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OVERVIEW:

Company Summary

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CORPORATE PARTICIPANTS

Peter Dannenbaum *Merck & Co Inc - Senior Vice President, Investor Relations*

Robert Davis *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Caroline Litchfield *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Dean Li *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

CONFERENCE CALL PARTICIPANTS

Daina Graybosch *Leerink Partners LLC - Analyst*

Vamil Divan *Guggenheim Securities LLC - Equity Analyst*

Christopher Schott *JPMorgan Chase & Co - Analyst*

Asad Haider *Goldman Sachs Group Inc - Analyst*

Evan Seigerman *Bank of Montreal - Analyst*

Umer Raffat *Evercore Inc - Equity Analyst*

Akash Tewari *Jefferies LLC - Analyst*

Terence Flynn *Morgan Stanley & Co Ltd - Analyst*

Courtney Breen *Sanford C Bernstein & Co LLC - Equity Analyst*

Trung Huynh *UBS AG - Analyst*

Timothy Anderson *Bofa Merrill Lynch Asset Holdings Inc - Analyst*

Alexandria Hammond *Wolfe Research LLC - Equity Analyst*

James Shin *Deutsche Bank AG - Research Analyst*

Mohit Bansal *Wells Fargo Securities LLC - Analyst*

PRESENTATION

Operator

Thank you for standing by. Welcome to the Merck & Company, Inc., Rahway, New Jersey, USA Q2 sales and earnings conference call. (Operator Instructions) This call is being recorded. If you have any objections, you may disconnect at this time.

I would now I turn the conference over to Mr. Peter Dannenbaum, Senior Vice President, Investor Relations. Sir, you may begin.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

Thank you, Shirley, and good morning, everyone. Welcome to the second-quarter of 2025 conference call for Merck & Company, Incorporated, Rahway, New Jersey, USA. Speaking on today's call will be Rob Davis, Chairman and Chief Executive Officer; Caroline Litchfield, Chief Financial Officer; and Dr. Dean Li, President of Research Labs.

Before we get started, I'd like to point out that we have items in our GAAP results such as acquisition-related charges, restructuring costs, and certain other items that we have excluded from our non-GAAP results. There is a reconciliation in our press release.

I will also remind you that some of the statements that we make today may be considered forward-looking statements within the meaning of the Safe Harbor provision of the US Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of our company's management and are subject to significant risks and uncertainties.

If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Our SEC filings, including Item 1A in the 2024 10-K, identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck & Company, Incorporated, Rahway, New Jersey, USA undertakes no obligation to publicly update any forward-looking statements.

During today's call, a slide presentation will accompany our speakers' prepared remarks. The slides, along with the earnings release, today's prepared remarks, and our SEC filings are all posted to the Investor Relations section of our company's website.

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

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

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 benefiting 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.

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.

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 in 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 eight 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.

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 cardiopulmonary program and reflects our commitment to transformative science in areas of significant unmet need. Upon closing the fourth quarter, we'll leverage our commercial capabilities to accelerate Ohtuvayre's successful launch and 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.

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 we'll 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 just a moment.

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.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Thank you, Rob. Good morning. 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. In oncology, sales of KEYTRUDA increased 9% to $8 billion with growth in both US 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-PD1 regimen approved for treatment of patients with this disease.

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 US.

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 US was attributable to price and higher demand, partially offset by CDC purchasing patterns.

(technical difficulty) 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 US, growth benefited 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 US, growth in certain international markets was offset by a competitor preferential recommendation in Japan.

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.

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 had 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 US, 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 US, 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.

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 benefited from improved supply.

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%. Taken together, earnings per share were $2.13.

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 long-standing 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 billion and $65.3 billion. This range represents growth of 1% to 2%, excluding a negative impact from foreign exchange of approximately 0.5% using mid-July rates.

Our gross margin assumption remains approximately 82%. 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 billion 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 million and $400 million. We now assume a full-year tax rate between 15% and 16%. 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 $0.15 using mid-July rates.

