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MRK.N - Q2 2022 Merck & Co Inc Earnings Call

EVENT DATE/TIME: JULY 28, 2022 / 12:00PM GMT

OVERVIEW:

Co. reported 2Q22 total Co. revenue of \$14.6b and non-GAAP EPS of \$1.87. For 2022, expects non-GAAP revenue to be \$57.5-58.5b and non-GAAP EPS to be \$7.25-7.35.

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by. Good morning. My name is Alan, and I will be your conference moderator today. At this time, I would like to welcome everyone to the Merck & Co. Q2 Sales and Earnings Conference Call. (Operator Instructions) As a reminder, this conference is being recorded. Thank you. I would now like to turn the conference over to Peter Dannenbaum, VP Investor Relations. Please go ahead.

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

Welcome to Merck's Second Quarter 2022 Conference Call. Speaking on today's call will be Rob Davis, President and Chief Executive Officer; 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'll 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 2021 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 speaker's prepared remarks. The presentation of 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, and thank you for joining today's call. I'm proud to report that the business continues to perform extremely well. We remain firmly guided by our strategic priorities to drive long-term growth and deliver value to patients and shareholders. We're executing on the opportunities in front of us today, while simultaneously making the necessary investments to sustain our success long into the future. I'm pleased to report that during the second quarter, we achieved robust top and bottom line growth and made additional important clinical advancements in our pipeline.

Turning first to our results. We again achieved exceptional performance this quarter led by strong growth of key products, including KEYTRUDA, GARDASIL and BRIDION. Our results were aided by revenue from LAGEVRIO, which is helping to in fighting against COVID-19. We're confident in the underlying demand for our innovative portfolio as we continue to see momentum in our business, which we are pleased to reflect in our updated guidance.

Moving to research organization. We continue to advance our pipeline most significantly across our suite of pneumococcal conjugate vaccines. VAXNEUVANCE received an expanded approval from the FDA for pediatric use, providing an important option for children in prevention of invasive pneumococcal disease.

We also presented positive results from clinical studies of V116, our pneumococcal conjugate vaccine candidate, designed specifically to address remaining disease burden in adults, and we've initiated pivotal phase III studies. These milestones reinforce the confidence we have in our population specific approach to address the distinct needs of children and adults.

We've also taken additional steps to help you understand the significant opportunities we see in our pipeline. In June, we hosted an investor event at ASCO which highlighted the depth and breadth of our oncology program. At the event, we reiterated our ambition to become the leading oncology company by 2025 and our goal of sustaining this success well into the next decade.

As I reflect on my first year as CEO, I'm very pleased by the significant progress we've made in advancing Merck's position as a global biopharmaceutical leader and the scent of momentum spreading across our business. The unwavering focus and dedication of our employees worldwide is driving strong execution on the significant opportunities in front of us. We're demonstrating impressive resilience across all aspects of our business in a very challenging global environment.

We're achieving record levels of production in our manufacturing operations, delivering exceptionally strong revenue growth, making meaningful advances in our pipeline and taking important steps to be more transparent about our outlook.

Our strategy is working and our future is bright. I was very confident a year ago, and I'm even more confident today that we are well positioned to achieve our near and long-term goals, anchored by our commitments to deliver important medicines and vaccines to patients and value to all of our stakeholders, including shareholders.

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

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

Thank you, Rob. Good morning. As Rob highlighted, we are maintaining this year's strong momentum with another quarter of exceptional performance in both revenue and earnings. These results further demonstrate that our focus on science and innovation as the core of our strategy is working. Our success is being enabled by the excellent execution of our dedicated colleagues across the globe and continue to deliver value for patients, customers and shareholders.

Total company revenues were \$14.6 billion, an increase of 28%. LAGEVRIO contributing \$1.2 billion in revenue. Excluding LAGEVRIO, the business delivered very strong growth of 18%.

The remainder of my comments will be on an ex-change basis. Our Human Health business continued its strong momentum with growth of 33% or 21%, excluding LAGEVRIO driven by our key pillars. Our Animal Health business also delivered stellar performance, with sales increasing 5%, driven by growth across both our livestock and companion animal products.

Now turning to the second performance of our key brands. In oncology, KEYTRUDA grew 30% to \$5.3 billion, driven by the vast global demand as well as continued expansion into new indications and to reflect the profound impact it is having on patients across the globe. In the U.S., KEYTRUDA continues to demonstrate momentum in metastatic indication and is experiencing strong growth from recent launches in early-stage cancers, including triple-negative breast, renal cell carcinoma and melanoma. KEYTRUDA is now approved with 6 indications in earlier stage cancers.

