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# **EDITED TRANSCRIPT**

MRK.N - Q2 2021 Merck & Co Inc Earnings Call

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#### **OVERVIEW:**

Co. reported 2Q21 total Co. revenues of \$11.4b and non-GAAP EPS of \$1.31. Expects 2021 revenues to be \$46.4-47.4b and non-GAAP EPS to be \$5.47-5.57.



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### **PRESENTATION**

#### Operator

Good morning. My name is Mary Sara, and I will be your conference operator today. At this time, I would like to welcome everyone to the Merck & Co Second Quarter 2021 Conference Call. (Operator Instructions) Thank you. I would now like to turn the call over to Peter Dannenbaum, VP, Investor Relations. Please go ahead.

#### Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Thank you, Mary, and good morning. Welcome to Merck's Second Quarter 2021 Conference Call. With me today are Rob Davis, our Chief Executive Officer; Dr. Dean Li, President of Merck Research Labs; Frank Clyburn, President of Human Health; and Caroline Litchfield, Chief Financial Officer.

Before we get started, I'd like to point to a few items. You will see that we have items in our GAAP results such as acquisition-related charges, restructuring costs and certain other items. You should note that we have excluded these from our non-GAAP results and provided a reconciliation in our press release. I would like to remind you that some of the statements that we make during today's call may be considered forward-looking statements within the meaning of the safe harbor provision of the U.S. Private Securities Litigation Reform Act of 1995.

Such statements are made based on the current beliefs of Merck'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 and the 2020 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 undertakes no obligation to publicly update any forward-looking statements. Our SEC filings, today's earnings release and an investor presentation with highlights of our results are all posted on merck.com.

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

#### Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Thanks, Peter, and good morning, everyone. I'm deeply honored to speak to you today in my new role as CEO. Merck is a special company, and I'm fortunate to be surrounded by talented and dedicated colleagues who are intently focused on bringing important life enhancing and life-saving medicines and vaccines to people and animals around the world.

This long-standing and unwavering commitment to our mission is real, is tangible, and is what drives us to perform every day. The prioritization of investment in research and development under Ken's leadership and the focus of resources behind key growth drivers has put us in a position of strength that I intend to build upon. As I consider Merck's future, I continue to believe investment in research and development with patients at the center of everything we do is core to who Merck is and is our best path to sustainable ongoing success and value creation.

However, how we go about both delivering the best external and internal scientific opportunities, as well as how we bring those innovations to patients, must evolve. As I transition to the role of CEO, I solicited candid feedback from colleagues and external stakeholders. What I heard reaffirms my convictions. There's a broad agreement that investment in R&D should remain our highest strategic priority.

Employees are confident that we're on the right path. We have rebuilt and reinvigorated our discovery research engine and have a growing and robust pipeline. We're successfully executing on clinical development, and we're delivering strong commercial growth across both our Human and Animal Health businesses now, and will continue to do so well into the future.

While we are on the right path, we need to work with more speed, urgency and agility, more closely matching the pace of change in the broader environment. We need to accelerate the delivery of our innovations to the patients who need them, and to be leaner, nimbler and more digitally enabled.

We need to leverage the scale and reach we have as a global biopharmaceutical leader, while also embracing a commitment to evolve to address new challenges. And we need to move with focus and intentionality, which is a priority for both me and my management team.

I know that it's not about promising, it's about performing. Actions speak louder than words. With that understanding, I pledge to do all I can to ensure that Merck remains a global biopharmaceutical leader long into the future, delivering value to current and future patients and growth and value for our shareholders.

Now turning to the quarter, we had very good performance with strong growth. Our results demonstrate that the impact of the pandemic on our business is lessening. Patient access to health care providers has improved, and we expect continued strong growth in the remainder of the year. We're also making meaningful clinical advancements which Dean will speak to you in just a few moments. Our seamless execution during a period in which we successfully completed a complex spin-off without business interruption underwent leadership transitions and delivered accelerated growth only increases my confidence in what our organization can achieve in the future.

Organon is now an independent company, an important milestone in our company's history. And this transaction is a meaningful catalyst to Merck becoming a more focused, more efficient and faster growing company.

Let me spend a moment speaking about KEYTRUDA, which again experienced very strong growth this quarter. I'm confident that KEYTRUDA will continue to be a foundational cancer therapy and achieved strong growth for years to come. We are a leader in immuno-oncology and are



determined to leverage this and to sustained success. We are rapidly advancing a diverse set of oncology assets, many of which we highlighted in our recent ASCO investor presentation.

Across our oncology portfolio, we expect over 90 potential new indications by 2028, more than tripling our current base. We have a wide array of clinical partnerships, providing valuable insights into the biology of disease and into important potential external innovation. With our expanding oncology portfolio outside of KEYTRUDA, we will extend our leadership in cancer long into the future. I also strongly believe we will successfully navigate the eventual KEYTRUDA loss of exclusivity given the breadth of opportunity in areas both within as well as outside of oncology. Internally, our leaders are intensely focused on this period and efforts are underway.

Externally, I understand the importance of providing investors with increased transparency into the breadth of opportunities we see in our pipeline that will help us do this. As we've done recently in highlighting islatravir, our broader HIV portfolio and our next-generation oncology assets, we are planning deep-dive investor events with our scientific and commercial leaders focused on other areas of our pipeline that we believe are underappreciated yet hold great promise such as our suite of vaccine candidates, our cardiometabolic assets, as well as others.

Business development plays an important role, and we are putting an increased emphasis on ensuring we are appropriately aggressive in accessing the best external science. Executing value-enhancing BD is a top priority, and we intend to add to our pipeline through acquisitions, partnerships, licensing deals and collaborations. We will be unbounded by therapeutic area, though we are mindful on the need to have a balanced portfolio over time.

We'll seek new products, modalities and platforms that allow us to establish beachheads in important areas. Our recent acquisition of Pandion and its potentially foundational immunology asset is a good example of this. We will look at both early and late-stage opportunities and we have the financial flexibility to consider deals of all sizes, particularly given the \$9 billion distribution from the Organon spin-off.