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.

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.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

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.

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.

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 shows 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 instead of PDUFA date of October 25. 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 heterozygous familial hypercholesterolemia 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 1 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.

Next to infectious disease. Last month, the FDA approved ENFLOSIA, our long-acting, monoclonal antibody for the prevention of respiratory syncytial virus lower respiratory tract disease in infants born during or entering to 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 million 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 investigation of 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.

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 castrate-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.

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 23; in the cardiopulmonary space, for WINREVAIR, the October 25 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.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

Thank you, Dean. Shirley, we're ready to begin Q&A now. We request that analysts limit themselves to one question today in order to get through as many questioners as possible. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Daina Graybosch, Leerink Partners.

Daina Graybosch - *Leerink Partners LLC - Analyst*

Hi. Thanks for the question. I wonder if you could help us understand CADENCE that you said has a September primary completion date. Specifically, can you help us put the outcomes in context?

I think you have a couple primary outcomes or primary and first secondary of PVR and a reduction or an improvement in 6-minute walk distance. What's your bar for success on both of those? And if you replicate those outcomes in Phase 3, can they support registration in this step test indication, or will you have to show benefit on a [hard] cardiovascular or a mortality outcome as well? Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Daina, thank you very much. This is Dean. As you're talking about WINREVAIR, right, we have a lot of data in pulmonary arterial hypertension. The data that we're exploring outside of pulmonary arterial hypertension is in CADENCE, and it is in a select population with heart failure. It's generally one that has hemodynamics that's a little bit more reminiscent of PAH than other diseases. And so, we're really interested to study whether we can move out of PAH but focus on those who have heart failure and have a PAH physiology.

In terms of the outcomes, you're right; it's PVR at 6 minutes. I would say, probably the most important thing --just because this is a patient population that's very different than a PAH population, the most important signal for me is really the PVR. I think the 6-minute walk will be also important. But to me, it's whether or not we can make a substantial impact on PVR in this patient population that is not PAH.

In terms of this question of whether or not one would need to do a Phase 3, I would say that we'll have to see the data. But my expectation in front of the data is, I would imagine that the FDA would be interested in a Phase 3 trial to really demonstrate the effectiveness of this treatment in this broader patient population.

Operator

Vamil Divan, Guggenheim Securities.

Vamil Divan - *Guggenheim Securities LLC - Equity Analyst*

Great. Thanks for taking my question. Maybe I'll just stick with WINREVAIR. One is actually a follow-up to the earlier question and then one question myself.

So just following up on the CADENCE discussion, I don't know if Dean or if someone could just maybe quantify the patient population as you mentioned patients may be [dynamically] a little more skewed to what we've seen on the PAA side, just a sense of the market size. It would be helpful because we've been getting a lot of questions on how to think about the opportunity.

But my other question -- my main question is actually the ex-US uptake of WINREVAIR, there's just sort of a little bit of growth in the second quarter. I know you're just kind of getting going with the launch ex-US. I'm curious, just as a relatively expensive product, recent US launch, has your ex-US strategy at all evolved given sort of the threat of most-favored-nation pricing? Are you thinking differently about what sort of pricing you might accept for WINREVAIR ex-US or which markets you may be targeting relative to what you were thinking a year or two ago?

And just any sense of the sort of broader ex-US market opportunity in PAH specifically for WINREVAIR would be helpful. Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yeah. I'll take the science question. This is Dean. In relationship to patients who have left heart failure, oftentimes, they have pulmonary hypertension and not pulmonary arterial hypertension, and it's due to increased pressures in their left heart, often measured by a wedge pressure that then backs up to the pulmonary artery. That's not the patient population that we're most interested in.

We're most interested in the patient population who has heart failure, and their pulmonary hypertension is elevated at a rate or a degree that is out of proportion to what their left heart pressures are. So in some sense, when I say a pulmonary arterial hypertension-like physiology, that's what this patient population is, and that's why we chose that.