We've seen strong utilization and are confident in its continued success as physician and patient experience growth. We have seen a particularly strong uptake in neoadjuvant, adjuvant, high risk early-stage triple-negative breast cancer based on KEYNOTE-522, offering a systemic treatment option to patients in an area of significant unmet need.

In the metastatic setting, KEYTRUDA maintained its leadership position in non-small lung cancer, capturing 8 out of 10 eligible new patients. Outside the U.S., KEYTRUDA was driven by continued uptake in non-small cell lung cancer and the ongoing launches in head and neck cancer and renal cell carcinoma. Initial indicators also point to encouraging trends in the earliest stage indications, including triple-negative breast cancer and renal cell carcinoma in key European markets.

Lynparza remains a market-leading part inhibitor. Our alliance revenue grew 17%, driven by uptaking certain patients with high-risk early-stage breast cancer following FDA approval based on the OlympiA study. We look forward to potentially expanding upon Lynparza's leadership by reaching additional prostate cancer patients based on the PROpel study.

Lenvima alliance revenue grew 33% due to strong demand following the launch of KEYNOTE-581 in advanced renal cell carcinoma and KEYNOTE-775 in metastatic endometrial cancer. New patient states across each of these tumors remain strong. Lastly, we continue to be encouraged by the uptake of WELIREG which is tracking in line with expectations.

Our vaccines portfolio again delivered excellent growth, led by GARDASIL, which increased 40% to \$1.7 billion. Outside the U.S., GARDASIL significant growth was driven by strong underlying demand, particularly in China as well as increased supply. In the U.S. sales decreased primarily due to CDC purchasing patterns, although we continue to see some impact from the pandemic on well visits.

We continue to invest behind activation campaigns to ensure that parents recognize the importance of routine physician well visits for their children, particularly during the back-to-school season. We remain confident in the growth trajectory of GARDASIL given the proven ability to help prevent certain HPV-related cancers in both females and males.

In our hospital acute care portfolio, BRIDION sales grew 15%, driven by greater share among neuromuscular blockage reversal agents and an increase in surgical procedures. Our animal health business delivered another solid quarter, with sales increasing 5%, livestock sales grew 6%, driven by higher demand in ruminants and poultry. Companion animal sales increased 3% due to global demand for the BRAVECTO line of product.

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 74.7%, a decrease of 1.8 percentage points. The decrease was due to the impact of LAGEVRIO, higher inventory write-offs due to increased manufacturing costs, partially offset by favorable product mix across the remainder of the portfolio and foreign exchange.

Operating expenses decreased 19% to \$5.2 billion, reflecting charges primarily related to last year's \$1.7 billion acquisition of Pandion which is reflected in our second quarter 2021 R&D expense. Operating expenses excluding these charges increased in line with our plan, driven by investments in our key growth drivers and pipeline. Other expense was approximately \$200 million, reflecting higher-than-expected pension settlement expense. Our tax rate was 13.8%. Taken together, we add \$1.87 per share.

Turning now to our 2022 non-GAAP guidance. The underlying strength of our business enables us to raise and narrow our full year revenue guidance. We now expect revenue to be between \$57.5 billion and \$58.5 billion. Our increased revenue guidance range represents growth of 18% to 20% or 13% to 14%, excluding LAGEVRIO and the impact from foreign exchange.

The projected impact from foreign exchange includes an incremental headwind of more than 1% using mid-July rates resulting in a full year negative impact of approximately 3%. We are maintaining our gross margin expectation of between 74% and 74.5%. We are increasing our operating expense projection to \$20.5 billion to \$21.5 billion, primarily driven by the \$219 million upfront payment from the recently announced collaboration with Orion Corporation.

As an ongoing practice, our guidance does not include significant potential business development transaction. We increased our expectations of other expense to approximately \$500 million, reflecting higher-than-anticipated pension settlement expense. We continue to assume a full year tax rate between 13.5% and 14.5%. We assumed 2.54 billion shares outstanding.

Taken together, we have narrowed our expected EPS range to \$7.25 to \$7.35. The operational strength in our business would have led to an approximately \$0.25 increase in our guidance. This strength is being offset by the upfront payment to Orion, by a pension settlement expense and an incremental headwind from foreign exchange of more than 1% using mid-July rates. Overall, our guidance reflects our confidence that the strong underlying momentum of our business will continue into the second half of the year.

As you consider your models, there are a few things to keep in mind. First, the pandemic was a tailwind to growth in the first half of the year. We expect the benefits to year-over-year growth to lessen over the remainder of the year. Also, we actively managed the impact of foreign exchange through our revenue setting program. To the extent we see further negative impact from foreign exchange, we will see additional benefits from our hedges in other revenues as we did in this quarter.

