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EDITED TRANSCRIPT

MRK.N - Q3 2021 Merck & Co Inc Earnings Call

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OVERVIEW:

Co. reported 3Q21 total revenues of $13.2b and non-GAAP EPS of $1.75. Expects 2021 revenues to be $47.4-47.9b and non-GAAP EPS to be $5.65-5.70.

REFINITIV

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PRESENTATION

Operator

Good morning. My name is Grace Lakra, and I'll be your conference operator today. At this time, I would like to welcome everyone to the Merck & Co. Q3 Sales and Earnings Conference Call. (Operator Instructions). After the speakers' remarks, there will be a question-and-answer session. (Operator Instructions).

I would now like to turn the call over to Peter Dannenbaum, Vice President of Investor Relations. Sir?

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

Thank you, Grace, and good morning. Welcome to Merck's Third Quarter 2021 Conference Call. Speaking on today's call will be Rob Davis, our Chief Executive Officer; Frank Clyburn, President of Human Health; Caroline Litchfield, Chief Financial Officer; and Dr. Dean Li, President of Merck Research Labs.

Before we get started, I'd like to point out 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 provide a reconciliation in our press release.

I would like to 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 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 in 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.

During today's call, a slide presentation will accompany our speakers' prepared remarks. The presentation, today's earnings release as well as our SEC filings are all posted to the Investor Relations section of Merck's website.

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

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

Thanks, Peter. Good morning, everyone, and thank you for joining today's call. I'm very pleased to report significant progress across our key growth and strategic priorities in Merck's first full quarter as a more agile and focused science-driven company.

We have strong momentum in our business. We have achieved notable clinical milestones, acted on a significant business development opportunity consistent with our strategy and executed commercially to drive strong performance this quarter.

We're also working with diligence and urgency, which is reflected in the speed with which we were able to bring forward our investigational COVID-19 antiviral, molnupiravir, and to rapidly file for Emergency Use Authorization with the FDA.

It's an exciting time at Merck, and we are determined to build on our recent successes as we pursue our mission to deliver innovations that save and improve lives and as we seek to create long-term value for both our patients and our shareholders.

Dean will speak to the significant pipeline advancements we're making in a minute. But I first want to congratulate him and our research colleagues, as well as our partners at Ridgeback Biotherapeutics, on the meaningful clinical results we recently reported regarding the development of molnupiravir.

From the onset of the pandemic, Merck has sought out opportunities to apply its scientific expertise in the global fight against COVID-19, and we are very pleased to now be in a position to make a meaningful difference. As you are aware, at a planned interim analysis of our Phase III trial in at-risk nonhospitalized adult patients with mild-to-moderate COVID-19, molnupiravir reduced the risk of hospitalization or death by approximately 50% compared with placebo.

Based on these results and in consultation with the FDA, we stopped our trial early. We are now working with the FDA as the agency reviews our EUA application, and we look forward to next month's advisory committee discussion. I'm pleased with the progress we are making to enter supply and purchase commitments with numerous governments and health care systems around the world and with the success of our effort to rapidly build supply.

I'm also proud that we will be positioned to provide access to patients around the world through voluntary license agreements, tiered pricing based on country affordability and to our agreement with the Medicines Patent pool.

We've also taken a meaningful step towards augmenting our pipeline through business development, a key strategic priority. The announced acquisition of Acceleron is a perfect example of our effort to identify and bring in the strongest external science to supplement our own work.

Acceleron's lead product candidate, sotatercept has the potential to become foundational as an add-on therapy in the treatment of pulmonary arterial hypertension, where there is a strong need for a new agent that can potentially address the underlying illness and not just the symptoms

of this grievous disease. We look forward to the completion of our tender offer in the near future and to receiving the necessary regulatory approvals that will permit us to close the transaction.

With its multibillion-dollar peak sales potential, and commercial exclusivity well into the next decade, sotatercept can contribute meaningful revenue growth in the KEYTRUDA LOE period, an important attribute of this and potential future targets. Dean and I will continue to work with our team to identify additional scientifically compelling business development opportunities, while also continuing to pursue a robust and growing internal pipeline.

Our business performed exceptionally well this quarter, and the team continues to display superior and focused execution. We achieved very strong commercial and financial results with meaningful growth across our Oncology, Vaccines and Animal Health businesses and even greater growth in earnings.

As expected, GARDASIL sales were particularly robust as we benefited from a sharp improvement in manufacturing output and availability of more doses to help address ongoing strong underlying demand. We are confident that the momentum we are seeing will continue through the end of the year, setting us up for continued growth over the next several years. We remain focused on our efforts to transform the way we work by evolving our operating model to be leaner, nimbler and more digitally enabled.

My leadership team is fully aligned behind the need for Merck to work with more speed, urgency and agility across all aspects of our business. We must stay ahead of the evolving external environment to ensure we are able to make the significant investments required to deliver future innovations that will address unmet medical needs across the globe. In doing so, we aim to deliver important medicines and vaccines to patients, while continuing to drive long-term sustainable growth and value creation for all of our stakeholders.

Finally, I want to highlight the recent publication of Merck's Environmental, Social and Governance Progress Report. This year's report highlights important updates on metrics and goals around our 4 ESG priority areas, which include access to health; our employees, including their health and safety as well as engagement and diversity; environmental sustainability; and ethics and values. These ESG efforts are grounded in the core values that have always guided our mission and support our business strategy. We look forward to providing ongoing updates on these important efforts.

With that, I will pass it to Frank to review the details behind our Human Health performance.

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

Thanks, Rob. Good morning. As Rob highlighted, the momentum in our Human Health business continued in the third quarter, and we achieved 17% growth, excluding the impact of foreign exchange.