In terms of the dimension -- how to dimension that, I would just say that to a large degree, that dimension is underdiagnosed in cardiology because there's no treatment for it. In those patients, there's very limited numbers. I would say that if you look at estimates in the absence of any treatment for these patients, I think they're going to be in the range of what -- in the range of pulmonary arterial hypertension and some factor maybe above that.

But I do believe that unlike pulmonary arterial hypertension, where there's very good epidemiology, here in this physiology, I don't know that the epidemiology is so certain, because there hasn't been a treatment. And when oftentimes, there's not a treatment, the epidemiology, one has to be a little bit thoughtful about.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. And Vamil, this is Rob. As it relates to the ex-US business, overall, to your point, it is still very early in the launch. And really, we're going to really see most of the reimbursements coming in the second half of this year, and that's when you're really going to see growth. But if you look at what happened in the quarter, we're actually seeing contracting is, in the markets where we are currently marketing the drug, like Germany, it's off to a good start.

What you saw from the revenues -- actually, there was a pricing adjustment in the quarter; that's why it appeared flat. But as we look forward, we do continue to see a strong opportunity for growth.

And just to contextualize, you might recall, this is about 90,000 patients worldwide and roughly half of that is the United States. The other half is Europe and Japan. And we expect -- we, I think, recently got approval in Japan. So that's coming in the back half of the year. And then we expect broader reimbursement through Europe. So as we sit here today, it's early; but I would say it's on track.

Operator

Chris Scott, JPMorgan.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

Great. Thanks so much for the question. I just wanted to dig into the $3 billion restructuring announcement. I know you mentioned in the press release you're planning to fully reinvest that. But just when we balance what seems like a large ramp in the pipeline and the Phase 3 programs over the next few years against this cost initiative, can you just help us a little bit of how we should think about either operating margins or absolute OpEx growth trending in the next few years? I'm just trying to get my hands around like what that looks like in any just qualitative sense you can provide? Thank you.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. I appreciate that, Chris. Maybe I'll give a high-level answer, and then Caroline can fill in some of the details. If you look at what this is about, this is, as we sit here today and look at really the impressive opportunity we have with these 20-plus launches, we will and we need to fully fund behind those launches. We need to continue, and we will fully fund behind our Phase 3 pipeline on an R&D basis.

To be able to do that and to continue to -- so we will be growing our spend over time, but we want to do it productively and efficiently. And that's why we're looking to reallocate money from -- and resources from the slower growth areas of the business to fully fund into the fast-growing areas of our business.

So really, this $3 billion that we've referred to is a reallocation within our portfolio from the slow-growing areas to the faster-growing areas with continued expectation that you're going to see overall growth in spend, hopefully, though, at a more productive level than you would have otherwise seen, and with those investments, as I said, targeted to our pipeline, making sure we fully fund the Phase 3s and to preparing for the commercial launch. But maybe Caroline can build out some details.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Yeah. So I think you've covered the headlines well, Rob. In terms of this $3 billion saving opportunity, that will come through productivity across our enterprise. It will impact the R&D line, SG&A as well as cost of goods.

That said, we will reinvest all of that $3 billion plus further investments, especially in R&D, given the strength of our pipeline as well as in SG&A over time as we launch the new products and look to excel in the marketplace with those launches in order to drive long-term growth for our company.

Operator

Asad Haider, Goldman Sachs.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Great. Thanks for taking the question. A three-parter on GARDASIL. First, on GARDASIL US, you noted positive price and demand offset by CDC purchasing. Recognizing that CDC purchasing dynamics are always lumpy, they've also been a significant driver over the year. So maybe just speak to your level of confidence on the demand dynamics from that channel in the current environment.

And then maybe also just as it relates to the potential for ACIP recommendation towards lower GARDASIL doses in the US, can you just update us on how you're thinking about the range of outcomes into the ACIP meeting this fall?