Other revenue also includes supply sales to Organon and to Johnson & Johnson for its COVID-19 vaccine as well as receipts related to out licensing arrangements. In total, we expect other revenue to be higher in the second half versus the first half of 2022. With respect to our products, for PNEUMOVAX23, we continue to expect a negative impact to U.S. sales, given the shift towards newer adults pneumococcal conjugate vaccines.

On Animal Health, we're seeing normalized industry growth rate as we (inaudible) the favorable trends in spending resulting from the pandemic and experience foreign exchange headwinds. However, given our broad and innovative portfolio, we are well positioned to continue to drive above market growth in 2022 and beyond. Finally, we continue to expect to expect LAGEVRIO's full year sales of \$5 billion to \$5.5 billion, with second half sales weighted to the fourth quarter.

Our capital allocation priorities remain unchanged. We will continue to prioritize investments in our pipeline and business to realize the value of the many near and long-term opportunities in front of us. We continue to pursue compelling external science through with strategic business development to augment our internal pipeline. Our recent collaboration with Orion is another example of our execution of this strategy. We remain committed to our dividend, which we expect to increase through the time. Finally, to the extent we have excess cash, we will return it to shareholders through share repurchases.

To conclude, as we enter the second half of the year, we remain very confident in strength of our business, driven by global demand for our innovative medicines and vaccines. Our excellent execution will enable us to continue to deliver value to patients and shareholders well into the future.

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

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Thank you, Caroline. It's my pleasure to provide an update on our progress since the first quarter call. We continue to execute on our pipeline strategy. We are advancing the latest signs to generate medicines and vaccines that provide clear benefit for patients.

Today, I will highlight recent progress in our vaccine pipeline and provide updates on our oncology program as well as LAGEVRIO. As Rob noted, we have made significant progress across our pneumococcal portfolio. Building upon the approval in the adult indication we received a year ago, last month, we received FDA approval for our 15-valent pneumococcal conjugate vaccine, VAXNEUVANCE, an important new option to help protect pediatric populations against invasive pneumococcal disease.

VAXNEUVANCE is the first pneumococcal conjugate vaccine approved for pediatric populations in almost a decade. VAXNEUVANCE provides comparable immunogenicity for 12 shared serotypes compared to the currently available 13-valent pneumococcal conjugate vaccine, improved immunogenicity for serotype 3 and expanded coverage for serotype 22F and 33F. Serotype 3, 22F and 33F are key invasive disease-causing serotypes known to be responsible for more than a quarter of all invasive pneumococcal disease in children.

Following FDA approval, the CDC's Advisory Committee on Immunization Practices voted unanimously to endorse use of VAXNEUVANCE as an option for children under 19 years of age. Additionally, the ACIP unanimously voted to include VAXNEUVANCE and the vaccines for children program. We await publication of the final CDC recommendation in the morbidity and mortality weekly report.

Also in June, at the International Symposium on Pneumococci and Pneumococcal Diseases in Toronto, we presented positive results from our Phase I/II study evaluating V116, our investigational 21-valent pneumococcal conjugate vaccine in pneumococcal vaccine naive adult. V116 is designed to significantly expand coverage compared to currently licensed pneumococcal vaccines by targeting serotypes that account for 85% of all invasive pneumococcal disease cases in adults aged 65 and older in the United States as of 2019.

As a strong indicator of our progress, we recently enrolled the first patient into the STRIDE-3 trial evaluating V116 in vaccine-naive adult, the first of 4 current Phase III trial. We have taken a thoughtful and tailored approach to establishing a pipeline of pneumococcal vaccine candidate designed to afford the protection by targeting strains posing the greatest risk to specific populations. I look forward to providing additional updates on the progress of our pneumococcal program for VAXNEUVANCE, V116 and V117, our investigational candidate, specifically targeting pediatric disease.

Turning to oncology. We continue to build on the momentum in earlier-stage cancers. We announced that the FDA has accepted our application of KEYTRUDA for the adjuvant treatment for patients with non-small cell lung cancer following surgical resection based on the results of the ongoing KEYNOTE-091 trial. The FDA has set a Prescription Drug User Fee Act date of January 29, 2023. However, further data may be provided during the review process that may delay this date.

At the American Society for Clinical Oncology Meeting in June, we provided expanded analyses and presented data on new endpoints in key subgroups 4, KEYNOTE-716, for the adjuvant treatment in Stage IIb and IC melanoma, KEYNOTE-522 in neoadjuvant, adjuvant high-risk, early-stage triple-negative breast cancer and KEYNOTE-564 in adjuvant RCC.

We are also delivering on our regulatory strategy outside the United States. Notable actions include 4 approvals for KEYTRUDA from the European Commission based on KEYNOTE-716 for the adjuvant treatment of patients 12 years and older with completely resected Stage IIb or 2C melanoma; KEYNOTE-522 in high-risk early-stage triple-negative breast cancer; KEYNOTE-164 and KEYNOTE-158 in MSI high and/or mismatch repair deficient tumors in 5 different cancer types; and KEYNOTE-826 in certain types of persistent recurrent or metastatic cervical cancer.