And given our strong operational momentum, we are most interested in transactions that are easily integrated and less disruptive, where value is principally derived by the introduction of innovative new products that address patient needs instead of the cost synergies.

Before I turn the call over to Frank to discuss second quarter performance on our Human Health business, I want you to know that I appreciate and applaud the increasing societal and investor demand and corporation stack responsibly. In fact, I believe our strong performance across environmental, social and governance issues has and will continue to create sustainable value for all of our stakeholders. Merck has a long track record and history of strong corporate citizenship, and I'm committed to remaining a leader in this area.

With that, let me turn the call over to Frank.

#### Franklin K. Clyburn - Merck & Co., Inc. - Executive VP & President Human Health

Thanks, Rob. Good morning. As Rob highlighted, our Human Health business continues to regain momentum, and we achieved 18% growth in the quarter, excluding the impact of exchange. Across our business, we've been engaging and investing with urgency to encourage more normal levels of physician office visits, oncology screenings and vaccination rates, including catch-up from misdoses. The agility demonstrated by our teams around the world to quickly reallocate resources to drive these patient activation programs has benefited our largely physician-administered portfolio.

In the United States, we are encouraged that wellness visits and surgical procedures have returned to more normal levels. And in oncology, we're seeing screening rates continue to improve. We're confident that these favorable trends and the strong underlying demand for our products will drive accelerated underlying business momentum in the second half of the year.

Now I'll turn to the second quarter performance of our key brands. My comments will be on an ex exchange basis. In oncology, KEYTRUDA sales grew 20% to \$4.2 billion, reflecting continued strong global demand. In the United States, KEYTRUDA continues to demonstrate strong growth, and over the course of the pandemic has increased its market share of new patients within the immuno-oncology class.



KEYTRUDA also maintains its leadership position in lung cancer, capturing 8 out of 10 eligible new patients. We continue to see strong growth across all key tumors, including renal cell carcinoma, bladder, adjuvant melanoma and MSI high indication. Additionally we are off to a very strong start with our launch of KEYNOTE-355 in metastatic triple-negative breast cancer, and we look forward to adding overall survival to the label. We're also excited by the recent approval and upcoming launch of KEYNOTE-522 in the neoadjuvant and adjuvant setting.

Outside the United States, growth continues to be driven by lung cancer indications, and the ongoing launches in head and neck cancer and renal cell carcinoma. LYNPARZA grew 34% in the quarter and remains the leading PARP inhibitor. Growth continues to be driven by approvals of recent indications, and we look forward to a potential future launch in adjuvant breast cancer based on the OlympiA data presented at ASCO this year.

LENVIMA grew 15% in the quarter, reflecting increased demand in hepatocellular carcinoma following the NRDL listing in China. We are also excited to launch the recently approved combination of LENVIMA plus KEYTRUDA in endometrial carcinoma. And in the near future to potentially launch in renal cell carcinoma based on KEYNOTE-581.

Our vaccines portfolio recovered sharply due to the return to more normal level of wellness visits. GARDASIL had a very strong quarter, growing 78%. In the United States, higher sales were driven by a recovery from the negative impact of last year's lockdowns. Outside the United States, growth was driven by increased demand in China. Sales also benefited from increased supply due to improved manufacturing, which I'll provide additional details on in a moment.

Our hospital business continued its recovery, BRIDION sales grew 67% year-over-year, driven by increased surgeries as patient access to hospitals improved from last year.

Turning to our outlook, the recovery we saw in the quarter gives us confidence that we will have a very strong second half resulting from both market recovery and strong commercial execution. Over the quarter, Merck quickly pivoted its focus and resources to patient activation campaigns to ensure that patients are putting their health first and recognize the importance of returning to physicians' offices for screenings, early detection and routine visits.

Our efforts in partnership with public health constituent groups paired with the continued rollout of COVID-19 vaccinations, has resulted in meaningful improvements in patients accessing health care providers.

In adolescents, we've seen more than 1/3 of teens in the United States vaccinated against COVID-19 with at least 1 dose. We assume that these rapidly growing vaccination rates and continued commercial execution will help to drive a near-normal back-to-school season.

Merck has also shown increased agility and efficiency across our organization, and importantly, we've made improvements that will enable meaningful future growth. Of note, we expect GARDASIL to significantly benefit from increases in productivity across our supply chain, which will allow us to fulfill demand that we were previously unable to supply.

Furthermore, as global demand for GARDASIL continues to outpace supply, our teams have been working to ensure we have the right regulatory approvals and lead time to appropriately allocate doses to areas of increased demand, particularly as the pandemic continues to force lockdowns in many geographies. These improvements alone will drive very strong sequential and year-over-year growth for GARDASIL in the back half of the year, especially in ex U.S. markets, such as China.

In oncology, we're encouraged by the recovery we've seen to date and our overall performance throughout the pandemic. We remain confident in the underlying demand for our broad and innovative portfolio, including KEYTRUDA, LYNPARZA, LENVIMA and if approved, belzutifan and expect to drive strong and sustained growth across key tumor types and stages of disease. Overall, the improvements in patient and access we are seeing in major markets gives us increased confidence as we look to the second half of the year.

Before I conclude, I would like to mention the strong execution of our commercial colleagues around the world that enabled our company to drive strong growth in the first half of the year, all the while, we're working to successfully complete the spin-off of Organon. We are confident that the



spin-off results in meaningful benefits to the commercial organization, including the ability to drive even stronger growth through more focused commercial execution.

To close, our business has regain momentum and we are well positioned to achieve strong growth in the third and fourth quarters. Our portfolio is rebounded by strength and demonstrated not only as resiliency, but it's value to patients globally. The strong recovery we saw in the quarter underscores our confidence in the underlying demand for our innovative medicines and vaccines, and we look forward to a return to robust long-term demand-driven growth.

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

#### Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Thank you, Frank. Good morning. Our business delivered meaningful growth in the quarter driven by strong underlying demand for products across our growth pillars and the continued recovery of the business as patient access improves. As we exit the quarter we are confident that our position of financial and operational strength will enable us to drive long-term revenue growth and meaningful margin expansion, creating value for our shareholders by delivering on our mission to improve the health and wellness of people and animals worldwide.