And then finally, on China GARDASIL, Caroline, I think you said no shipments through at least the end of this year. So any early thoughts on how you're thinking about 2026 would be helpful. Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

So this is Dean. I guess I'll take the ACIP question first, and then I'll leave the other questions to Caroline and Rob. I can't speculate what the ACIP may do. I just want to emphasize how confident we are in the safety and efficacy of G9, GARDASIL 9. But I would emphasize that I think one of the things that has become clear to the ACIP is that there is a clear disparity between the stringent clinical requirements outlined by the FDA versus the ACIP proposals that's there.

And the FDA has been very clear on the high evidentiary standard required for a single dose. I mean, they keep emphasizing to us efficacy against disease endpoints, not just infections, data in males and females. And this is something that's emphasized to us because we get reminded that HPV-related cancers in males is actually, I think, now trending higher than cervical cancer in females. They have a very high statistical bar in a long-term; they want very long-term durability of protection.

In terms of the ACIP, there's no agenda posted for the August, September, and October. However, this was sort of a topic that got postponed. So we imagine that there will be discussion about it, but we are very clear on the safety and efficacy and the clear disparity between the FDA's high evidentiary standard and any data to date in relationship to a single dose.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And then in terms of the commercial, in the United States, we saw strong growth driven by price and demand, but that was mostly offset by the CDC channel, where there was a buy down in the second quarter this year greater than what we had seen in the second quarter of 2024.

As we look at our opportunities for GARDASIL, we do expect growth in 2025 and beyond. But that does not contemplate any change in the dosing schedule for the United States. And we'll need to see what happens as the ACIP continue those discussions.

As it pertains to China, as noted in the prepared remarks, demand remains soft, and inventory remains elevated. We are on the ground doing all we can to activate demand, both with females as well as now with males. That said, we will not ship further product this year, and we will assess at the year-end on what the appropriate schedule should be for 2026.

I should note, GARDASIL China represents a fraction of our company now, much less than 1%. We're not counting on it for growth. We are counting on our new products, the excellent execution we have in our existing products to drive growth for our company in the second half of this year and into the future.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - *Bank of Montreal - Analyst*

Hi, all. Thank you so much for taking my question. As we think about business development going forward, I'd love if you could expand on your approach to diligence in assets between Chinese and Western companies. I'm specifically asking in context of the recent Verona acquisition versus a recent collaboration announcement by a competitor for Chinese PDE3/4 inhibitor. Thank you so much.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Well, this is Dean. We have a very high standard, whether it's from China or from the United States. But in specific relationship to your question about Verona, I mean, Verona is a company we have followed at least for five years. We were always intrigued by it because they had a dual inhibitor of PDE3 and 4 with the possibility of bronchodilatory and non-steroidal anti-inflammatory properties. And as we watched it, we had recognized that it could be the first novel mechanism, and it is now the first novel mechanism to get approved for inhalation for COPD.

And so for us, the fact that it's approved within the United States and the fact that we've talked to patients and physicians who use it, we believe that it lays a beachhead or groundwork for this field and our ability to move that quickly with Verona is an advantage to us, especially when we're a company who is revisiting our roots in cardiopulmonary and cardiometabolic. And we believe that there are other innovations around this pathway that will be important.

But having that first-mover advantage within the United States and more broadly is really important. When we looked at other assets within this space, specifically related to China, they were not in that position of a first-mover advantage, which we thought was critical for Merck to enter the field.

Operator

Umer Raffat, Evercore.

Umer Raffat - *Evercore Inc - Equity Analyst*

Thanks for taking my question. I feel like there's been a ton of interest in the valuation paid for your Chinese partner, LaNova on the PD-1/VEGF. And my question is, considering the ongoing Phase 1 is an open-label study, can we reasonably assume everything is in fact on track, and you are still in a position to start a potentially registrational Phase 2 like a KEYNOTE-021 G in the next few months? Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yeah. So this is Dean. In relationship to PD-1/VEGF, you're exactly right. We've been interested in the dual signaling in this space for some time. I would actually mark 2018 as our interest in relationship to our broad collaboration with our collaborators, Eisai.