In addition, we received a positive EU CHMP opinion for adjuvant treatment with LYNPARZA for patients with serotypes of high-risk early-stage breast cancer based on the Phase III OlympiA trial. And finally, we are encouraged by the positive readout of KEYNOTE-869 or EV-103 and first-line urothelial cancer, which is in collaboration with Seagen.

Next, I want to discuss our ongoing efforts to treat prostate cancer. Prostate cancer impacts millions of men and those with advanced disease have low rates of 5-year survival. We continue to generate insight about prostate cancer from our ongoing work, and we remain focused on improving patient outcomes. Business development and licensing remains a key element of our strategy to build and maintain a strong and diverse pipeline.

Earlier this month, we announced a global development and commercial relation agreement with Orion for its investigational oral, steroid synthesis inhibitor, ODM-208, which is currently in Phase II development for the treatment of metastatic castrate-resistant prostate cancer.

ODM-208 targets cytochrome P450 11A1, a novel approach that is complementary to our broad-based prostate cancer program, which includes the combination of KEYTRUDA with chemotherapy based on KEYNOTE-921, KEYTRUDA with antiandrogen therapy based on KEYNOTE-641 and KEYNOTE-991 and LYNPARZA with anti-androgen therapy based on the PROpel trial.

Next, to COVID-19 and LAGEVRIO. The pandemic persist and SARS-CoV-2 continues to evolve. There are solid emerging evidence for the threat of resistance to antibody therapies from Omicron variants, notably B4 and B5. The rate of transmission and increased hospitalizations with these variants reinforces the need for multiple effective antiviral treatment options, especially for those most vulnerable. For high-risk patients, evidence continues to show that prompt therapeutic intervention improved outcome.

Importantly, a large proportion of high-risk individuals, including older adults, are likely receiving additional medications for chronic conditions. LAGEVRIO's low propensity for drug-drug interaction avoids the need to adjust existing dosing regimen and monitor liver and kidney functions during treatment, which can facilitate timely intervention for appropriate patients. Recently, data reported from Denmark, Hong Kong and Poland have provided support for the utility of LAGEVRIO in real-world settings. We plan to share more data as they become available.

To conclude, I am proud of the advancements across our pipeline to date and look forward to providing further updates on our scientific progress in the future.

And now I will turn the call back to Peter.

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

Thank you, Dean. Alan, we're ready for the Q&A session. If you could please assemble the queue.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question will come from Terence Flynn with Morgan Stanley.

Terence C. Flynn - Morgan Stanley, Research Division - Equity Analyst

Maybe a 2-part one here. Just wondering if there's a pathway to extend the IP on KEYTRUDA via either a subcu formulation or maybe some other type of formulation patents? And then is there anything from a technical perspective that would prohibit a co-formulation of KEYTRUDA with an antibody drug conjugate?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

I guess I will take this. This is Dean. In relationship to different routes of administration, I think you've highlighted that, especially as we go into early stages of cancer, there will be a demand, demand by the patients and the providers to really come up with other formulations besides intravenous formulations where you have to go to an infusion center. So subcutaneous pembrolizumab could be very important to serve that need. And the innovation required for subcutaneous KEYTRUDA is viewed through the past history, and I would imagine the current situation is novel, useful and nonobvious. So I think there is a path to think about how to think about that innovation.

In relationship to co-formulations. In general, co-formulations work well with, for example, when we do IO-IO with PD-1, then CTLA-4, TIGIT or LAG-3. The issue with chemo-based or antibody drug conjugate basis, I would be a little bit hesitant to do that. Oftentimes, they're based on weight

base, and so I think that co-formulations of, for example, any IO agent with any chemotherapy or antibody drug conjugates could be challenging to take that clinically.

Operator

That will be from Evan Seigerman with BMO Capital Markets.

Evan David Seigerman - *BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst*

So with the widespread news reports of a potential deal with Senators management and Schumer, can you provide us with your thoughts on kind of the structure for Medicare to directly negotiate with manufacturers for drug reimbursement and the potential impact on R&D going forward?

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

Yes. Evan, thanks for the question. This is Rob. As you said, there is reports out, really it just came out yesterday, of a potential deal with Senator Schumer and mentioned in that is elements of what have been part of the Build Back Better Plan related to drug pricing. So as we look at that, I think it's important to understand, first and foremost, we do have significant concern on one very important element of the provision, which is the fact that there is what we see as price setting, it's termed in negotiation. But in effect, what it is, it is price setting on drugs after a period of time.