We have continued to invest with urgency in patient activation programs that improve patient awareness and encourage more normal levels of physician office visits, oncology screens and vaccination rates. These actions, while ended benefiting patient health, also meaningfully benefited our largely physician-administered portfolio in the quarter.

In the United States, we are encouraged that wellness visits and surgical procedures remain at mostly normal levels. In oncology, while screening rates and diagnosis continue to improve, they are unfortunately still below pre-COVID levels, and this is impacting new patient starts. Outside of the United States, our business performance remains strong, despite lingering impacts from the pandemic in certain markets.

Now turning to the third quarter performance of our key brands. My comments will be on an ex exchange basis. In oncology, KEYTRUDA sales grew 21% to $4.5 billion, reflecting continued robust global demand. In the United States, KEYTRUDA continues to demonstrate durable momentum across all key tumors, including growth from our recent launches such as KEYNOTE-522 in neoadjuvant adjuvant triple-negative breast cancer.

KEYTRUDA is continuing to extend its very strong overall IO class leadership, improving new and total patient market share. KEYTRUDA continues to maintain its leadership position in lung cancer, capturing 8 out of 10 eligible new patients despite continued competition. Outside of lung, key tumors contributing to growth, include renal cell carcinoma, triple-negative breast, MSI high, esophageal and head and neck. We are also excited

by the recent approval and upcoming launch of KEYNOTE-826, which is the first anti-PD-1 combination, approved as a first-line treatment of cervical cancer.

Outside of United States, KEYTRUDA growth continues to be driven by lung cancer indications and the ongoing launches in head and neck and renal cell carcinoma. We are continuing to see the opportunity to expand our reach into earlier lines of therapy materialize.

We are very excited about the potential upcoming adjuvant launches of KEYNOTE-564 in renal cell carcinoma and KEYNOTE-716 in melanoma. In fact, in the United States, we expect over half of KEYTRUDA's growth to come from indications in early-stage treatment settings through 2025 and to represent roughly 30% of total contributed sales by that time.

Lynparza sales grew 25%, and it remains the leading PARP inhibitor. Growth was driven by our breast cancer indication and continued uptake of the most recent indications, including ovarian and prostate, and we look forward to the potential launch next year in a broader prostate population based on the PROpel trial.

Lenvima sales grew 30%. In the United States, growth was driven by renal cell carcinoma and endometrial cancer. We've seen very encouraging early trends from the launch of KEYNOTE-581 in first-line renal cell carcinoma. Outside the United States, growth is reflective of increased demand following NRDL listing in China in March of this year.

We're also excited by the recent approval of WELIREG for patients with certain VHL-associated tumors. We received very positive feedback from scientific leaders, providers and patients about the benefits of WELIREG, which is off to a promising start, and we are hopeful to extend the reach of WELIREG to broader RCC indications in the future.

Our vaccines portfolio continued to deliver strong growth from GARDASIL, which grew 63% to $2 billion and has grown 35% year-to-date. In the United States, the increase in year-over-year growth was primarily driven by the timing of CDC purchases, which helped us overcome a below normal back-to-school season. Underlying demand for GARDASIL remains strong, and we are seeing some benefits from recovery of missed doses due to the pandemic.

Outside the United States, growth was largely driven by strong underlying demand in China, as well as increased supply and our ability to reallocate doses.

In our hospital acute care portfolio, BRIDION sales grew 15%, driven by our ability to capture increased market share within the growing neuromuscular blockade reversal plans.

Turning to our outlook. The robust underlying demand for our products, paired with our continued excellent commercial execution, gives us confidence in the outlook for our business. Merck has shown increased urgency and agility across our organization that has resulted in improvements that will enable meaningful future growth.

On GARDASIL, we continue to expect robust ex U.S. demand and increased supply to drive fourth quarter performance. We expect to see more normal seasonality for GARDASIL with the third quarter reflecting the highest in sales. Our teams have been working to ensure we have the right processes in place to appropriately allocate doses to areas of increased demand, particularly as COVID variants continue to impact certain geographies.

These dynamics will drive very strong year-over-year growth for GARDASIL in the fourth quarter, driven by ex U.S. markets such as China. Given global HPV vaccination levels remain low, we continue to believe long-term growth opportunity for GARDASIL remains significant.

In oncology, we are encouraged by our strong performance throughout the pandemic, with new launches more than offsetting the headwinds seen from reduced new patient starts. We remain confident in the underlying demand for our broad and innovative portfolio, including KEYTRUDA, Lynparza and Lenvima, and we expect to drive sustained growth across key tumor types and in earlier stages of disease.

Next let me provide a few comments on the outlook for molnupiravir. As Rob mentioned, we are very excited about the potential to offer the first oral treatment option to at-risk adults with mild-to-moderate COVID-19 in an effort to help combat the pandemic.

Merck is committed to providing widespread access to molnupiravir globally and is implementing a tiered pricing approach based on World Bank country income criteria. We have announced a number of supply and purchase commitments to date, and we continue to have discussions on similar agreements with customers around the world.

We are also encouraged by the recent unanimous vote by the Advisory Committee on Immunization Practices. Upon adoption as a final recommendation by the CDC, this sequence would offer patients the broadest coverage with a strong immune response against serotypes responsible for about 2/3 of invasive pneumococcal disease cases in adults.

As we think about our pneumococcal portfolio more broadly, we are excited about the potential opportunity for VAXNEUVANCE in the pediatric setting, which represents a larger market segment.

To conclude, there is continued momentum in our business, driven by demand and strong commercial execution, and we are well positioned as we move through the end of the year. The growth in the third quarter underscores our confidence in the underlying strength of our business and global demand for our innovative medicines and vaccines, and we look forward to driving that growth long into the future.