In relationship to the LaNova program itself, everything is going exactly as planned. Now clearly, we're keeping an eye on the external environment and external data. But as related to LaNova program moving forward, that is going exactly as planned as we -- according to the plan when we initiated the partnership with LaNova.

Operator

Akash Tewari, Jefferies.

Akash Tewari - *Jefferies LLC - Analyst*

Hey. Thanks so much. So we're seeing an increase in patient adds for WINREVAIR after some modest decreases over the last few quarters. What's the right cadence when you think about this going forward, not only for the rest of 2025, but really 2026 and onwards now that you have the HYPERION and ZENITH results?

And really, what's your progress in terms of progressing WINREVAIR into earlier lines of setting? Are you starting to see doctors adopt this medication more aggressively?

And then maybe if I could just sneak in one more question, on the Hansoh GLP-1 asset, can you confirm that that drug has actually moved into the clinic? Thank you.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Maybe I'll start, and Caroline can add as well. So I appreciate the question on WINREVAIR. As we look, we've been pretty consistently adding 400 to 500 patients per month. So I wouldn't read the 1,600 in the quarter relative to -- as some shift.

It has been actually pretty steady, and we do continue to expect to see that kind of steady growth going forward as we move through the rest of the year. So that would -- I think that was the first part of the question, and then maybe Caroline can take the next part.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And then the second was how we're doing in penetrating the different patient segments. What we have as of now is 75% of the use is for patients with triple therapy or a background prostacyclin. That is increasing as we move forward. And indeed, of the 1,200-plus physicians that have now prescribed WINREVAIR, more than 50% of those have prescribed the product in patients that are less severe or on dual therapy. So that gives us a lot of confidence in our future as we continue to not only help those severe patients, but increasingly move into those patients who are less severe.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

I think it's safe to say that HYPERION and ZENITH both are contributing to that growing confidence. So everything is moving as we would hope it would as we entered the space.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

I think just to mention something in WINREVAIR, I mean I've actually talked to many of the KOLs at the major centers. I think there's just a stream of information that will be helpful. It's not one event per se. I think a label update would be really important.

I do think that many of the KOLs have been waiting to see the data from HYPERION because it gives them a sense of prescribing it earlier in their journey. So they'll be very interested in that.

There is a patient population in PAH, for example, who are overlapped with connective tissue diseases. And they're going to want to see the culmination of all that data across trials. And that data individually, and that data pooled will be very important.

And clearly, the continued [SOTERIA] and the fact that the adverse effects and all of this sort of thing are well within the label are things that are going to create an interest of the KOLs to begin to adopt this earlier in the journey and to other patient populations such as connective tissue disease.

In relationship to the Hansoh GLP-1, we said that it's moving to clinic this year, and everything is on schedule.

Operator

Terence Flynn, Morgan Stanley.

Terence Flynn - *Morgan Stanley & Co Ltd - Analyst*

Hi. Thanks for taking the question. I was just -- I was wondering if you could offer any preliminary perspective on how a 15% tariff on pharmaceuticals would impact your 2026 outlook. Recognize you're not going to give guidance at this point, but I was just wondering if you could help frame for us the potential impact there? And then any insight if this would be phased in over time or if this would be implemented more near term? Thank you.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Terence, this is Rob. I appreciate the question. Maybe I'll take the second part of it first. So we need to see more clarity both from the administration and just overall as to exactly how this is going to play out. So it's still not clear exactly how this relates relative to the 232 investigation and the timing, so to speak, whether these apply now or will be phased in. Until there is further guidance, I can't really speak to it.

But what I would tell you is as we look at -- and I don't want to get '26 guidance because we're not giving forward guidance -- but as you look at '25, I would tell you, if this was implemented immediately, it would be minimal impact based on all the work we've done around inventory management and moving our manufacturing to the US. We're very well positioned overall as we look forward to be able to do that.