And we do believe that will be highly chilling on future innovation because, especially if you think about an area like oncology, oncology is an area that the development of the drug continues long after the first approval. If you take KEYTRUDA, that launched in 2014, between 2014 and 2022, we had something like 30-plus indications approved. We expect to have well more than double that between 2022 and 2028.

And our concern is that if you start to have the threat of discounts, mandatory discounts it could cause companies to question that innovation because you'll have to question whether or not you're going to see the return. So we see a higher chilling effect of that, and it's something that we will continue both at Merck as the industry to make sure that we communicate our concerns there.

And the only other thing I might add is, as you think about how we think about this to our business going forward. It's important to understand that as we look at this, while obviously, it will have an impact, importantly, as we've planned for the future of the business, we have always assumed some form of price pressure coming, including in the United States. I think we've communicated that in the past. So as we look at this, and you think of a relative to the guidance we've given in the past of expectations for strong growth through our long-range period. That continues and includes the assumptions around this. So while I think we will manage it, I do worry about what it will do to innovation in the industry.

Operator

Will come from Andrew Baum with Citi.

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

A couple of questions. Firstly, you've announced a couple of licensing from China of ADCs. I think one of them is in late-stage development. It's obviously widely reported that you're in talks with Seagen, which has Phase III data from another ADC molecule, which would compete with HER2. In general, I'm just interested, Dr. Pastor seems to have closed the doors on seeking approval in the U.S. using data from Chinese trials. But operationally, how fast does it enable you to go, knowing that you have efficacy and safety signals in a Chinese population in expediting the move into Phase III i.e., is there an advantage here that could enable you to catch up with the market leaders in those respective categories?

And then second question on islatravir, perhaps you care to update us how are your discussions with Gilead in terms of -- and the FDA in terms of resuming trials. Is this drug alive as a prophylactic, in PrEP as a treatment, both or neither?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

So this is Dean. Thank you very much for those questions. To tackle your first question related to our recently announced partnership with Kelun. I should just emphasize this was recently announced, but we've had a productive, a really productive partnership for the past 2 years. And most recently, they have announced progress in 2 programs. One that they've declared, which relates to TROP2-ADCs, and they're advancing it in China in relationship with breast cancer and non-small cell lung cancer.

In relationship to what you've said in -- of moving those molecules, for example, in the United States, I think the FDA and we support this. The FDA has been very clear of the importance of doing those trials, not in a single geography such as China, but to have global studies that include the United States. And so the ability for our partners to give us a signal in a human population is really important and allows us to navigate how to think about it at a global level. And so we are hopeful that this partnership will allow us to accelerate the benefits of this TROP2-ADC to as many patients as possible.

To your second question in relationship to islatravir. As you've noticed, islatravir is our NRTTI. It's extremely potent that has a resident time in tissue and has a high barrier to resistance. And we had 2 Phase III studies that have excellent results. Nevertheless, we also had reduction in lymphocytes across a number of our programs, most of it asymptomatic, but in a combo trial with MK-8507, there was clinically meaningful reduction that's still dependent. We have spent the last 6 months understanding that. We understand it far better. We believe that there is a potential path forward to maintain and to have that efficacy and also reduce the effects on the live blood cells. We are in active discussions with the FDA. So I don't want to get ahead of myself there, and we clearly have active discussions with our partners.

In relationship to the question of treatment and PrEP, I just want to make sure that everyone recognizes we have always thought that this class of molecules NRTTI and islatravir is just one compound within this class, could be broadly used in treatment and in PrEP, and we are interested in applying both of those -- advancing both of those possibilities, but we are in the midst of discussions with the FDA that I think we should provide them the data that they will need.

Operator

That will be Louise Chen with Cantor.

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

So I wanted to ask you about the checkpoint inhibitor strategy. What are your thoughts on the changing treatment paradigm for checkpoint inhibitors in the neoadjuvant and adjuvant cancer setting. How do you think about adoption and uptake in this setting? And do you think doctors are convinced of the opportunity yet? Or is there more work to be done?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Well, let me answer it from a scientific standpoint. Maybe we'll have Caroline or Rob answer it from a market standpoint. I do think it's really important to just highlight, at least for me, PD-1s have been incredible in metastatic through a broad range of tumor types. And we keep going in for earlier stages. And it's not top priority that a medicine that works in the metastatic patient who has a very different benefit/risk ratio will be truly effective in the early stage. And it's been impressive. We have 6 approvals, whether it be in breast, in renal cell carcinoma and melanoma. And we have a positive trial in relationship to lung, and we have many others advancing.

So I think that part of it is -- I think the uptake has been good, but the most important thing is that scientifically, the data has been very good. And I think the field will adopt it. I think one of the things that will be critical as the field adopts it is that oftentimes, you're now talking not necessarily about a medical oncologist. So there will be work for us to do, but I think the results speak for themselves. And I would recommend that people look at that data, and I think that it's an important advancement in the field. But in terms of the uptake, Caroline, do you want to take care of that?

