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# EDITED TRANSCRIPT

MRK - Merck & Co Inc at JPMorgan Healthcare Conference

EVENT DATE/TIME: JANUARY 09, 2018 / 12:30AM GMT



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## CORPORATE PARTICIPANTS

**Kenneth C. Frazier** *Merck & Co., Inc. - Chairman, CEO and President*

**Roger M. Perlmutter** *Merck Research Laboratories - President*

## CONFERENCE CALL PARTICIPANTS

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

## PRESENTATION

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

Good afternoon, everybody. I'm Chris Schott from JPMorgan. And wrapping up our first day of the conference, I'm very pleased to be introducing Merck. From Merck, we're going to have both Ken Frazier, company's Chairman and CEO; as well as Roger Perlmutter, who is Merck's President of R&D. We're going to do a fireside chat format today and we're not going to be doing a breakout after the presentation.

So with that, welcome and happy new year, guys. And I'm going to turn it over to Ken to make some opening comments, and then we'll go into the Q&A from there.

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**Kenneth C. Frazier** - *Merck & Co., Inc. - Chairman, CEO and President*

So I want to thank everyone for being here this afternoon. And I want to thank you, Chris and JPMorgan, for having us. Let me start by saying we believe Merck is in a very good place right now. Coming out of last year, which was a high-paced and high-performance year, we were able to grow notwithstanding about \$2.5 billion worth of patent expiries for -- through the first 3 quarters as well as other issues that impacted our business. We continue to invest in R&D, which we believe is the key to our long-term success. And we're coming out of 2017, we think, with very good operating momentum. And we anticipate growing in 2018 on both the top and bottom lines.

Looking at it from a longer-term perspective, we have several pillars of growth, including oncology, which is anchored by KEYTRUDA but surrounded by a large internal pipeline of oncology assets including LYNPARZA through our collaboration with AstraZeneca; vaccines including our on-market products like GARDASIL as well as a terrific pipeline of novel vaccines; select hospital and specialty products including BRIDION in HIV, products in neuroscience and more; and finally, Animal Health, where we've driven growth across multiple species and have a very strong growth portfolio.

In addition to supporting our R&D activities, we continue to look for additional opportunities for innovation through business development, which remains a priority for Merck going forward. And along with driving value through our pipeline long term, we continue to return cash to our shareholders through share repurchases and dividends. So there's a lot that's going on and value inside Merck. We remained committed to our fundamental business of innovation.

And with that, I know, Chris, you have a lot of specific questions for us.

## QUESTIONS AND ANSWERS

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

Sure. Maybe just to kick off, I know you mentioned '18 is a year of growth. But can you talk through -- I know you're not going to give formal guidance at the conference, but just maybe some of the pushes and pulls we should think about as we think about both Merck's top line and earnings for this year.



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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

Certainly. And we will provide guidance when we provide our fourth quarter earnings in early February. But just in terms of your question, in terms of pushes and pulls. So obviously, we still have the remnants of patent expirations like ZETIA and VYTORIN. We have some headwinds with respect to ZEPATIER and ZOSTAVAX. At the same time, we have tremendous growth with KEYTRUDA. We continue to look forward to growth through LYNPARZA. We -- GARDASIL 9 continues to grow very strongly as a result of the fact that people around the world see the opportunity to eradicate cervical cancer. So as we move forward, as -- we have BRIDION growing, et cetera, as I said in my opening remarks. I would say overall, we have some pretty substantial headwinds, as I just mentioned, but we see the tailwinds as being more than capable of offsetting those headwinds.

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

And then just the second kind of bigger picture question, as we think of the longer-term Merck story, how do you see the company prepared to drive top line growth and ongoing margin expansion? How do you think about those dynamics for the business given there are some longer-term LOEs you need to focus on? So just maybe talk a little bit about how you see the company positioned longer term.