Now turning to our second quarter results, which reflects Merck on a continuing operations basis. Total company revenue were \$11.4 billion, an increase of 22% or 19%, excluding the positive impact of foreign exchange. Further adjusting for the estimated impact of the pandemic, total revenues grew 8% year-over-year, evidence of the underlying strength of our business.

The remainder of my comments will be on an ex exchange basis. As Frank highlighted, our Human Health business showed improving momentum, growing 18% or 6% when adjusted for the estimated impact of the pandemic. Animal Health had an outstanding quarter, increasing 27% driven by very strong global demand across companion animal and livestock, which increased 38% and 20%, respectively. Animal Health sales grew 19% when adjusted for the estimated pandemic impact. In companion animal growth was driven by higher global demands for vaccines as well as parasiticides including the BRAVECTO line of product. Performance in livestock reflects increased global demand across ruminants, swine and poultry products along with higher demand for our animal health intelligence product.

I'll now walk you through the remainder of our P&L, and my comments will be on a non-GAAP basis. Gross margin was 76.5% in the quarter, a decrease of 0.6% and reflecting the unfavorable effects of foreign exchange, pricing pressure and higher manufacturing costs, partially offset by favorable product mix. Operating expenses increased 13% year-over-year to \$4.8 billion, driven largely by higher clinical development costs, increased investment in our early-stage pipeline and higher promotion costs in support of returned care activity for our key growth drivers.

The effective tax rate for the quarter was 14.6% an increase of 1.3% from a year ago, driven by discrete items last year. Taken together, we earned \$1.31 per share, an increase of 27%.

Before turning to our 2021 guidance, I want to remind you briefly of the benefits we expect to achieve as a result of the spin-off of Organon. With the spin completed, Merck is now a more focused company and better positioned to unlock the full potential of our growth pillars and drive accelerated profitable growth. We are very excited about our future. And as we look out to 2024, we continue to believe that our revenue potential is underappreciated.

Now for 2021, health systems and patients have largely adapted to the impacts of the pandemic, and we assume this trend will continue. We are narrowing and raising our expected revenue range to \$46.4 billion to \$47.4 billion, representing growth of 12% to 14%, including a positive impact from foreign exchange of less than 2% using mid-July rates. The underlying demand for our growth pillars and our strong commercial execution provides us with confidence that we will continue to see strong momentum throughout the remainder of the year. As such, we expect total revenues to be sequentially higher in each consecutive quarter.

Our gross margin is expected to be between 76% and 77%. We expect operating expenses to grow at a high single-digit rate, driven by increased investment in promotion and patient activation programs to accelerate our near-term business momentum. And by increased R&D investment to



advance our exciting pipeline to support sustainable long-term revenue growth. As a reminder, our operating margin from continuing operations will be lower than what they were as a combined company, but our guidance range implies significant operating leverage in 2021. In addition, we continue to expect operating margins of greater than 42% in 2024, driven by our accelerated revenue growth and disciplined investment in our business.

In other income and expense, we expect expense of approximately \$300 million. We expect our full year tax rate to be between 14.5% and 15.5%. We assumed 2.53 billion shares outstanding. Taken together, we expect non-GAAP EPS to be -- excuse me, to be between \$5.47 and \$5.57, reflecting growth of 21% to 23%. This range includes a positive impact from foreign exchange of approximately 2% using mid-July rates.

As you consider your models and the allocation of revenues to various products, there are 2 areas to focus on: GARDASIL and Animal Health. Frank described the strong acceleration in growth expected in GARDASIL, and we also expect continued momentum in our Animal Health business. Our updated guidance also reflects the benefits of the approval of KEYNOTE-522, and as a reminder, does not include revenue from the potential launch of molnupiravir.

Turning to capital allocation. We received \$9 billion cash distribution from Organon, which we intend to deploy in value-enhancing strategic business development opportunities that align with the parameters Rob outlined. In the absence of meaningful business development, we will return cash to shareholders through share repurchases. We remain committed to investing in support of our key brands and progressing our innovative pipeline. And we will look to increase our dividend payout ratio over time.

To conclude, as a leaner, more focused and agile company, Merck is prepared to capitalize on the meaningful opportunities that lie ahead and is better equipped to succeed in an ever-changing landscape. Merck remains in a position of financial and operational strength, which we will leverage to drive long-term sustainable growth and value creation for our patients and shareholders.

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

#### Dean Y. Li - Merck & Co., Inc. - EVP

Thank you, Caroline. I'm delighted to be here today to provide an overview of progress made over the past quarter. I will cover key regulatory milestones and clinical updates, initially in oncology and then across the broader pipeline.

As Rob highlighted, we continue to show strong momentum in our oncology pipeline which positions us well. And it's worth reiterating our goal: to potentially deliver 90-plus approvals and new indications by 2028. A recent report from the American Cancer Society noted that there's been a rapid decrease in lung cancer and melanoma deaths from 2014 to 2018. One factor attributed to this decline is advancements in research including targeted therapies and immune checkpoint inhibitors.

The report also notes there is an urgent need to accelerate a decline in death rates for breast, prostate and other cancers where Merck is just beginning to make an impact. We are hopeful that our contributions and the advances being made industry-wide, will continue to fuel this decline.

Notably, during the last quarter, we achieved several milestones for treatments targeting women's cancer. In triple-negative breast cancer, the most aggressive subtype of breast cancer where historically treatment options have been limited, I am pleased to announce several advancements, which will improve options for patients. The first is FDA approval for a new indication in high-risk early-stage triple-negative breast cancer based on results from the pivotal Phase III KEYNOTE-522 study, where KEYTRUDA was evaluated in combination with chemotherapy as neoadjuvant treatment and then as monotherapy adjuvant treatment post surgery.

These practice-changing event-free survival results were presented just 2 weeks ago, which demonstrated a remarkable 37% reduction in the risk of progression including definitive surgery, local or distant recurrings, second primary malignancy or death from any cause compared to chemotherapy alone in patients.