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

Yes. Thank you, Dean. So Louise, we are really excited about the opportunities that we have moving into earlier stages of cancer. Clearly, if we can impact patients then, the possibilities of better outcomes are greater. We have seen in our early-stage cancers, impressive performance. We're seeing very strong performance in triple-negative breast cancer, renal cell carcinoma and melanoma. And if I just touch on triple-negative breast cancer, we had the KEYNOTE-522 approval here in the United States July of last year.

During the second part of last year, we saw tremendous uptake in the first segment of treatment, the neoadjuvant treatment ahead of people then getting their surgery some 24 weeks later. What we're now seeing is not only patients coming on to KEYTRUDA for neoadjuvant triple-negative breast cancer, we're also seeing them return to treatment following their surgery. So we're very optimistic about the opportunities we have in the adjuvant setting and the impact that we can have on patients.

Operator

We will go to Umer Raffat with Evercore.

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

I have 2 here, if I may. First, Rob, I know you've mentioned M&A is critical to further diversification of the business away from KEYTRUDA. And you could explore M&A in -- basically in a non-oncology bucket like Acceleron or in oncology. And I guess that brings me to my first question, which is in oncology, it's a very high-quality problem of KEYTRUDA being this foundational treatment across so many different tumors. And how do you approach that given the increased FTC focus on looking at a lot of deals based on market shares on individual markets, considering KEYTRUDA basically has a market share in so many different tumors. And how do you think about oncology deals in general given KEYTRUDA's roll in. I'm sure you guys have thought about that at length to the extent you're thinking about any capital deployment.

Separately, Rob, also, you mentioned drug pricing and mandatory discounts. And I'm sure you've run exercises internally attempting to quantify how much in discounts. And what I'm getting at is for key franchises like KEYTRUDA, considering the price of U.S. and ex-U.S. is fairly comparable, wouldn't there be not much mandatory discount at all? I just want to make sure I'm not off track there despite KEYTRUDA being a top Part B drug.

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

Yes. I appreciate the questions. And on your first question around the M&A space and what we see in the oncology field. No, I would just start by saying, obviously, we are very proud of the success we've had with KEYTRUDA and the fact that it's been able to impact so many people's lives, as you say, across so many different tumor types. But I think it's important to understand that oncology continues to be an incredibly competitive field, and importantly, it's not monolithic. You have to look tumor by tumor and even modalities, whether it's IO or targeted therapy. So there are multiple different approaches, multiple modalities and it is a very tumor specific. And as you know, we have to develop these drugs indication by indication of investing in the science to bring each of those forward.

And in that regard, as we look at it and as we thought about it, we continue to believe that while the environment is more complex. And obviously, we'll have to be very thoughtful on how we navigate it, I believe, we believe, as long as we are doing deals that are science-driven, where we accelerate innovation, and we can show that we can expand access to patients around the world and in the United States to medicines that there are still deals to be done and that there's a path to move forward.

And so that's very much where we're focusing and why we continue to believe the opportunity exists to continue to expand treatments for patients and for the benefit of, frankly, all stakeholders, including shareholders.

On your second question, and I think it depends on the way you look at it, as far as the upcoming regulation. Obviously, if you look across what is being proposed, if you're speaking specifically to the potential for mandatory price discounting at some point. Obviously, the language has to be finalized. But if you look at where it is today, the way it is being proposed is that for a period of time after a drug is approved during its period of exclusivity for -- right now, it's roughly 7 years for negotiation for slow molecules, 11 years for large molecules, you were able to operate with no discount.

At that period of time, there would be a discussion and opportunity for HSS to select the drug depending on their determination of which drugs to look at. Right now as the language is discussed, we'll pick 10 drugs a year and up to the HSS to determine which drug they'd pick. But importantly, then the negotiation itself once it is done and the discount is determined and that discount is outlined in the legislation would take effect at year 9 for a small molecule, year 13 for a large molecule.

So as you think of something like KEYTRUDA, we're really talking about periods of time that are out around the time of loss of exclusivity in 2028. And obviously, there's other language that's being proposed potentially to allow for an exception if there are biosimilar products in development coming that then you would not be subject to it.

So the reality of it is it's unclear what the impact will be, in the short term, we don't see impacts from that specific part of the regulation. It will be longer term as it relates to our important drugs, KEYTRUDA and GARDASIL. And then obviously, we have to see how the final language comes out. But in the language there will then be specified discounts that will be set. So it's not reference price in the way they're setting it up right now.