**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

Well, let me start by saying I think that's why companies that focus on innovation are able to succeed over the long term. A couple of years ago, if somebody's asked me how are we going to grow through ZETIA and VYTORIN, I wouldn't say I know I have the pathway. It's going to be KEYTRUDA and it's going to grow faster the first 3 years in the market than everybody could believe. As we look forward, we see tremendous opportunities to grow KEYTRUDA going forward. We see the opportunity that I think is a very underrated opportunity with LYNPARZA, which is a really important drug that we've got access through our collaboration with AstraZeneca. We have 50% of that drug going forward, and we think we got it on very good financial terms. When you think about vaccines, I mentioned GARDASIL and our pipeline. We're looking forward to bringing forth our pneumococcal conjugate vaccine. That could be a very important contributor going forward. And then the diabetes space, which is what you're referring to with JANUVIA, our combination with ERTU going forward. We think depending on how the cardiovascular outcomes studies come out, that could be a very big contributor and it could in some ways mitigate the loss of patent exclusivities on sitagliptin going forward. So our Animal Health business is fine. Our HIV portfolio is fine. We have much more than KEYTRUDA in oncology. We have 20 products, potential products that are owned proprietary mechanisms in oncology, including many that are in the clinic or about to go into the clinic. So we think we have opportunities to grow the business going forward.

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

Great. Shifting gears a little bit. Let's move over to just KEYTRUDA and the I-O portfolio. Maybe first, you can just give us your latest thoughts in terms of where we are in terms of uptake with KEYTRUDA, specifically the front-line lung opportunity. How has that rollout been progressing?

**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

Well, I think we've been very pleased by what we've seen. So we'll start with in the front-line lung, we are the only drug that's available as a monotherapy for first line, and in the U.S., in a chemo combination. What we've seen is very, very strong uptake, particularly with respect to the high expressors in monotherapy but also with others in monotherapy in first-line lung. With the chemo combination, we're seeing really good traction now that we've got subsequent data that shows what the trend is on overall survival. And in the long run, as you know, what really is important in these markets to patients and their physicians is, can you demonstrate overall survival? And that's why we decided to make a co-primary endpoint out of overall survival in our 189 study. So we're very pleased with the uptake in the U.S. and around the world, and we have many more opportunities to grow this going forward. Roger, do you have anything to add?



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**Roger M. Perlmutter** - Merck Research Laboratories - President

Well, I think Ken got it exactly right. We see great opportunities going forward. I mean, the pipeline is rich with many chances to gain substantial advantage for the patients whom we serve.

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

Right. So I guess one -- so KEYNOTE-189, I think, is a big focus point for the story right now, a very important data point for Merck. I know you touched on it a second ago, but can you just again elaborate a little bit more in terms of the decision to move to the co-primary for that study? And I got a couple of follow-ups from there, but kind of what led to that decision?

**Roger M. Perlmutter** - Merck Research Laboratories - President

Well, the decision in many respects was not so hard to make. When we first obtained the data from the 021G study, the result with respect to progression-free survival was extremely strong. But at 12 months, there was relatively [limited] separation for overall survival. Remember, a quite small study, just 60 patients per arm. At the time, we were at 18 months of follow-up, at which time we no longer had the power, of course, to examine the study further, the trend, just as Ken said, was very strong for overall survival, Chris. And with that in mind, the 189 study, which essentially is identical in design to 021G, it's 2:1 randomized, but in other respects, it's essentially identical. The 189 study looked like a place where we could actually demonstrate overall survival. And from the perspective of greatest good for greatest number, which after all is what we're trying to achieve at the trial, gaining overall survival in that setting, saying that the combination of chemotherapy plus KEYTRUDA was better than, in essence, sequential administration of KEYTRUDA because remember, this study is really comparing early versus late. Almost everyone who fails on chemotherapy will get KEYTRUDA thereafter. And so it's either the combination or it's chemotherapy followed by KEYTRUDA. And demonstrating that, that combination provides overall survival benefit seems to us to be very important. So we wanted to make sure that we actually were powered to evaluate that question. And hence, we included it as a co-primary endpoint. The reality is that the study dates, the time lines that we have had didn't really change at all. All that changed was the way in which you listed in ClinicalTrials.gov, which I can understand gave certain people some pause. But we feel very confident about that study.

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

Sure. And I guess on that topic, I know The Street was a bit surprised by the time line, particularly the kind of early 2019 final analysis. How do we think about that kind of maybe 1 year plus gap between, I think, when we had expected PFS to read out and now when we're thinking about this final kind of OS, PFS look. I know we had obviously have interims to look at. But can you help us bridge that a little bit of why we should think about that?