Now additionally, we announced positive clinically meaningful top line overall survival results from the Phase III KEYNOTE-355 study evaluating KEYTRUDA in combination with chemotherapy in patients with untreated metastatic triple-negative breast cancer, whose tumors express PD-L1 with a combined proportion score greater than -- or equal to 10. This positions KEYTRUDA to be the first anti-PD-1 therapy in combination with chemotherapy to show statistically significant overall survival in metastatic triple-negative breast cancer. We will work with the regulators to expand the existing indication to include survival benefits and will aim to share full results soon.

Now also for early-stage breast cancer, along with our partners at AstraZeneca, we presented results at ASCO from the Phase II OlympiA trial, evaluating Lynparza for the adjuvant treatment of certain patients with germline BRCA high-risk HER2-negative early-stage breast cancer. These findings clearly demonstrated that Lynparza reduced the risk of invasive breast cancer recurrence, second cancer or death by 42%. Results will be submitted to global regulatory authorities, and the trial continues to evaluate overall survival.

Now also at ASCO, with our partners at Seagen, we presented additional encouraging data from the HER2CLIMB study TUKYSA in patients with early-stage HER2-positive breast cancer. It is clear that Merck is establishing an important beachhead in breast cancer with multiple agents. The progress we are making in this area of significant unmet patient need is one example of our strategy to expand into earlier lines of therapy and our strong conviction that our oncology assets have the potential to change the way early-stage cancers are treated.

We are also making progress across women's cancer more broadly. We received an approval from the FDA for an expanded indication for the combination of KEYTRUDA and LENVIMA for the treatment of certain patients with advanced endometrial carcinoma where along with our partners at Eisai, we showed results from the confirmatory Phase III KEYNOTE-775 study earlier this year.

And finally, we had positive results from the pivotal Phase III KEYNOTE-826 trial investigating KEYTRUDA in combination with platinum-based chemotherapy with and without bevacizumab for the first-line treatment of patients with persistent, recurrent or metastatic cervical cancer regardless of their PD-L1 status. The trial met its dual primary endpoints of overall survival and progression-free survival. Results will be presented at an upcoming medical meeting, and submitted to regulatory authorities.

Additional FDA approvals this quarter included 2 new indications for KEYTRUDA. The first is in combination with trastuzumab and chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma based on results from the Phase III KEYNOTE-811 study.

The second approval was an expanded indication for cutaneous squamous cell carcinoma for patients with locally advanced disease that is not curable by surgery or radiation. This was granted under accelerated approval based on a Phase II KEYNOTE-629 study. The FDA also granted priority review based on Phase III data from KEYNOTE-581 in first-line treatment advanced renal cell carcinoma, and we expect the decision in the third quarter.

Now outside the United States, the European Commission approved a new indication for KEYTRUDA plus chemotherapy in certain patients with esophageal cancer or HER2 negative gastroesophageal junction adenocarcinoma based on results from KEYNOTE-590. And in China, Lynparza was granted conditional approval for certain patients with metastatic castration-resistant prostate cancer who progressed following prior treatment with certain new hormonal agents. This is the first PARP inhibitor to be approved for advanced prostate cancer in China.

Now also at the ASCO virtual meeting new data supporting the benefit of KEYTRUDA in earlier lines of therapy from the pivotal Phase III KEYNOTE-564 trial for the adjuvant treatment of certain patients with renal cell carcinoma was presented. KEYTRUDA given after surgery demonstrated a statistically significant and clinically meaningful reduction in the risk of disease recurrence or death by 32% compared to placebo. Results will be submitted to global regulatory authorities and the trial will continue to evaluate overall survival.

We are making progress on our strategy to extend the benefit of KEYTRUDA to more patients. This includes the initiation of a Phase III trial evaluating a subcutaneous formulation of pembrolizumab in combination with chemotherapy in patients with non-small cell lung cancer. We believe this new formulation could be an important additional option for patients. This study will be enrolling soon with a readout expected in early 2023.



And finally, belzutifan continues to make good progress with additional Phase II data presented at ASCO, and an expected FDA action date in September and a development program with 3 Phase III studies in renal cell carcinoma that are gaining momentum.

Now turning to our broader pipeline. In response to the outbreak of SARS-CoV-2 in India. We made the decision to enable access to molnupiravir in low and middle-income countries through voluntary license agreements with several Indian generic manufacturers. While the ongoing studies in India are recruiting a different patient population, we are encouraged by the data being generated and we look forward to continuing to help with the crisis.

We remain excited by the progress of molnupiravir and the data we've seen to date. Along with our partner, Ridgeback Biotherapeutics, we announced the presentation of full results from the dose-finding phase of Phase II/III studies in both outpatient and hospitalized patients at the European congress of clinical microbiology and infectious disease 2021. We look forward to the readout from the Phase III portion of the study in the October timeframe.

Additionally, we posted a new Phase III study evaluating molnupiravir as a post-exposure prophylactic option and look forward to a readout in the first half of 2022. In HIV, we continue to progress our islatravir development program, our investigation on nucleoside reverse transcriptase translocation inhibitor. Phase II data presented at the International AIDS Society Meeting a few weeks ago continued to support the safety and tolerability profile of oral once-monthly islatravir in the PrEP setting.

We are continuing to enroll patients across diverse populations and geographies in the Phase III EMPOWER trials, and are moving forward with studies evaluating islatravir in treatment and prevention settings.

In vaccines, I am pleased to note the FDA approval of VAXNEUVANCE, the first in a suite of promising pneumococcal conjugate vaccine candidate for the prevention of invasive pneumococcal disease in the dose 18 years and older caused by 15 serotypes. Along with immune response data showing that VAXNEUVANCE can maintain progress achieved to date based on noninferiority to serotypes shared with PCV13, VAXNEUVANCE also induced superior immune response to PCC 13 for shared serotypes 3 and for the 2 serotypes unique to VAXNEUVANCE, 22F and 33F. These immunogenicity data position this vaccine to offer an important new option and protection of adults from invasive pneumococcal disease.