And then obviously, beyond that, there is what they have around the Part B reforms, which actually what we support because we believe that will reduce the out-of-pocket costs for patients at the counter, but our -- the reason we continue to oppose the overall legislation is a strong belief that, that focus on mandatory discounts after a period of time is chilling to innovation. So I'm not sure I got your question, but I think that's what you were trying to get at.

Operator

That will be from Geoff Meacham with Bank of America.

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

I just had a couple of quick ones. Dean, I wanted to ask you on KEYNOTE-412, the recent -- it didn't hit significance. Did CRT add complexity to the study in terms of your assumptions? And more broadly, if you look at other indications, does a CRT backbone present any particular challenges when you look at other keynote studies? And then on COVID, the recent infection trends just over the course of this year or the emergence of any new variants, does that change the strategy about the future investments you guys are going to make in LAGEVRIO or even other orals?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

All right. I'll take both of them, I'll take the Keynote-412. So you're speaking about the -- us trying to go in for early stage at a neck and you're speaking about that 412, which, as you've emphasized, there was improvement in event-free survival for patients who received the KEYTRUDA regimen compared to the placebo plus CRT.

However, these results did not meet statistical significance based on our pre (inaudible) statistical plan. So there's clearly a positive signal, but it did cross the line. In relationship to -- how to think about CRT or radiation and other indications in this. I would not say that it gives you extra complication. We'll have to see in these other trials when -- not just us but other people in relationship to the combination there.

But I would just emphasize that it was an improvement in EFS. So I wouldn't say that it was a complicating issue for us. We just did need statistical significance. I do want to make sure that everyone recognizes that this isn't our only foray into head and neck early stage. We have a KEYNOTE-689

that's also in the neoadjuvant and adjuvant treatment as well. So we're cautiously optimistic that we can break into early stage at a neck despite the fact that KEYNOTE-412, it had a positive EFS did not lead to statistical significance.

In relationship to the pandemic, I need to be a little bit careful because everyone who's predicted what will happen with the pandemic have all had one common thread. They've all been not so right. And so we'll have to see what happens with the pandemic. We'll have to see what the emergence of resistance is, but I would emphasize the importance of having multiple mechanisms of action is clear. I would just emphasize that it is quite surprising to me how quickly this virus can mutate around those therapies, for example, focused on this like protein. That's actually it takes many amino-acid changes to do it. And it might take very few amino acids changes to get resistance to, for example, other therapies, but we'll have to see what it is.

But I just want to also emphasize that, especially outside of the United States, there's been a great use of it and uptake, and it's really based on the fact that if you have a patient population where you believe that they're extremely vulnerable and you can give this drug and you're most interested in reducing mortality, which this drug has an impressive impact on mortality and you want speed such that you can really see the patient and who may be on multiple medicines, have other complicating medical issues and feel free that you can give this, if those are the important sort of attributes then we have found that LAGEVRIO does quite well and the real-world evidence throughout the world has begun to substantiate.

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

And Jeff, this is Caroline. The only thing I would add in terms of further investments is our belief in the molecule as being a molecule monotherapy as seeing a molecule that could be impactful, not only against COVID-19, but also pan-coronavirus, RSV and flu. And as a result, we will invest in appropriate programs to try and prove that out.

Operator

That will be from Mara Goldstein with Mizuho.

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

Firstly, I just wanted to understand the statement about KEYTRUDA supplemental PDUFA for adjuvant non-small cell lung cancer? And have you been asked for additional data? Or are you planning for a major amendment?

And then secondarily, I just wanted to also get some clarity on the comment about excess cash for share repurchase. And at what threshold should we be thinking about that if you're also committed to raising dividend?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. So I'll -- this is Dean. I'll take the KEYNOTE-091, 0-9-1, so that's the lung adjuvant. And just to remind everyone, that had dual primary endpoints. And the reason I want to emphasize that the dual primary means that if you hit on one of the endpoints, you have a positive trial. And this is a distinction from those trials that are co-primary where you have to hit on both. So this is a positive trial because in the disease-free survival, it's positive in all comers regardless of PD-L1.

Our -- the dual primary of DFS in terms of those with a TPS greater than 50%, there is a positive trend, but it's not significant. And the OS has got a (inaudible) trend as we move forward. I would imagine, as data matures people may want to see those data, and I just want to emphasize that in relationship to early-stage lung cancer, we have other trials as well, which is KEYNOTE-671, KEYNOTE-867 and KEYLYNK-012.

So I could imagine that as people deliberate on this, they will be interested in understanding how the data is maturing. These are event-driven and they're part of our FDA discussions and the PDUFA date, as you've said, is January 29, 2023. But we could see a situation. There's nothing formally that's been asked of us, but we could see a situation where evolving data is asked for.