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

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

Thank you, Frank. Good morning. Our team drove exceptional financial performance in the third quarter. The investments we are making in our strong portfolio and pipeline, as well as in business development, are helping us deliver outstanding near-term performance while also positioning us to continue to deliver important innovations and long-term value to patients and shareholders.

Now turning to our third quarter results. Total company revenues were $13.2 billion, an increase of 20% or 19%, excluding the positive impacts of foreign exchange. The remainder of my comments will be on an ex exchange basis. As Frank highlighted, our Human Health business achieved improving momentum, growing 17%. Our Animal Health business also delivered robust growth with sales increasing 14%, driven by strong global demand across both companion animal and livestock. Companion Animal sales increased 18%, driven by global demand in parasiticide, including the BRAVECTO line of products, as well as Companion Animal vaccines. Livestock sales increased 12%, reflecting strong global demand for ruminant and poultry products, including our Animal Health Intelligence products.

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 76.8%, an increase of 0.3 percentage points, reflecting the favorable effect of product mix, partially offset by higher manufacturing costs. Operating expenses increased 11% to $4.7 billion. This was driven by investments in our key growth pillars, particularly in supportive return to care activities and in our early and late-stage pipeline, including molnupiravir. Other expense increased by approximately $200 million, reflecting higher pension settlement costs. The effective tax rate was 13%, a decrease of 1.4 percentage points driven by discreet items. Taken together, we earned $1.75 per share, an increase of 26%.

Turning now to our 2021 non-GAAP guidance. While the pandemic continues to impact many regions around the world, health systems and patients have largely adapted, and we assume this trend will continue. Our guidance assumes the Acceleron transaction will close during the fourth quarter, subject to the successful completion of the tender offer and regulatory approvals and does not include potential sales or earnings from molnupiravir.

The underlying strength of our business enables us to narrow and raise our expected revenue range to $47.4 to $47.9 billion, representing growth of 14% to 15%, including a positive impact from foreign exchange of approximately 1.5% using mid-October rates.

Our gross margin is expected to be approximately 76.5%. We continue to expect operating expenses to grow at a high single-digit rate. In other income and expense, we expect expense of approximately $450 million. We expect our full year tax rate to be between 14% and 14.5%. We assumed 2.54 billion shares outstanding. Taken together, we are raising and narrowing our EPS range to $5.65 to $5.70 reflecting significant growth of 25% to 26%. This range includes a positive impact from foreign exchange of approximately 2% using mid-October rates.

As you consider your models, there are a few areas to focus on. Starting with molnupiravir revenue. We expect the global opportunity to be approximately $5 billion to $7 billion through 2022, including $0.5 billion to $1 billion expected to be realized this year. This assumes emergency use authorization in December. As a reminder, we will share any profit equally with our partner, Ridgeback. Merck is responsible for recording global revenues and costs and will reflect the profit share within cost of sales.

For GARDASIL, we have had excellent momentum driven by strong demand and benefit from the step function increase in supply we are achieving this year. Fourth quarter sales will be lower than the third quarter due to normal seasonality and timing effects; however, we expect the growth in the quarter to remain very robust.

Animal Health has had exceptional growth in the first 3 quarters of the year, driven in part by the pandemic effect on pet adoption and pet spending. In the fourth quarter, we will anniversary that effect, and we expect a more normalized year-over-year growth rate as a result.

Our operating margin in the third quarter benefited from very strong revenue performance, including the normal seasonality of our vaccine business. As we move through the fourth quarter, we expect operating margins to normalize due to this seasonality and phasing of spend.

More broadly, as we look out to 2024, we remain confident in our revenue potential and continue to believe it is underappreciated. And we remain on track to achieve our 2024 operating margin target of greater than 42%.

Our capital allocation priorities remain unchanged. We will continue to invest in the business to drive the many significant near- and long-term growth opportunities we see in our derisk portfolio and rich pipeline. We also continue to execute on our business development strategy, including our announced acquisition of Acceleron. We will pursue additional value-enhancing and strategic business development opportunities, and we retain significant balance sheet capacity to do so.

We remain committed to the dividend with the goal of increasing it over time. To the extent we have excess cash, we will return it to shareholders through share repurchases.

To conclude, Merck continues to make exceptional progress on its commitment to drive growth and value for patients and shareholders. We remain in a position of financial and operational strength, which will enable us to deliver on that promise now and well into the future.

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

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

Thank you, Caroline. Good morning, everyone. It is a pleasure to be here to provide a summary of progress made since our last quarter call. I will provide an update on our oral antiviral candidate, molnupiravir, highlight the proposed Acceleron acquisition, spotlight some recent progress with islatravir and finish with the synopsis of notable regulatory milestones and clinical updates from across the pipeline.

The need for additional treatment options remains key in combating the COVID-19 pandemic. Interim analysis from MOVe-OUT, our Phase III study evaluating molnupiravir in at-risk, nonhospitalized patients with mild-to-moderate COVID-19 showed an approximately 50% reduction in the risk of hospitalization or death compared to placebo.

Of note, through day 29, no deaths were reported in patients who received molnupiravir compared to 8 deaths on placebo. This is the first oral antiviral for a respiratory virus to demonstrate benefits based on robust clinical outcomes and the first to show a meaningful 5-day window for therapeutic intervention after symptoms onset.

Based on these positive results and at the recommendation of the Independent Data Monitoring Committee and in consultation with the FDA, recruitment into the study was stopped early. In light of these findings and given the urgency to address the pandemic, our teams worked tirelessly to submit a robust package to the FDA for EUA within 10 days of receiving data. We look forward to discussing the EUA submission at an upcoming meeting of the Antimicrobial Drugs Advisory Committee scheduled for November 30. And in the interim, we continue to engage with the FDA to support its review.