We look forward to further engagement with the ACIP, including discussing the positive results we achieved through our robust development program, studying a broad range of adult populations and clinical circumstances, including adults at increased risk.

Building on our clinical evidence for VAXNEUVANCE, we also announced that 2 of our Phase III pediatric study met their primary immunogenicity and safety endpoints in supporting potential use in healthy infants who may have previously started a pneumococcal vaccination series with PCV13 and in a catch-up setting for healthy children who have either not received pneumococcal vaccine or received a full or partial regimen with lower valency pediatric PCVs. We continue to anticipate data from our Phase I/II program evaluating V116, our adult-focused vaccine, to read out later this year.

To conclude, I remain excited about the progress in our broader pipeline and efforts stemming from Merck Research Labs that contribute to improving options and treatments for diseases that affect people globally. We continue to deliver on our strategy with speed and urgency to harness the benefits of our cancer therapies for as many patients as possible while advancing a broad pipeline of promising vaccines and therapeutic candidates.

Now I will turn the call back to Peter.

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Thank you, Dean. Mary, will you please start the question-and-answer session?

(Operator Instructions).



#### QUESTIONS AND ANSWERS

#### Operator

(Operator Instructions) Our first question comes from the line of Chris Schott from JPMorgan.

#### Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

I guess just for my one question here, just a picture one for Rob. Can you just elaborate a little bit more on the business development environment, I guess now that you're post the Organon on transaction, I mean you're highlighting R&D as a priority, kind of bringing more innovation to the company as a priority.

But how are you thinking about deals that would accelerate the company's kind of investment in oncology where they obviously have a competitive strength versus more therapeutic area diversification?

And can you maybe just walk through the pros and cons as you consider and think about larger transactions versus a series of smaller deals? I know you're looking at everything, but I'm just trying to get sense of all else equal, is there a bias kind of one way or the other at this point?

#### Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Sure. I appreciate the question, Chris. As we as I said in the prepared remarks, we're very focused on business development and it's something that we recognize we need to do, we need to augment the pipeline. But I also just want to reinforce, and I think, hopefully, you heard it through what Dean just walked through. We also have a strong internal pipeline, and I don't want to lose sight of that, and we really do have a lot of confidence in what we can bring forward across the breadth of both oncology assets, as well as assets outside of oncology and vaccines. Obviously, in HIV, all the areas that Dean touched upon. But with that said, we know we need to add more and build upon that, and we are very focused there.

Clearly, we see ourselves, and I made a comment about this in the prepared remarks with the strength in oncology, and we want to build upon that strength and actually see ourselves as a company that over time can be a broad player across oncology, really leveraging the foundational position we have with KEYTRUDA. They're going well beyond KEYTRUDA and we're already starting to do that.

So as we think about business development, I always will look at that because if you look right now in the space of where there's still one of the largest unmet needs despite the advances we've made with KEYTRUDA and other new agents, which are phenomenal and what they're delivering for patients, the truth is the majority of patients still don't have a solution yet for the cancers they face.

So this is still an area of unmet need. There's a ton of science being done in this area, focused just in this area. And as I said, we have the strength to leverage the position of KEYTRUDA and really the data we have within our oncology space to really be a differentiated and, I think, unique observer of the space to be able to select the best opportunities. So that will be our focus.

But I also recognize we have to do more than that. We need to be balanced and we are looking to areas outside of oncology as well. And I would like to see us do things in both. So build the strong foundation, continue to lead in oncology, leverage the data we have there but look to where can we balance that and augment the portfolio in outside areas.

On the second part of the question, on the pros and cons between large and small deals, in a perfect world, we would -- where we think we bring the greatest value is if you get assets that are a little bit earlier in development, where we can bring the prowess we have from as clinical side to bring those through and really add value, those are the deals we've been doing historically.



But we are not foreclosed to doing larger deals. And as we've always said, and I continue to believe, it's more about finding the right science and driven first with science as the key component. Informed by the portfolio impact where we believe we add value, and if we can find those deals, we will move on them whether they are large or small. But clearly, one of the areas we continue to believe we do not need to go is to the very large synergy-driven deals. I think we have enough firepower in our own pipeline and through it what we can add across the portfolio with deals focused on the science. We don't need to go to those large type of deals at this time.

#### Operator

Our next question is from Umer Raffat with Evercore ISI.

Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

I thought I'd focus a little bit on molnupiravir since that's the trial that's coming up, and presumably, it's also the biggest needle mover on numbers for next year as we think about it. So my question is this, the 0.5 to 0.7 log antiviral benefit that you're seeing, what feedback are you hearing on that magnitude of viral load drop?

And what's the feedback on the clinical benefit observed with that in the mobile trial? And I ask because it looks like even though you are limiting your primary analysis to patients enrolled in less than 5 days, I still think -- there's a fair amount of seropositive embedded within the way you're looking at the data. And I almost wonder if seronegative is probably that population where you probably see the most cleanest signal. I'd be very curious.

#### Dean Y. Li - Merck & Co., Inc. - EVP

Yes, this is Dean. Let me take that question. So we are advancing molnupiravir in a Phase III clinical trial. It is focused on the outpatient setting, and we are focusing it on high-risk patients. The reason I emphasize that is your observations and relationship to viral load and such are important observations.

But I would just call out that at least we've done the U.S. regulatory framework. The viral load is not the critical issue for the regulatory framework. It is whether or not we can affect clinical events. And so the need to focus on high-risk patients is the critical issue that we want to focus on.

In relationship to that trial, it has a primary completion date that's listed as October. And we are very enthusiastic of how this trial is progressing, and we hope to see data over the coming months for the trial. I would emphasize that this is a blinded global study, and it is focused on high risk and many of -- the pandemic keeps shifting. And so -- It's not just within the U.S. and the EU, but important countries like South Africa, Brazil, Colombia. Those countries are extremely important for our ability to show not just the reduction of viral load but a big impact on clinical effect. That's what we need to look for in this trial.

#### Operator

Our next question comes from the line of Louise Chen with Cantor.

Louise Alesandra Chen - Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD

My question for you is just how we should think about your margin expansion opportunities? I know you've given some longer-term guidance, but let's say, over the next 12 months. How would that progress?



