreef Lipids study demonstrating statistically significant and clinically meaningful reduction in LDL cholesterol for the treatment of adults with hypercholesterolemia on a moderate or high intensity statin or with documented statin intolerance. This is the third positive Phase 3 trial for enlicitide.

We look forward to presenting the detailed results of the CORALreef Lipids study as well as the CORALreef study focused on familial heterozygous hypercholesterolemia at the American Heart Association Scientific Sessions meeting next week in New Orleans.

Please mark your calendars for an investor event at AHA on the evening of Sunday, November 9th where we will highlight these results and provide an overview of our cardiovascular and pulmonary program.

[SLIDE 28 - Many important upcoming milestones through 1H 2026]

We continue to see strong momentum across the pipeline. As Rob noted, there are approximately 80 Phase 3 trials underway across multiple therapeutic areas. We have initiated more than 15 Phase 3 trials this year and expect to have an increasing number in 2026.

As we look through the first half of 2026, we anticipate a regular cadence of milestones across therapeutic areas, including:

- In oncology:
  - the February 20th PDUFA date for certain patients with platinum-resistant recurrent ovarian cancer based on KEYNOTE B96;
  - the April 7th PDUFA date for certain patients with earlier stage MIBC based on KEYNOTE-905.
- In HIV:
  - the April 28th PDUFA date for the combination of doravirine and islatravir, an oral once-daily treatment regimen; and,
  - data from the Phase 3 ISLEND-1 and 2 trials evaluating islatravir in combination with lenacapavir, as a once-weekly oral treatment regimen.
- In immunology:
  - Phase 2 data for tulisokibart from the ATHENA study in SSc-ILD.

- In cardiopulmonary:
  - For WINREVAIR
    - data from the Phase 2 CADENCE study in pulmonary hypertension due to left heart disease;
  - For enlicitide:
    - presentation of detailed results from three Phase 3 trials from the CORALreef development program.

We continue to make progress with a diversified pipeline across multiple therapeutic areas, and I look forward to providing further updates on our programs in 2026.

And now I turn the call back to Peter.