Applications have also been submitted to multiple regulatory agencies around the world. I do wish to take a moment to thank the investigators, patients and their families for their participation in the MOVe-OUT study. I am also grateful to our collaborators at Emory University, Ridgeback and Merck's internal teams for the incredible work done in conducting this program during a very challenging time.

A comprehensive vaccination strategy remains the best sustainable means to confront this COVID-19 pandemic. Timely intervention following symptoms onset with an oral agent that can be self-administered at home may provide an additional meaningful option for patients, health care systems and public health, which could make a significant and positive impact on the pandemic.

Based on a valuable viral sequence data, molnupiravir showed consistent efficacy against the gamma, delta and new COVID-19 variant. As a reminder, we continue to actively recruit participants in the MOVe-AHEAD trial, which is evaluating the safety and efficacy of molnupiravir and preventing the spread of COVID-19 within households as a post-exposure prophylactic with a planned readout in the spring of 2022.

Now turning to the proposed Acceleron acquisition. Acceleron has an excellent scientific pedigree, which has yielded important treatment for anemia in adult patients with certain rare blood disorders. Their lead clinical candidate, sotatercept, has the potential to be a foundational asset as an add-on therapy for the treatment of pulmonary arterial hypertension and provide a complementary addition to our growing cardiovascular pipeline. As such, following the close of the deal, our strategy would be to advance the wide-ranging Phase III clinical program.

Now on to the portfolio and pipeline, starting with HIV. We continue to generate clinical data that reinforces the foundational potential islatravir and HIV. At the European AIDS Conference in London this week, we presented data from the Phase II study evaluating doravirine and islatravir in previously untreated adults with HIV infections, which demonstrated continued maintenance of viral suppression through 144 weeks. We also recently reported positive top line results from 2 pivotal trials evaluating a once-daily oral regimen of doravirine and islatravir in a SWITCH setting in adults with HIV infection, who are virologically suppressed on other HIV therapy regimen.

At 48 weeks, both trials met their primary efficacy endpoint for percentage of participants with levels of HIV RNA greater than or equal to 50 copies per milliliter, demonstrating comparable efficacy with those receiving the comparator antiretroviral therapy. We plan to present these findings at upcoming medical congress and incorporate the data into global regulatory submission.

This week, we also announced the start of a Phase II clinical study evaluating a once-weekly oral combination of islatravir and lenacapavir in people living with HIV, who are virologically suppressed on an antiretroviral therapy. We have made great progress in our collaboration with Gilead and look forward to reporting our future developments, including our long-acting injectable co-formulation.

Next, on to VAXNEUVANCE. We received a positive opinion for VAXNEUVANCE from the European Medicines Agency's Committee for Medicinal Products for Human Use in individuals 18 years of age and older. And more recently, in the U.S., the CDC's ACIP unanimously to provisionally recommend VAXNEUVANCE followed by PNEUMOVAX as an option for pneumococcal vaccination in adults 65 years and older as well as for adults aged 19 to 64 with certain underlying medical conditions with both patient populations being studied in our clinical trials.

Vaccine performance is multidimensional and includes eliciting a strong immune response as well as providing coverage for important disease serotype. Our 2-dose regimen accomplishes the best of both by eliciting a robust immune response across the 15 serotypes in VAXNEUVANCE, including serotype-3, as well as providing the broadest serotype coverage among current pneumococcal vaccine options, of which 4 that are unique to PNEUMOVAX.

Furthermore, VAXNEUVANCE has the most extensive clinical development program of the newly-licensed TCV. This includes completed or ongoing evaluations among those with certain chronic or an immune-compromised conditions that increase the susceptibility to and severity of pneumococcal disease.

We also announced positive top line results for VAXNEUVANCE from the pivotal PNEU-PED study, evaluating immunogenicity, safety and tolerability in the pediatric setting and have submitted an application to the FDA. Evidence indicates the incorporation of serotypes 22F and 33F as well as strong immunogenicity against serotype 3 has the potential to play an important role in the prevention of pneumococcal disease in infants and children. These 3 serotypes represent more than 1/4 of all cases of invasive disease in children under the age of 5. We will present full results at an upcoming scientific congress.

And finally, to oncology. The rich flow of data from our clinical development programs across tumor types continue. We maintain momentum in the development of new treatment options for women's cancer with the approval of KEYTRUDA plus chemotherapy with or without bevacizumab for recurrent or metastatic cervical cancer based on data from KEYNOTE-826. This study showed a meaningful 36% reduction in the risk of death. This is the first anti-PD-1 combination treatment option for patients in the first-line setting and together with our industry-leading human papillomavirus vaccine, GARDASIL and GARDASIL 9, we are uniquely positioned to address certain unmet needs in cervical cancer with a focus on both prevention and treatment.

At ESMO in September, we presented final results from KEYNOTE-355, our study of KEYTRUDA, in combination with chemotherapy for advanced triple-negative breast cancer, which showed a reduction in the risk of death by 27%. KEYTRUDA is the only immuno-oncology agent approved in metastatic triple-negative breast cancer. This, along with additional data presented across endometrial and ovarian cancers, reinforces the remarkable progress being made in our broad women's cancer portfolio.

We are also making inroads in new cancer types, including prostate cancer. With our partners at AstraZeneca, we announced positive results from the Phase III PROpel study for the frontline treatment of metastatic castration-resistant prostate cancer. This study demonstrated that Lynparza, in combination with abiraterone, significantly delayed disease progression regardless of biomarker status. Lynparza is the first PARP inhibitor to demonstrate clinical benefit in radiographic progression-free survival in combination with a new hormonal agent in this setting.