And we have made very good progress as we look at even '26. We'll give the specific guidance as we move forward. But for '25, this would be minimal.

Operator

Courtney Breen, Bernstein.

Courtney Breen - *Sanford C Bernstein & Co LLC - Equity Analyst*

Hi. Thank you so much for taking my question today. Coming back to the comments you've made around the cost savings program and the reallocation of this, can you give us a little bit of context on your intentions to -- with KEYTRUDA, specifically recognizing that that asset is coming nearer to the end of its life cycle, yet there are still many launches as well as a subcutaneous product launch ahead, and so how you're planning on a allocating in the context of KEYTRUDA, SG&A relative to the newer opportunities that you need to fund in both R&D and those new launches? Thank you very much.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Courtney, thank you for the question. As you think about where we sit in oncology -- and maybe just to contextualize, and I'll answer the question -- obviously, we've been the leader in IO therapy with KEYTRUDA. And as we've consistently said, we have every intention of not only

being and continuing to be the leader but to broaden our leadership across the broader suite of oncology assets we have, which, as you know, now across the tissue targeting agents antibody-drug conjugates across all of the small molecules we have, we have one of the broader, if not the broadest, pipeline now moving forward in the oncology space.

So as you look at the spend, to your point, we're not necessarily looking to pull back spending on oncology. We're going to grow, and it's about reallocating the resources and adding to those resources as we start to move away from just being focused on KEYTRUDA to the broader suite of opportunities. So you're going to see other oncology gross spend as KEYTRUDA is pulled back.

Operator

Trung Huynh, UBS.

Trung Huynh - *UBS AG - Analyst*

Hi, all. Thanks for taking my question. It's just one on the One Big Beautiful Bill expanding the orphan drug exclusion under the IRA and how that affects the timing of KEYTRUDA's potential selection for IRA price cuts.

So when KEYTRUDA was initially approved, it carried an orphan designation. Its first non-orphan indication was approved about a year later. So does this One Big Beautiful Bill update effectively shift KEYTRUDA's IRA selection from 2028 to 2029? And then would the presence of biosimilars by that time actually mean KEYTRUDA won't be selected for IRA? Thank you.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yes. I appreciate the question. So maybe just from a policy perspective, we are very supportive of the language that was put in, in support of orphan drugs. We've long believed that investing behind orphan and rare disease is important and that the more we can do to support that, it is something which will benefit patients going forward. So in that sense, we're very much supportive of what the One Big Beautiful Bill included in that regard.

As it relates specifically to your question, you are correct that -- so KEYTRUDA did launch with an orphan indication in melanoma in 2014. The first non-orphan indication was in lung cancer in 2015. And based on the reading of the bill, as you've done, if you look at what is in there now, that would imply that you would expect now to see the drug selected for negotiation in '27 for implementation of the negotiated price in '29.

I'm not going to speculate to whether or not it continues to be included or not as it relates to the LOE -- then pending LOE. We'll have to see how that plays out.

But I also think it's important to also understand with all this said, what we're focused on is how do we grow the business post the impending LOE of KEYTRUDA and drive for sustainability in our business long term. So that is our focus. This is nice but does not change that fundamental view of our business.

Operator

Tim Anderson, Bank of America.

Timothy Anderson - *Bofa Merrill Lynch Asset Holdings Inc - Analyst*

Thank you. A couple of long-term questions for Rob. So Rob, you continue to describe the loss of KEYTRUDA as being more of a hill than a cliff. Our model shows the same, but I don't think investors and consensus really believe that. And you say you're confident in return to growth downstream of that period. So two questions.

On the hill comment, can you just remind investors the biggest offsets that you see today for how losing a product that's 50% of your revenues the time of expiry will, in fact, not be a cliff? And then second, when you talk about confidence in growth over the longer term, can you put parameters around that for when that would be likely? We show trough revenues 2031; that would be three years past patent expiry. All parts, is that a realistic timeframe for when consistent growth would return?