**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes. So 3 things. The first thing is to emphasize yet again that from the perspective of greatest good for greatest number, what we would like to be able to demonstrate is that overall survival is improved if you simultaneously administer KEYTRUDA plus chemotherapy, traditional platinum-doublet chemotherapy, to patients who are being treated with non-small cell lung cancer, nonsquamous non-small cell lung cancer. That's the most important thing. So we don't know when that overall survival difference will appear. It will likely appear before we saw it in 021G just because with many more patients in the clinical trial, we are powered now to see that difference at an earlier point. But we don't know when that will appear. That's the first thing. The second thing is that progression-free survival is a co-primary endpoint. And the study is under the supervision of the Data Monitoring Committee. There are opportunities for the Data Monitoring Committee to take interim looks in the study, and those interim looks could very well reveal a difference in progression-free survival before overall survival data are mature. At that time, again, the question will be greatest good for greatest number. If, in fact, what has happened is that the vast majority of patients have already progressed on the chemotherapy arm, there's no point in not announcing the study at that point because after all, most people have already moved to KEYTRUDA therapy. They progressed on chemotherapy and they're going to get KEYTRUDA thereafter. We're comparing early versus late KEYTRUDA. So there will be opportunities for interim analysis going forward, and we should all keep that in mind. The third point is -- and this is very much worth



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remembering. In the United States, the largest market for non-small cell lung cancer, we are currently approved, based on the 021G study, for first-line administration in combination with chemotherapy in all-comers. We are approved. Data that come from 189, a study that is identical to 021G, are immediately on label. They're consistent with label. So if those data become available, they become part of what we can use explaining to providers and to payers and to patients exactly what KEYTRUDA is capable of doing. So we immediately will put those data into our discussions with appropriate audiences because those are consistent with label. And that's how we intend to proceed. So when you think about the -- what you call the gap, the distance, it's worth remembering both that there may well be earlier looks at the data that could provide an interim result, number one; and number two, that those data that we obtained are immediately consistent with what we already have. I have every reason to believe that the 189 study will recapitulate the results seen in 021G. The reason why we have made the changes that we've made is because we strongly believe in the outcome of these studies.

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

Great. We saw also recently saw PFS and some initial OS data from one of your competitors with the IMpower150 study. Just interested in your thoughts what that means from a competitive landscape, just perspective on that data set.

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Well, again, our expectation is that the combination of chemotherapy with PD-1 or PD-L1 antagonism should prove to be better than chemotherapy alone. That's what we demonstrated in 021G and we believe that should be extrapolatable. What was shown in IMpower150, a different patient population treated differently and with the addition of Avastin was, in many respects, consistent with what I just said although not exactly precisely the same study. It is unfair to compare results from 2 different studies with different agents and different patient populations. But overall, I would say over time, what we should expect to see is that when you combine chemotherapy, which, at a minimum, we expect to kill tumor cells and release neoantigens into the system, if that is done in the presence of a PD-1 antagonist that permits more robust immune responses, it is likely we'll see more powerful antitumor activity. And we expect to see that almost everywhere and certainly in our own studies.

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

So taking those 2 things together, that is why we feel very good about our position. We have the confidence in what we believe 189 will show based on what 021G showed, and we are the ones that are in the marketplace now as both monotherapy and chemo combination in the United States. And doctors every day are not just getting experience via studies. They're actually seeing it with their own patients. They're using these drugs. They're getting experience with it. They're getting positive results. So we feel very strongly that we're in a great position. And if you're able to manage this for the long term, you definitely want to get that overall survival data, particularly, as Roger was implying, because we can go immediately, out and discuss it while other people will have to file and get it approved. So actually, we don't see this gap as big as what other people see it clearly.

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

Sure. So I think -- so to summarize, I think there's -- we get this question of if someone gets there a couple of months one way or the other on the OS, it sounds like from your perspective, that doesn't really shift the -- in terms of your -- you're maintaining your leadership position a couple of month delta on OS is...

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

I don't believe that's the case. I think being there first is important but we are there first. That's the point we're making in there. We don't need to get a subsequent FDA approval in order to promote this drug for that use.



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

Excellent. Maybe one last one on the I-O front. Beyond 189, just some of the near-term data points we should be watching and thinking about for Merck as we go through (inaudible)?