We are encouraged by this study and the potential to help the increasing number of men diagnosed with metastatic castration-resistant prostate cancer. Results will be presented at an upcoming medical meeting and submitted to regulatory authorities globally.

Next, to renal cell carcinoma, which represents an important area of expansion. In August, we received FDA approval for WELIREG, a first-in-class HIF-2 alpha inhibitor therapy for the treatment of adult patients with Von Hippel-Lindau disease, who require therapy for associated renal cell carcinoma, central nervous system, hemangioblastomas or pancreatic neuroendocrine tumors, not requiring immediate surgery.

This approval provides us a (inaudible) as we evaluate WELIREG potential and broader RCC indications and beyond. Also in RCC, in partnership with Eisai, following FDA priority review, we received approval for the combination of KEYTRUDA and Lenvima in the frontline setting based on results from the KEYNOTE-581 trial. This brings forth an important new first-line treatment option for patients with advanced RCC. We are also rapidly expanding programs into earlier lines of therapy.

During the quarter, the FDA granted priority review for our application for KEYTRUDA as an adjuvant therapy for patients with RCC at intermediate high or high risk of recurring following nephrectomy, or following nephrectomy and resection of metastatic lesions from the KEYNOTE-564 study.

Additionally, we received priority review for KEYTRUDA for the treatment of patients with surgically resected high-risk Stage 2 melanoma based on results from the KEYNOTE-716 study that showed an improvement in recurrence-free survival compared to placebo. Both of these studies demonstrates the benefit of expanding the use of KEYTRUDA to earlier stages of disease, allowing us to extend treatment benefits to more patients sooner. We look forward to a decision on both studies by the end of the year.

To conclude, I am proud of the progress across our broad pipeline and look forward to providing further updates on our scientific progress in the future. Now I turn the call back to Peter.

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

Thank you, Dean. Grace, can you please start the Q&A portion of the call? And I'd like to ask the questioners to limit themselves to 1 question today in order to get to as many different questions as possible.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Your first question comes from the line of Umer Raffat of Evercore ISI.

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

(inaudible) in the rest of the call. So I'll just ask on KEYTRUDA and adjuvant lung instead. Have you had an interim? And does the staff plan allow for hierarchy where PD-L1 positives is first? And do you expect the benefit to show in patients that did and did not get adjuvant chemo?

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

Yes. Thank you very much. I appreciate the question. First, I just want to elevate for just a second. We are excited by the emerging data of the role of PD-1s and PD-L1s in the early treatment and adjuvant space. For us, we are gratified that in renal, melanoma, breast cancer is (inaudible), there appears to be great effect. And these are cancers where there are frequently employed methods for early screening.

In relationship to lung specifically, we enjoy a dominant position in lung cancer. And in lung cancer, the treatment of latter stage cancer is the predominant stage. The data, as you somewhat alluded to from other companies, indicate that in lung cancer, the PD-1, PD-L1 class could be effective in early and adjuvant.

In specific in relationship to -- we have a number of early and adjuvant stage lung cancers, and it was enumerated in the slide. KEYNOTE-091 is also known as the PEARLS trial. KEYNOTE-091 PEARLS is a collaborative study with the European Organization for Research and Treatment of Cancer. And Merck is a collaborator on this trial. This is an event-driven study, and we are in active communication with EORTC, and together, we are awaiting data from the [IA2] before the end of the year, and I would hazard to guess that any public announcement from Merck would be announced at the beginning of the new year.

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

Great. Thank you, Umer. Next question, please.

Operator

Next up, we have Daina Graybosch from SVB Leerink.

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

I ask maybe a 2-part question on molnupiravir and how you're moving forward. The first is there's been some concerns publicly about the genotoxicity. And I wonder if you could address the data you have that makes you not concerned about that. And then the second concern is maybe with

resistance, and I wonder how you're thinking about the future and combinations and whether that will be needed to prevent any resistance maybe from low compliance to molnupiravir.

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

Yes. Thank you for that question. This is Dean. I would just emphasize, we are very confident in the safety profile of molnupiravir based on our preclinical and clinical data. In relationship to the clinical data, I think most people recognize that in the interim analysis, we had a profound reduction in hospitalization or death compared to placebo, and it was stopped early in -- by the guidance of the DSMB and in consultation with the FDA.

And in that interim analysis, the incidence of any adverse effect was comparable in both molnupiravir and placebo. And actually, if you look, there are a few subjects in the molnupiravir group who discontinued therapy due to an adverse event compared to the placebo group.

In relationship to our confidence in the safety profile based on our extensive preclinical evaluation, I think it's important to recognize that molnupiravir is a nucleoside analog that functions by creating errors in the genetic material of RNA viruses. These nucleoside analogs are often used in many other antiviral treatments, including HIV and hepatitis. And we have done a comprehensive nonclinical program to characterize the safety profile of molnupiravir.

It's been written by other people. There's actually been written in the sort of scientific journals as well, and we will be presenting all of this data, I believe, in the AdCom that the FDA will be holding. But probably the most important pieces of information is the -- in 2 distinct in vivo rodent mutagenicity assay, commonly called the Big Blue and the Big A, which are well characterized and considered to provide a robust measure of the ability of a drug or chemical to induce mutations in vivo.

In these studies, we're administering molnupiravir for longer and higher doses than those employed in the human clinical trial. And the totality of the data from these studies indicate that molnupiravir is not mutagenic or genotoxic in these in vivo mammalian systems. Now we have shared these results throughout with the regulatory agencies worldwide, and we'll continue to provide additional data as this process continues.