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Yeah. Jim, thank you for the question. Actually, I very much appreciate it, because this is the core of the valuation thesis for our company. And my own view of this is that I do think the Street underappreciates the power of what we have in our pipeline.

And as we see that play out -- as I've consistently said, as we see those proof points continue to play out -- and I would point to WINREVAIR is the first. We're now seeing it with CAPVAXIVE. I think clesrovimab will be another one. We have enlicitide coming, sac-TMT. All of these opportunities, as they roll out, I think that confidence will grow over time.

But to your specific question, what are we focused on? Recall that we've given guidance in a broad sense to the fact that we see over $50 billion of potential opportunity from our different therapeutic areas, starting with oncology. Broad-based oncology, we now have over 60 Phase 3 clinical studies, I think, across, was it, 13 different tumor types, which will be coming over the next five years, incredibly broad across our antibody-drug conjugates, across all of the small molecules. We have the individualized neoantigen therapy; the list would go on.

But we think those alone are over $25 billion, and we had an opportunity at ASCO to begin to talk about some of that. And we will continue to show more of that as we go forward. Our confidence there is better today than it was even at ASCO. With every card we turn, we feel better about that going forward.

And then you look beyond that in the cardiometabolic, we've directed to approximately $15 billion in the cardiometabolic space, really what's foundational elements coming from WINREVAIR, which we talked about, and we continue to be very enthused by what we're seeing there. Enlicitide or oral PCSK9, we continue to think is a huge opportunity.

We'll continue to focus on what we have in MK-6024, which is our MASH product. We're going to see, I think, data later this year. We continue to feel very good about that. So our overall suite of the cardiometabolic space, we feel very good about. That's the $15 billion.

Ophthalmology, I think, is underappreciated with a multibillion-dollar opportunity. We just recently went through our HIV portfolio with approximately $5 billion of opportunity, and we feel very good about that and the data we have and where our portfolio is going to go. It's very important.

Immunology is another $5 billion, which is important to focus on animal health. You look at the quarter of the growth we showed in animal health this quarter. This business is going to be a fast-growing business for this company throughout our long-range plan period and is really based on a new product story very much like the human health business, [where] actually just got approval in Europe for NUMELVI, our JAK inhibitor, for dermatitis. We just got approval for our injectable, once-annual in the United States. Those are the first of multiple new product offerings coming in that business that is going to allow us to more than double it by the time we get out to the mid-2030s.

And then all of this excludes what else we're going to do in business development. The fact that we just did Ohtuvayre, which added another multibillion-dollar opportunity that wasn't in that $50 billion when we said it, is further block -- a building block being added as well.

And then we still have a lot to do on business development. We've been very clear. We're not stopping. And we have an early-stage pipeline, which as we move into '26 and especially into 27, you're going to see increasingly things coming out of our Phase 1 pipeline into our Phase 2, which will be visible that are all very exciting.

So all of that is why if I sit and look at where we're at, I feel very good. And then obviously, we continue to have subcutaneous KEYTRUDA and the base of what we believe will be the KEYTRUDA business, which we will continue to be able to benefit for patients through those offerings.

So I think your characterization is fair. I actually agree with it. And as far as though, as it looks to how quickly we get back to growth, it would be one where I would say -- I don't want to give specifics on years, but we've been very clear. We want to minimize the cliff, which I think we have done. That's why I talk about the hill, and we want to get back to growth quickly. And I do see a path to do that, and I'm confident we will.

And I think if you go back to the JPM presentation we gave, we had a slide in there which was a representation, if you will, the cone of opportunity within our long-range plan, that kind of gives a profile very similar to what you just described.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

Great. Thanks, Tim. I know we're over time. We have time for a few more questions. So Shirley, next question, please.

Operator

Alex Hammond, Wolfe Research.