#### Caroline Litchfield - Merck & Co., Inc. - Executive VP & CFO

Louise, this is Caroline. So first I'll start with our pipeline is rich, and therefore, as a company, we are focused in growing expenses to support the near-term and long-term opportunities that we have, which will enable us to drive long-term revenue growth. That said, we are also expecting to drive margin expansion. And that margin expansion would come from a few different factors. It will come through from the revenue growth, it will also come from a change in our product mix, and it will also come through efficiencies across our business and our commitment to deliver \$1.5 billion dollars of operating efficiencies over the 3-year period.

Finally, we do expect an increase in margin in 2024 as a result of the step down of royalties specific to KEYTRUDA and GARDASIL. So as I think about margin expansion, our guidance for this year at the midpoint of the range assumes a 2 percentage point increase in margin. And I expect that margin expansion to continue to grow as you look out to the coming year.

#### Operator

Our next question comes from the line of Terence Flynn with Goldman Sachs.

#### Terence C. Flynn - Goldman Sachs Group, Inc., Research Division - MD

Two-Parter, I guess, Rob. Just curious if you're setting any internal time lines for use of the Organon proceeds and would welcome your latest view of asset valuations. And then for Dean, there's obviously been a tremendous amount of progress with new platforms over the last 12 to 18 months, and Rob, you touched on some of these. But any of that particularly stand out to you as having a potential to be as transformative as antibodies were 20 years ago?

#### Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Yes. So Terence, thanks for the question. As we look forward, we're actively looking and we want to move with speed. I don't want to put a time limit on how fast because obviously, some of it is based on market factors and where assets are in their own life cycle and discussions we're having. So right now, we're focused on trying to find the ways to deliver to the pipeline through BD, but it's not time down. I think what Caroline is really trying to say is, eventually, if we don't find those opportunities, we're not going to sit on the cash forever, but I want to make sure that we put the priority on BD first before we make that determination.

#### Dean Y. Li - Merck & Co., Inc. - EVP

In relationship to your second question, it's almost -- there's such a laundry list of advancements in data and technology that whatever I say, I'm going to miss saying something. And I will just focus not so much in platforms. There's a lot of movement in data platforms that I think are critically important, but also in what I would call technology platforms that are important for making molecules, as you said, such as antibodies.

Clearly, there's a lot of movement in protein engineering. Clearly, there's movement in protein degradation. Clearly, there's movement in antibody drug conjugates. And we are interested in all of them. I think one of the critical questions that often people think about, especially in relationship to us as a vaccine company is in relationship to mRNA. And really the success of monovalent SARS COV2 vaccine is something that demonstrated the speed which we've always recognized but also scalability. And we were one of the first to invest in mRNA for vaccines, for ID and for oncology.

And so we're taking some of those lessons and we're prioritizing programs where we believe that mRNA will be important. I do want to emphasize that those programs -- that said, programs such as pneumococcal vaccine, I don't think is a place where mRNA vaccines is a place to take it.

And complex multivalent vaccines with profound and proven clinical benefits such as GARDASIL, I'm not so sure that that's where I would drive an mRNA vaccine. Outside of infectious disease, we continue to have a very productive partnership with Moderna on oncology. We're a little bit more careful with outside of the use of vaccine. We watch with interest the progression of that technology.



#### Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

So -- and Terence, my apologies, I recognize I didn't answer the last part of the question on valuation. So what we are seeing in the marketplace, things tend to still be fully valued. And as we know, there's a lot of capital flowing into the biotech space. So that obviously presents a challenge. But I would just point to you that we recognize we need to be appropriately aggressive as we go after these opportunities. And I continue to believe that if we apply where we see differential opportunity based on our scientific lead and what's out there, we can still create value while we're strategically adding to the pipeline, and that's really where we're focused.

#### Operator

Our next question comes from the line of Andrew Baum from Citi.

#### Andrew Simon Baum - Citiqroup Inc., Research Division - Global Head of Healthcare Research and MD

The market doesn't credit the pipeline as due to increasing growth such as the later (inaudible) remains focused on the (inaudible) for KEYTRUDA at the end of the decade, which might say is — previously, Rob, you've highlighted Merck recognizes me to raise the curtains on the pipelines assets to a great degree it sounds historically. so you have very large databases on is it ILT4, CTLA4 among others. When should we expect to see that curtain being raised? And then just to add on the (inaudible) question, Merck has a prodrug of islatravir, they're taking into the (inaudible). Do you believe it infringes your intellectual property?

#### Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

And Andrew, we'll try to answer the question, to be honest with you came through very garbled. So I think your question -- the first part of the question was about pipeline transparency and when are we going to be showing more information if from that. As I said, that is an area of focus. We did with when we showed you the broader HIV portfolio and the work we did recently to give some insights to our broader -- early stage oncology portfolio outside of KEYTRUDA.

Our thought thinking is probably as we approach probably closer to the end of the year. I think we're going to plan to have another session. And then obviously, we'll think about as we move into next year. But areas we wanted to highlight as we move forward, clearly, as I mentioned, cardiometabolic is an area where we have growing conviction and interest.

We're very interested in our broader vaccines portfolio and we see a lot of opportunity there. So those will be some areas where we'll be focusing in the future. And then I think you're asking if we sold a prodrug issue with islatravir, I'll turn it over to Dean, if he's aware of, if I got the question right.

#### Dean Y. Li - Merck & Co., Inc. - EVP

Right. So first of all, islatravir is a foundational element that one could build on. And that's what our strategy is built on, monotherapy for prevention and combination in terms of treatment. So the interest in islatravir, I kind of take it as a validation of how strong we believe in islatravir and its mechanism.

In terms of the legal status, we're very comfortable in where we sit in relationship with islatravir. I don't want to speak directly to freedom to operates and all of that in relationship to other people's compounds until we see the details of structure and all of this. But we are very confident in our investment and our patent position and relationships to islatravir.



#### Operator

Our next question comes from the line of Daina Graybosch with SVB Leerink.