**Roger M. Perlmutter** - Merck Research Laboratories - President

Yes. So just first of all, let's point out that KEYTRUDA was registered in September of 2014. And since the time that it was registered, there've been 12 indications approved in the United States for KEYTRUDA, which is remarkable. We also have 12 Breakthrough Designation and another Breakthrough Designation which you'll hear about soon. So that's an enormous amount of progress. Just this morning, we announced the -- with our colleagues at EORTC, the results from our adjuvant melanoma study in which we demonstrated that adding KEYTRUDA in the setting of a postsurgical treatment for melanoma resulted in a longer relapse-free survival as compared to the standard of care, which in this case was just launching. So that's a really important result because it broadens still further what can be done with KEYTRUDA in the melanoma setting. But beyond that, in the future, we're going to see, as we've said, the 189 data, which recapitulate 021G. We're going to see similar kinds of data from the 407 study in the squamous cell population. We're also going to see additional data in chemotherapy combination from 048 in head and neck cancer, which promises to be very powerful. We're going to see further data with respect to the first-line lung cancer setting from the 042 study, which will, we hope, broaden utilization beyond those individuals who have the highest level of PD-L1 expression, greater than 50% of cells, to patients who have lower levels of PD-L1 expression, meaning that KEYTRUDA monotherapy in that setting, particularly for individuals who could not withstand chemotherapy, would be beneficial. That's just some of what we expect to see. But if you look at ClinicalTrials.gov right now, we have nearly 700 studies that are registered for KEYTRUDA. Now not all of those are, in fact, pivotal trials, but there's a very large number and a very large number of combination studies, more than 300. So those studies actually are going to provide data, and a lot of those data are going to be very good. So 2018 is going to be pretty exciting for KEYTRUDA.

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

Yes, absolutely. Shifting gears a little bit, payer environment is a question, I think, for the whole sector that we've been all kind of grappling with and access to the patient. How do you see the industry kind of adapting and addressing some of the challenges with access that seems to have become more prevalent in this space over the last few years? And how is Merck specifically kind of dealing with these dynamics?

**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

So I think I'll make a couple of points about this. So first of all, so obviously, the whole question about affordability is a huge issue. It's a political issue. It's an economic issue. It's a patient access issue. And from our standpoint, what Merck has always tried to do is to be extremely responsible in our own pricing. And we try to be very transparent so that people can see that, for example, with respect to annual price increases, we've always been around sort of low to mid-single digits in terms of our price increases. Importantly, we engage government and policymakers on ways of making these products, that is to say branded pharmaceuticals, integrated pharmaceuticals, more affordable. Part of that is to help people understand the intense negotiations that go on already in Part D and in Part B. And I think the good thing is that I do think -- my sense of it is that the policymakers do understand that. They also understand that roughly 30% of the price of any branded pharmaceutical is rebated back into the supply chain and the challenge that patients are facing directly is that unlike in net or hospital visits or physician visits, those rebates don't get passed onto people at the counter. And so I think there's a lot of focus now on how do we ensure that this robust set of negotiations that resolve in these rebates actually benefit the people who need it. So I think that's a very important issue in terms of how do we proceed from here. I have to say I think the good news is that my sense of it is that while we're going to continue to see incremental pressure on price, I don't see either through public agencies or through the private payers any kind of significant jump in that pressure.

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

Right. Great. Just jumping around again, tax reform, big topic end of the year last year. What does tax reform mean to Merck as we think about your tax rate, your capital structure, just how you run the business? Any thoughts on that as we've had some time to digest the changes, I guess?



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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

Well, we're still digesting them, and we're not giving guidance today, but I will say a couple of things. So first of all, I think we can expect that the overall blended rate for us will be lower with this legislation compared to what it would have been without the legislation. That's the first point. As it relates to capital allocation, I think it's probably fair to say that it doesn't really change our capital allocation strategy per se. We're going to continue to use cash and to use our resources to do the things that we have been doing with respect to business development. For example, with the kinds of deals that we've been ideally targeting, I think we've had enough access to cash and we've had enough power on our balance sheet to do those deals before tax reform. But this is actually obviously a benefit to us because it gives us greater financial flexibility. So going forward, I will expect that we'll continue to focus on business development in a similar way. I don't think it changes the world for us in a great way.

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

Okay. And just maybe on those topics, can you just elaborate a little bit on your priorities for business development at this point?