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

And Mara, in response to your question on our utilization of excess cash, the capital allocation priorities of our company are unchanged. We continue to invest first and foremost in our business and the great opportunities that are in front of us. Business development is a strategic priority for us, and we will invest in business development as we have done in the past.

We intend to continue to raise our dividend over time and we will then return any excess cash to our shareholders via share buyback. We do not intend to sit with multiple capacity on our balance sheet for periods of time and not use that cash in this regard. So I hope that addresses the use of our cash.

Operator

It will be from Seamus Fernandez with Guggenheim.

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

So maybe just one M&A question. Can you just clarify whether any acquisition plans or that Merck will consider is likely to be all cash or if there would be a potential use of equity that would be or could be considered in a potential transaction.

And then separately, just wanted to get a little bit of the vision for V116? And where and how you see V116 competing in the overall market? Are we really just looking at that as a potential opportunity solely for adults? Or do you envision the '21 balance actually being a high-use target opportunity in the pediatric patient population as well. And then just trying to get a sense of timing of when we could see V116 actually competing in market and how you see the overall market evolving over time?

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

Yes. Thanks, Seamus, for the question. Obviously, business development remains a priority for us, as we've discussed. And importantly, we look to add wherever we can find the best science and innovations that enhance our pipeline and drive long-term growth and value for shareholders. I don't want to speculate on specific future transactions or the specific combination of cash or equity we would use because it really would be fact specific to the deal at hand. And so in that sense, I think we'd have to wait.

The broader point, I think, that I want to enforce and we've said consistently is we have the capital and the balance sheet strength to go after anything that we feel is strategically important that brings that scientific innovation that I mentioned that will allow us to continue to augment what we have in our own internal pipeline. So we have the capacity and the flexibility to structure it, how we see best to optimize the business, how you do that between cash, debt and equity is really deal-specific.

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes, in relationship to the questions that you had about V116, I just want to reiterate or reemphasize the strategy that we think, which is in different age groups or different populations, the serotypes that are most troublesome for different populations is very different. So the whole focus of V116, the whole focus of the V116 is to recognize the serotypes that are specifically important for adults and to target that. And that's what V116 is, and that's why we had the first of 4 current Phase III trials that have to run its course.

There is not a view from my standpoint, scientifically, that this is a vaccine that I would drive into the pediatric population because the epidemiology as of right now would suggest that, that would not be the right place to put this vaccines. We want to put the vaccines where the serotypes match what is happening to that patient population.

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

Yes. I might just add to that. If you look at it as we think about the future commercially, we see a real opportunity when you think about this bespoke approach where you have actions that we think will be highly effective in combating the serotypes that cause disease in infants and children as our pediatric approach. And then you have a separate approach with V116 aimed at the adult market.

We will go after 85% of the residual disease, understanding that if you've treated it in children, you obviously have a different set of serotypes that are driving it in adults. And we are focusing on both of those as bespoke therapies aimed to what is most aligned with the needs in those populations.

I think this will be highly effective and will allow us to be very competitive, in fact, cover more than what the competitor products cover in the disease-causing serotypes than you see today either in what they have in both the pediatric and adult market.

So I think this is something we're very excited about. And in fact, we see V116 as really bringing to fruition that strategy. So we're excited about it. And we're going to drive it with speed because I do think this is going to be an area where we can definitely be highly competitive and successful.

Operator

That will come from Carter Gould with Barclays.

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

Dean, just real quick, I want to ask you, come back to the subcutaneous formulation of pembro. Is that Phase III in non-small cell still on track to read out early next year? And how should we think about sort of the clinical measures in that study, not just sort of -- I think the primary end points are around some of the biomarker endpoints? And should that study alone sort of be warranting a filing? Or should we be thinking about it differently?

Dean Y. Li - Merck & Co., Inc. - Executive VP & President of Merck Research Laboratories

Yes. So I just want to emphasize that, that trial is on track, and that trial should -- our intention is it should support filings? I should also emphasize that we have more than just one subcutaneous program and different images and different subcutaneous because we think that there may be a different patient population that will be important for different sort of formulations, the group formulations. I should also emphasize that just like we have Q3 weeks and weeks Q3 weeks -- Q3 weeks and Q6 weeks were intravenous. I think it's also important that we open up that possibility in the subcutaneous range as well.

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

Thank you very much, Carter. Rob, any closing comments?

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

Yes. Well, I'd just like to thank everyone for joining us today, and maybe I'll just conclude by reiterating my appreciation for the tremendous efforts of the Merck team and really, we're continuing to perform exceedingly well in a tough environment to advance our science and ensure our important medicines and vaccines reach the patients around the world that are counting on us.

So I appreciate that, and I can tell you, I remain very confident in our underwriting momentum, and I look forward to continuing to give you updates on our progress as we move forward.

With that, have a great day.

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