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

Great. Thank you, Dean.

Operator

Next up, we have Andrew Baum from Citi.

Andrew Simon Baum - *Citigroup Inc., Research Division - Global Head of Healthcare Research and MD*

Questions for Frank on molnupiravir. Just in relation to supply, it strikes me, given some of the published improvements in manufacturing and the 4-gram per patient dose, the 20 million looks like a very conservative estimate, given particularly the inclusion of third parties, what could be achieved given the dosing and the API. I'd like you to comment, please, on where you think the 2022 real supply could be? And then second, perhaps you could just comment on the appetite of Merck to use direct-to-consumer advertising or other promotion on molnupiravir. I understand that promotion and advertising is allowed under an EUA, if you could confirm or deny that would be great.

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

Yes, Andrew, this is Frank. So a couple of things that I want to highlight is, first, we have -- in line of sight, we will produce 10 million courses this year, Andrew, in 2021. And as we have mentioned, that we have line of sight and we will, at a minimum, double that in 2022. So to your question,

we're going to do everything we can to increase the supply for this product. In addition, we have voluntary license partners you have seen, and we also have a number of partners that we're working with to provide global supply. So rest assured, Andrew, we're going to try to do everything on the supply front.

On direct-to-consumer, I think it's a little bit early for us on that. We have not made a decision around that. We are really focused on doing everything we can to sign up agreements with governments, get the product available globally, and we'll be providing additional information as we go forward on molnupiravir, but this is our #1 priority for the company, and it's something that we're really looking forward to trying to help address the pandemic going forward.

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

Andrew, this is Rob. And I just want to make sure because as I listen to your question, I think Frank hit it, but just to emphasize in case others on the phone aren't catching this. The $20 million or saying more than doubling what we can do next year, that is Merck's production. We are not including in any of those numbers the 8 voluntary license partners in India, nor anyone who the Medicines Patent Pool signs up. So obviously, global production in molnupiravir will be significantly more next year. We're just speaking to what volumes we will produce within Merck.

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

Let me just add one thing because I recognize that this question is also somewhat linked to the other question that, and it relates to how we think about molnupiravir scientifically in the pandemic phase. And there's going to be an endemic phase, and potentially, there could be other phases after that.

But for the pandemic phase, I just want to emphasize, we have the MOVe-OUT trial, and then we'll have to see the potential in the MOVe-AHEAD to see whether we both have a treatment and prophylaxis.

In the endemic phase, when the pandemic somewhat recedes, it's highly likely that SARS-CoV-2 will become an endemic infection. And we all have to recognize and it's related to the previous question, during this phase, there will be a large reservoir of individuals across the globe with high copy number of viruses in many of these individuals that may lead to a constant brewing of variance.

So this question of resistance becomes very important. It is important to emphasize that molnupiravir has an extremely high barrier to resistance. It has broad efficacy across all SARS-CoV-2 variants to date. And in our preclinical studies and preclinical studies of others, it not only has a broad efficacy across SARS-CoV-2 variants, but a broad variety of RNA viruses and probably the broadest than all other current mechanisms that we know being developed.

I should emphasize this high barrier to resistance is critically important, both in the pandemic and the endemic phase as has been highlighted, and I need to emphasize for this reason, we prioritize molnupiravir over our other programs, including an internal protease inhibitor given the paramount importance we place on ensuring the highest barrier to resistance given where we are in the world right now.

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

Great. Thank you, Andrew. Next question, please, Grace.

Operator

Next, we have Carter Gould from Barclays.

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

Unsurprisingly, I'm going to focus on (inaudible). I guess maybe for Frank and Caroline, I'm just trying to understand exactly kind of what's baked into that guidance in terms of what's being distributed for next year between kind of your supply, crossing that with the -- to your point, the supplying sort of low- and middle-income countries with -- through the MPP. I acknowledge that there's going to be tiered pricing, but it seems like you're still becoming far short of distributing your full capacity. So any color on that front would be helpful.

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

Yes, Carter, this is Frank. I'll start and see if Caroline wants to add anything. So in our assumptions, and I appreciate this is a very fluid situation. We do assume an Early Use Authorization in December this year. And we are including the contracts that we already have in place as well as those that are underway. So we are comfortable with that $5 billion to $7 billion range through '22. And just to reemphasize, the numbers based on the agreements signed, those in line of sight and others that have high probability of execution.

A couple of other things, as we've mentioned and Rob reiterated, we will produce 10 million courses of therapy by the end of '21 and have committed to at least doubling that in '22. Our focus initially are as important that it's on the treatment with COVID-19. And you mentioned the broad global access, which does come with global tiered pricing around the world, and that's an important aspect that the pricing will be tiered based on affordability measures. If our post-exposure prophylactic trial is successful, as Dean was highlighting, with an expected readout in spring, there is potential upside to these estimates.

Furthermore, throughout 2022, we do not assume, to your question, all of the supply is used. As such, we have the ability to fulfill additional demand. We also do assume that there will be other oral antivirals in the market, and we'll have to see how that unfolds. We look forward to providing you some additional detail and clarity as we learn more over the next couple of months.

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

Thank you, Carter. Next question please, Grace.

Operator

Next, we have Steve Scala from Cowen.

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

Merck views its competitive position in pneumococcal vaccines as strong, but ACIP did not appear to agree viewing the cost benefit of the 20-valent as superior, even when assuming it was ineffective against serotype 3. So where does Merck think ACIP errored? And how does Merck change that narrative?