Daina Michelle Graybosch - SVB Leerink LLC, Research Division - MD of Immuno-Oncology & Senior Research Analyst

I think I will ask one on pneumococcal, I wonder if you could give us your base and best case for the October AICP meeting given the sort of the June preview analysis didn't consider some of the strengths of your vaccine around serotype III and other [strains]?

#### Dean Y. Li - Merck & Co., Inc. - EVP

Yes, let me first take it, and then I'll pass it on to Frank. We're very confident in the clinical program of our V114 VAXNEUVANCE. And the strength of the data that serves as the basis for the filing, which showed broad protection against disease-causing serotypes and improved immune performances for serious serotype that persist. This will be an important point. Not all serotypes are equal. There are certain serotypes that are far more important than others. And so I think it will be very important at the ACIP to understand the epidemiology and how one thinks through that.

Now we've demonstrated that the immune response data really shows that we have noninferiority to serotype share with PCV13 and that we have superior for 3 that are quite important from a an epidemiologic standpoint.

I think the other issue that I just want to sort of also elevate is that we also are advancing V114 or VAXNEUVANCE, not just in relationships to adult, but we're advancing it aggressively in relationship with pediatrics. And we are also advancing a more bespoke adult focused vaccine V116 that we hope to share data on over the next year or so. Frank?

### Franklin K. Clyburn - Merck & Co., Inc. - Executive VP & President Human Health

What I would say is, one, we're very -- we're excited about the opportunity we have overall for pneumococcal franchise. To your question on the ACIP, we are waiting to better understand the future recommendations really of all the vaccines, Pneumovax, VAXNEUVANCE and Prevnar 20. You saw some of the information that came out in June. At this time, there may be a shift and some preference towards some of the newer pneumococcal vaccines that they go with an age-based recommendation.

There are number of populations that they're looking at in their recommendations. And right now, we're focused on really making sure they understand our data and the benefits of our offerings across our both PNEUMOVAX 23 and VAXNEUVANCE. So if there is some risk to PNEUMOVAX, as I mentioned, we'll have to see how that plays out. But I would also highlight that this is for us, especially with VAXNEUVANCE as Dean talked about, sort of the beginning. We think we have a very competitive offering in adults. We're very excited about the opportunity we have. For pediatric, and you heard Dean mentioned our 2 Phase III trials in pediatrics as well as we're continuing to develop V116 for adults and also V117. So when we look at the overall pneumococcal franchise and I would say vaccines as a growth pillar for our company. We're very confident in the continued growth for vaccines for the company both in near term and in the long term.

#### Operator

Our next guestion comes from the line of Geoff Meacham from Bank of America.

#### Geoffrey Christopher Meacham - BofA Securities, Research Division - Research Analyst

Rob, I want to ask you another strategy question just coming off the completion of the spin. And to see what the guardrails are when you think about BD. So the question is we're diversifying the revenue mix away for oncology, take priority over the op margin expansion you're expected to



have. And then to put a finer point on the therapeutic areas, I know you lead role with a science state, but what are your thoughts on the orphan drug arena or expanding the footprint in neuroscience now that there's apparently a more favorable FDA environment?

#### Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Yes, Geoff, I appreciate the question. So as we think about business development and how we think about that relative to the margin goals we have for the company. A couple of comments. One, it's important to say we do believe, over time, as I said, we need to have a balanced -- more balanced portfolio and we'd like to bring that diversification.

I would make one clarification to your point. I see a difference in diversification away from KEYTRUDA versus diversification away from oncology. Obviously, oncology is a broad field and as I said it earlier, huge unmet need still rests there.

So that's an area where we can leverage the strength we have with KEYTRUDA, the foundational position we have, the data we have, the insights we get from basically being tested either combined with or against pretty much every agent out there. And so I see an expansion and diversification across broader oncology as an important goal for its future into the future.

And then I do believe we also should look for other therapeutic areas, we have a strong position in vaccines. We're looking there. We've mentioned the cardiometabolic is an area and in fact, Dean can make a comment on neuroscience. But we actually have several ongoing early-stage programs in the neuroscience space. So we're excited about that.

To your question on what do we prioritize, first and foremost, I prioritize long-term sustainable growth. And that in our business is about innovation and investment in science. So we always will prioritize that, I believe we can both deliver that and bring operating margin expansion to the business, but it's a matter of driving cost reduction or investing in growth, I always will invest in growth.

#### Dean Y. Li - Merck & Co., Inc. - EVP

Let me take a shot at the question that you had in relationship to orphan disease and neurosciences. I would highlight that if we're looking at rare diseases, I do like rare diseases because it's a very quick way to understand proof of concept that can move quickly and then once you're at that situation, the ability to expand from that sort of beachhead is very important.

And the reason I want to emphasize that is deals like belzutifan, although in oncology is really a rare disease play with the possibilities of expanding into broader cancers. So whether we see that in cancer or in noncancer assets and pathways and possibilities, that's something that we're very interested to replicate. In relationship to neurosciences, you're right, there has been movement recently at the FDA and the important biomarkers, but I do want to sort of level set back that the importance of biomarkers must also be balanced by the importance of being able to show changes in important clinical events for patients.

It has changed, and we're very anxious to understand how we can best utilize that movement for biomarkers and especially, for example, our phospho-Tau program, which were very enthusiastic of advancing how that should navigate and how we should think about, for example, biomarkers such as Tau biomarkers in that clinical strategy is of intense interest to us giving the shifting landscape.

We have other neuroscience programs, MK-8189 is in Phase II for schizophrenia. We have MK-1942 that we're advancing for treatment resistant depression. So the regulatory landscape changing in neuroscience is important. It is something that we take into account and it is affecting how we navigate the field and accelerate the program that we have, and it also changes how we look at business development as well.

#### Operator

Next question comes from the line of Ronny Gal with Bernstein.



#### Aaron Gal - Sanford C. Bernstein & Co., LLC., Research Division - Senior Research Analyst

I was wondering if you can talk a little bit about -- more about using mRNA on a multivalent approach, you kind of notice that it's a hard problem. Is this impact a theoretically impossible issue or it's just an engineering issue of getting messenger RNA vaccines to be multivalent?