Alexandria Hammond - *Wolfe Research LLC - Equity Analyst*

Thanks for taking the question. For enlicitide, the team has highlighted it as a platform to add other cardiometabolic assets on to. With that context, what combinations and indications could we expect, and when could we receive updates? Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yeah. So thank you very much for the question. So just to reset, our ambition is that this is going to be the first oral PCSK9, and it will not just be first. It will be the best in relationship to everything that we've seen from competitor data.

And we expect to have it be the most effective oral LDL-lowering option, and it should have confidence in cardiovascular outcomes that are comparable, but actually, we believe could be better than the biologics. And we think that with the data that we have, we recognize that 70% of patients with ASCVD, even treated with statins, do not treat the LDL cholesterol.

So when you think about that, LDL is one axis in relationship to cardiovascular outcomes. And LDL, clearly, there would be combinations that you would make with enlicitide to even deepen that response and more. So that's a combination that would be advanced -- that can advance quickly. But I think there's also evolving data in relationship, and we will see that probably from others in relationship to, for example, Lp(a).

I think in that patient population, if reducing Lp(a) is indeed shown to be important for lowering cardiovascular outcomes, then the potential of having an Lp(a) molecule that can do that -- but also recognizing that PCSK9 adds further reduction of Lp(a) and in the patient populations who have high Lp(a), the way that I've treated them is I give them PCSK9 -- that a combination there may be something that's really important. And then in the future, other combinations potentially related to other axes -- I talked about LDL, Lp(a) -- we would clearly be interested in inflammatory accesses and other accesses in combination.

So enlicitide is a really important molecule. It is a molecule that we believe can serve as a platform to be driving cardiovascular outcomes in increments of 20%, 25%, 30%, and we're very excited for that future.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

We have time for two more questions, please.

Operator

James Shin, Deutsche Bank.

James Shin - *Deutsche Bank AG - Research Analyst*

Good morning. Thank you for squeezing me in. One for Dean. Dean, I appreciate everything is on schedule for MK-2010, but was Merck notified of Sino Biopharm's interest in LaNova? And does that have any bearing on Merck's commitment to 2010 or the development of a PD-1/VEGF bispecific more broadly? Thank you.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

I would just emphasize, our commitment is based on our interest in the space since 2018. So our commitment has not changed. And as I've said, the LaNova program that we have is moving forward as planned. In terms of notification or not notification, that's something that we don't comment in terms of business development.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Correct.

Operator

Mohit Bansal, Wells Fargo.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Great. Thank you very much for taking my question. So I have a question regarding the guidance. So if I compare the guidance on FX basis versus the prior quarter, it does seem like you have lowered the upper end of the growth from (technical difficulty) just wanted to understand if there is a change in the operational business that we need to be aware about. Thank you.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

Your line cut out. I think the question was about the reduction -- you see a reduction in the guidance, but can you talk about guidance, Caroline?

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Sure. So the guidance that we've given this quarter is to maintain the midpoint for revenues and to increase EPS by $0.03. There was a very modest tailwind from foreign exchange, and that has really offset a few headwinds.

The first would be a low level of COVID cases during the summer season, which has impacted our outlook for LAGEVRIO. The second is we have seen an early entrant of a biosimilar for pembrolizumab in Argentina, which has impacted revenues there.

All of that said, we are confident in our ability to drive growth in our business this year of between 1% and 2%. And when you exclude the impact of the headwind of China's GARDASIL, we have underlying growth of between 6% and 8%. So we're confident in our future despite the uncertain macroenvironment that does exist for our industry.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President, Investor Relations*

Great. Thank you, all, very much for your questions. As always, Investor Relations is available for any follow-ups. Thank you very much.

Robert Davis - *Merck & Co Inc - Chairman of the Board, President, Chief Executive Officer*

Thank you.

Operator

Thank you. This concludes today's conference. We thank you for your participation. At this time, you may disconnect your lines.