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

First, we're very confident of our V114 VAXNEUVANCE. There's 2 places that we're advancing it. It's in adult and pediatrics. As you know, the pediatric market, and I'll let Frank speak to it, is a quite robust market, and we're advancing our program. We have submitted to the FDA, and we hope to hear back from them in short order. So we're very focused in the pediatrics.

In relationship to the adults, the critical issue for us in relationship to (inaudible) is that we, as I said in the prepared comments, I think it's very important to give the best coverage in terms of serotypes, but not just by immunogenicity, by actually studying clinical events, especially in those

patients who are compromised or at risk or have some other condition that might increase their susceptibility to have invasive pneumococcal disease.

And we think that clinical data and the way that we've studied it in these patient populations directly. We have not extrapolated from immunogenicity. We've actually studied it. it is something that's critically important as one looks at the true efficacy of a vaccine. Frank, did you want to answer?

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

Yes. The only thing I want to add is actually, we were very pleased that it was unanimous approval for the sequence of VAXNEUVANCE and PNEUMOVAX. And we feel as though that the sequence offers patients really with the broadest coverage, with strong immune responses against serotypes that are responsible for 2/3 of pneumococcal disease in adults as well as the ACIP did highlight that the regimen was both cost effective as well as cost saving in the 65-plus patient population. And then as Dean mentioned, we're also really excited about the opportunity for VAXNEUVANCE in the pediatric segment, which we believe is the larger market opportunity.

So overall, from our perspective, we feel really good about the ACIP's recommendation.

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

Thank you, Steve. Next question, please, Grace.

Operator

Next, we have Geoff Meacham from Bank of America.

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

You touched on it a little bit. You touched on a little bit with molnupiravir in the first call. But how do you expect to plan (inaudible) versus the booster strategy for the vaccine? Would you expect any more formal guidelines from CDC or other health authorities about how might molnupiravir fits into the algorithm?

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

I'll maybe try this. Geoff, I apologize, you were kind of garbled. I'll repeat what I think your question was, and then you can clarify if I got it wrong. I think your question was, this is the first oral antiviral. But obviously, we continue to have out there vaccines that are important as really the first line, and do we think there's any discussion on how this will fit into the regimen. I don't think we can really comment on how Advisory Committees, the FDA or others, the CDC would look at that. But what I will tell you from our perspective, first and foremost, people should be vaccinated that it continues to believe what we think is the right answer.

We see our therapy as something that is an important addition to the armamentarium. And obviously, there are places where people cannot get the vaccine or unfortunately, if people get vaccinated and have breakthrough virus. So there's definitely a need for this, but it is in collaboration as a complement to the vaccine not in place of it. That's our perspective. We'll let the government speak to their own.

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

Thank you, Geoff. Next question, please, Grace.

Operator

We have Chris Schott from JPMorgan.

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

I'm just trying to get my hands around GARDASIL and the results in the quarter. So can you just clarify or quantify a little bit how much of the $2 billion in sales this quarter was stocking versus underlying demand? And maybe more broadly, are we still in a position where demand is exceeding supply, I guess, on a global basis, as we think about the recent capacity expansion? And I guess I'm trying to get my hands around like will there be another step up in sales for this franchise as we look out to 2023 and beyond with the new facility coming online? Or is the capacity efforts you've made so far kind of addressing most of the demand that's out there.

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

So Chris, this is Caroline. I'll start, and I'll hand over to Frank. So in the quarter, as you know, we've had an exceptional quarter, and that's driven by strong global demand and the step-up we have in supply. We also did benefit from CDC timing, and that was approximately $125 million of buy-in in the third quarter of this year. And that contrasts to buy-out actually in the third quarter of 2020. So year-over-year, we feel we've benefited by approximately $180 million to the results.

Now in terms of how we see this going forward, we're very excited about the opportunity. We see opportunities for increased supply through '22 and beyond as we see the other capacity come online. But let me hand over to Frank to talk about the demand that we have.

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

Yes, Chris, thanks for the question. A couple of other things I do want to highlight as you think about GARDASIL, and this is something we've been discussing for a while, is both the near-term results, as you mentioned, with the long-term prospects. First off, I want to highlight that only 9% of the -- what we see is the eligible cohort globally has been vaccinated. So Chris, I start there and say this, we still have significant opportunity.

And if you think about markets, such as China, if you think about the approval in Japan, if you think about the gender-neutral opportunities that we have in Europe as well as other age cohorts in adult, mid adult in the U.S. because we feel that there is significant opportunity for continued GARDASIL growth. As you saw a step up in our supply, we will continue to see that. It will be a little bit more modest pace in next year. But rest assured, as we bring on the 2 new bulk manufacturing facilities in '23, this is why we feel that the long-term growth prospects for GARDASIL are very significant and it will be a key growth driver for the company going forward.

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

Thank you, Chris. Next question, please, Grace.

Operator

Next up, we have Tim Anderson from Wolfe Research.

Timothy Minton Anderson - *Wolfe Research, LLC - MD of Equity Research*

A question on additional M&A. So maybe for Rob. On the Acceleron investor call you held, I asked whether Merck would do more M&A, even if it meant taking a rating debt downgrade. And you were very frank in your answer, and you said yes. But the company has not been willing to kind

of quantify what debt -- additional debt that would potentially be that would trigger a downgrade. My understanding is that another $10 billion cash deal would be enough to trigger a 1-notch downgrade. And if it was something like a $30 billion cash deal, that could be a 2-notch downgrade. So my new question here is, would Merck actually do the deal big enough to cause a 2-notch rating downgrade?

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

I appreciate the question. I would start more high level. Do we continue to pursue additional business development? The answer is yes. It will be driven, as it's always been based on what we see as a compelling scientific opportunity, where we see science addressing an unmet need that is strategically aligned with us and where we can bring value. So that is unchanged.