#### Dean Y. Li - Merck & Co., Inc. - EVP

I'll take that question. The issue with multivalency is it's the more valence that you have in any vaccines, it becomes a more complicated issue. The other issue is the dose that you need and what we would call the reactogenicity every time that you add something. So I don't -- it would be remissed for me to say that anything is impossible. Science and technology changes. But the framework that I was trying to lay out is that there are places where I think the field would raise in relationship to mRNA, to have an impact clinically and then there are other parts of the field where I think more discovery and development of the technology, there will be an intense interest to overcome some of those initial barriers.

#### Operator

Our next question is from Mara Goldstein with Mizuho.

#### Mara Goldstein - Mizuho Securities USA LLC, Research Division - MD of Equity Research Department

I have a question on pricing [unless] as we rounded and into the beginning of this year, one of the things that Merck had commented on was that pricing was potentially a major -- continue to be a major issue for the pharmaceutical industry and that pressure was only going to increase. We saw a few days ago, a little bit of hand waving, I think, on the part of the Biden administration about -- talking about the federal government being able to negotiate pricing in Medicare system. So I'm just wondering, as a rounding out of 2021 and 2022, what the company's thoughts around pricing are.

#### Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Yes. Thank you. I'll take that question. Clearly, we continue to expect to see ongoing pressure on pricing. And I think the dialogue that you're pointing to the tapping right now with Congress, and then also with the Biden administration only reinforces that, that threat continues to be there.

But I think as we focus on it a couple of points. One, as we look forward, all of the expectations we have for our growth in the company that we've communicated in the past does assume we face meaningful price pressure. So we continue to believe our growth will be driven by -- more by volume than price. And I think that's important as you think about the long-term risk position of the company. As we look out over the next 5 plus years, we're largely derisk to our revenue goals and I think can achieve it regardless of price.

Putting that aside, as you think about it from a policy perspective, we are very willing to engage with U.S. government in discussions about how best to achieve a goal of reducing the out-of-pocket costs for patients. That is our foremost goal. We actually recognize that need and are willing and want to work with them around that goal. Understanding we want to protect innovation because we also want to be able to ensure we can bring the innovations for the next generation of patients that need them.

I think the whole situation with COVID has shown why you want a robust and innovative industry because at the moment you need it, it's important that it's here in our country and we can invest and drive it. So that's our focus. But again, it's really about where is it that we can see reductions in out-of-pocket cost, areas where they look either legislatively or otherwise that don't shift any kind savings to the patients at -- in their pocket book we're opposed to.



#### Operator

Our next question comes from the line of Carter Gould with Barclays.

#### Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

I wanted to touch on the performance in China. You had a very nice quarter there. I was hoping to get you a little bit more color on exactly kind of what drove the performance. Was it GARDASIL or more LENVIMA? And I ask really in the context of your messaging around sort of the GARDASIL performance you expect in second half and the additional supply capacity coming online. So some color on those fronts would be helpful.

#### Franklin K. Clyburn - Merck & Co., Inc. - Executive VP & President Human Health

Yes. Hi, Carter. It's Frank. Yes, China grew very strong this quarter. I think it was 42%, if you exclude foreign exchange. It was really driven by GARDASIL, very strong growth as we've mentioned and we anticipate that will continue as we move forward because of the significant number of patients and still a relatively small penetration that we have for GARDASIL in China. So clearly, we see opportunities there.

I'd also like to highlight that we did see very strong growth. Again, within oncology, LENVIMA, Lynparza, KEYTRUDA grew very strong this quarter. So a number of our growth drivers. And in addition, to that, we also are still seeing strong growth for JANUVIA/JANUMET, diabetes in China as well. So we anticipate that we'll continue to see growth. I think this ties very well through our strategy where we pivoted and focused more on our innovative portfolio of products for China and that's why we're very confident in the future growth within China.

#### Operator

Our last question comes from the line of Steve Scala with Cowen.

#### Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

Can you provide an update on the anti-ILT4 antibody? A number of new trials have been initiated recently, what does the Merck sees in this target that is interesting?

#### Dean Y. Li - Merck & Co., Inc. - EVP

Yes, this is Dean. ILT4 is a program that we're watching very carefully in our own pipeline. It is a program that was initiated by us looking at patient data from clinical trials with pembrolizumab and looking at those patients who are responsive, but more importantly, those patients who are not responsive and understanding what are possible mechanisms.

The other point that I would just emphasize is ILT4 in some sense is a checkpoint inhibitor, but it is not the T-cell checkpoint inhibitor. And there's always been a discussion of whether another class of immune cells, such as the myeloid cells could be really important. And so that's the second reason why we're very interested.

But quite frankly, the third point I would make is, all of that is interesting science and is a great hypothesis. But fundamentally, we have to have clinical trials that show that. We are advancing clinical trials for ILT4. And I think that the interest in other companies to follow our lead in ILT4 is based on the fact that they see us advancing it, and we believe that our data will support us advancing it, and we'll just have to see what that benefit is, but it is a highly differentiated first-in-class mechanism, not just in the molecule, but in the cellular sort of approach of how we're attacking cancer broadly.



Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Thank you, Steve, and thank you all for your really good questions today. I'll turn it to Rob for some closing remarks.

#### Robert M. Davis - Merck & Co., Inc. - President, CEO & Director

Great. Thanks, Peter. As we discussed today, hopefully, what you'll get a sense of is that we do have significant opportunities for growth in value creation. I'm committed to make it happen, and I know my team is as well. And importantly, we're confident we'll be able to do so.

Merck is a company that matters. And as we think about that, we know we need to evolve. We hold a special place in the world, and we're committed to delivering for the patients who count on us and frankly, to deliver the sustainable growth that I know our shareholders want to see and I'm confident we will do so. So I look forward to giving you updates on our progress as we move forward, and I wish you all to have a great rest of your day.

Peter Dannenbaum - Merck & Co., Inc. - VP of IR

Thank you very much.

#### Operator

This concludes today's conference call. Thank you for participating. You may now disconnect.

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