And as we look at capacity, I would just say, we believe we have the firepower to do and frankly, any deal that's out there that we would have a strategic interest in doing. The balance sheet will not be a rate limiter for us. We have very strong balance sheet capacity. I don't think we want to get into trying to get specifics. Some of your numbers, frankly, were quite a bit off, actually, but I don't want to start getting into those kind of specifics because it depends on rating agencies. It depends on the target cash flows coming from the target. So with that, I think the important message is balance sheet capacity is not going to be limited for us.

Operator

Next up, we have Seamus Fernandez from Guggenheim.

Seamus Christopher Fernandez - *Guggenheim Securities, LLC, Research Division - Senior Analyst of Global Pharmaceuticals*

So just a quick one on the earlier stage pipeline. I'm a little surprised you guys are presenting your first oral PCSK9 inhibitor in a late-breaker at AHA in 2 weeks, but it isn't included in your pipeline summary. Could you just help us understand why not? And just as a follow-up to that, when might we hear more about the earlier-stage pipeline? Will this be at an R&D Day in 2022? What's the right time to start, I guess, showing a little bit more of the earlier-stage pipeline that Merck has been building over the last 3 to 4 years via acquisition and then internally?

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

Yes. This is Rob. Maybe I'll let Dean just comment specifically on the oral PCSK9, then I can give a comment on the additional transparency question you're answering.

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

Yes, specifically in relationship with the oral PCSK9, it is going to the American Heart Association. It is flipping into a Phase II. And that's why we often in our pipeline leave it at Phase II, but we're trying to demonstrate increased transparency by showing something that's about to enter that. The presentation at the American Heart Association, I think, will be well attended. I think trying to create an oral PCSK9 has been a holy grail in the cardiovascular field for some time and has not been achieved and we believe we have achieved it. It is about that product, but it's also about the ability of Merck to do things that other people can't do. And when one looks at how we've created that molecule, one can immediately ask yourself, wow, what is that capacity? What's that technology that allows them to do that for PCSK9? What other targets could they be doing as well. Bob?

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

Yes. So thank you. And as Dean highlighted, we tend -- our view is that as things move from Phase I into Phase II, that's when we'll start discussing it. So this is just in that process. And I would highlight indeed to get into it, but there's a lot of -- we have other assets in the cardiovascular space

that are also either have moved or moving into Phase II. That's why we really see our cardiovascular pipeline as a growing area of excitement and strength, and why we were so excited about the complementary nature that Acceleron is to that pipeline.

And as you ask about the transparency, our intention, the next area we'd like to highlight is cardiovascular because I can tell you, I'm excited about what we have. We've got a lot going on that I don't think is appreciated. Obviously, we would like to wait to see the Acceleron deal completed so we can include their assets in that discussion, and that will come as soon as we can figure out when that will happen, either later this year or early next year.

Beyond that, I was very pleased with what we did when we gave -- added visibility to our HIV pipeline. The excitement we have around islatravir, that's a foundational drive. Oncology continues to have just multiple shots on goal both with KEYTRUDA and a growing number of new mechanisms. We've highlighted that. And once we get past the cardiovascular, I assume we'll start to talk about our CNS portfolio because we also have a lot in the neurology space, I think is pretty exciting.

So our view is to do it area by area as things start to move into those Phase II realm, and we'll bring it forward as quickly as I can with the cardiovascular being first once Acceleron is done.

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

Thank you, Seamus. It's a little past 9. I think we have time for 1 more question. Next question, please, Grace.

Operator

Your last question comes from the line of Louise Chen from Cantor.

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

So there are several players trying to bring lower-priced checkpoint inhibitors to the market. And do you believe that these discounted pricing strategies will have any traction? Why or why not?

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

This is Frank, and I'll take that from a couple of different angles. I know there's been discussion there. And I first want to make sure that we really continue to emphasize that oncology we see is really data driven. And the importance of strong clinical data, and I think you have seen that position us well, and also the wall of data that we've established with a product like KEYTRUDA with 33 indications right now and just the familiarity and the growth that we're seeing across so many different cancer types that I was highlighting, we feel we're very well positioned. We also think that the regulatory role for new entrants increases with additional KEYTRUDA approvals. And as physicians continuing to gain experience, we think that also you would have to have a broader structural change, would be required in the U.S. to adopt broadly.

So our view is we'll continue to monitor the competitive landscape, as we always do, but we feel very confident in KEYTRUDA and our growth prospects going forward.

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

Great. Thanks, Louise. Rob, any final points?

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

Yes. Maybe just a couple of points. First, I want to thank and recognize our Merck employees across the globe for their hard work and dedication with the pandemic. The way we've been able to execute, really, I think shows the best of who we are, and I couldn't be more proud across all elements of our business, clinically, commercially, manufacturing, it's really phenomenal. So I do want to first recognize them because I think that's important.

And hopefully, what you took from the call is this is an exciting time at Merck. We really have growing momentum and I can tell you, growing confidence that we have the ability to grow not only in the near term, but a growing portfolio of assets that set us up to sustainably be an important contributor to human health and to continue to deliver significant value for our shareholders.

We're a more focused company. We're a faster-growing company. We're working with urgency to achieve our mission and deliver for patients and shareholders. So hopefully, that came through. And I'm also quite pleased with the amount of progress we've made in a short period of time. You've heard today good developments across businesses, but development -- good developments and delivering an incredibly strong quarter, moving fast with what we're doing with molnupiravir, great results coming with islatravir and our broader oncology portfolio. So we're firing on all cylinders, and I'm confident and proud of where we are, and I thank you for your time.

Operator

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