**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

Well, I would start by saying business development remains a significant priority for us as we think about -- you asked earlier about this situation with JANUVIA going off patent. It's an important issue for us as we try to build the company long term. But our business development philosophy is based on our overall strategy, which is we're looking to bring great drugs to market. And so what we're trying to do is we're trying to find those opportunities through licensing and bolt-on acquisitions to acquire the kinds of science that will lead us to great drugs that will be differentiated and make a meaningful impact on unmet medical need. And we're going to continue to do that. We're going to do it in a financially disciplined way because that's the way we've always proceeded on that, but it's a very important issue for us going forward.

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

And you have the LYNPARZA deal last year, and that was -- I think fit that criteria of very interesting financial structure. Do you see more opportunities for deals like that? Or are those fairly few and far between that you can structure a transaction like you were able to last year?

**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

I don't expect that we'll see one that would be necessarily exactly like that for the size of it. But I also do think that we're going to continue to look for deals, collaborations, partnerships where we can actually bring value to the partner. And I think that tends to be the case in earlier-stage deals. We're very pleased with the deal that we did with Rigontec to get -- acquisition through another oncology asset. The structure may be somewhat different than this one because this one's unusually not -- essentially around 3/4 of the payments are really tied to milestones, either regulatory milestones or sales milestones. And we might not be able to duplicate that in every deal, but that's the kind of deal that we're looking to do.

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

Right. And then maybe just a bigger picture M&A question. I mean, there's been a lot of discussion in the investment community that 2018 could be a busy year for M&A, including larger deals, as we think about tax reform, we think about pipeline. Just based on your thoughts there, I guess high level, do you see the forces in place right now that could lead to further large consolidation across the space?

**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

I do. I think there a lot of forces that could drive consolidation, including large deals. I don't think that consolidation will happen for every company in exactly the same way. And I think for a company like Merck, we'll continue to be focused on innovation, not consolidation as a strategy. And so





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when we look at opportunities, while we don't rule anything out, we look across the whole spectrum of opportunities. Our focus is really, as I said before, in doing the kind of deals that will allow us to bring great drugs to the market.

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

Great. And the last minute or so here. A lot of focus on I-O but you've got obviously a lot in the pipeline beyond that. Maybe just highlight for us a couple of things in the pipeline that maybe get a little less attention that we should be thinking about as we think about the longer-term Merck story.

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

Well, I'll let Roger give his point of view. But for me, for example, vaccines is a big area. As I mentioned earlier on, the pneumococcal conjugate vaccine, which was a 15-valent vaccine, we think, could be a very important contributor to Merck going forward. The work that we're doing in HIV is important. And I'll turn it over to Roger.

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Right. As we announced today, our file for doravirine was accepted by the FDA today. Not unexpected, of course, but it is an important molecule. It's now about 1/4 of a century since we first introduced a meaningful therapy for HIV infection in indinavir, CRIVAN. And since that time, virtually all of the major classes of HIV-directed therapy have been first introduced by Merck, including non-nucleoside reverse transcriptase inhibitors, strand transfer inhibitors, many others. So we've been working very hard to improve therapy for HIV-infected patients. Doravirine is a non-nucleoside reverse transcriptase inhibitor, the next generation that has, in our view, equal efficacy but a much improved adverse experience profile. And we formed the foundation of a new approach to HIV infection, which includes our very potent nucleoside polymerase inhibitor, 8591, as well as a number of long-acting strand transfer inhibitors and protease inhibitors that together can be combined in such a way as to create extended duration therapy. Extended duration therapy can be extremely good for HIV eradication and can also be useful for prophylaxis. We think that's going to be important over time, and it builds on our successes more broadly in antiviral therapies, which we've demonstrated repeatedly. So you look at it, oncology, vaccines, antiviral therapies, our recent approval of our SGLT2 inhibitor in collaboration with our colleagues at Pfizer. We have significant activity in metabolic disease, cardiovascular disease and also in neuroscience. It's not a bad portfolio. We're enthusiastic about it.

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

Great. We're out of time. Thank you, guys, so much for the comments. Very helpful.

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**Roger M. Perlmutter** - Merck Research Laboratories - President

Thank you.

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

Thanks so much.

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**Kenneth C. Frazier** - Merck & Co., Inc. - Chairman, CEO and President

Roger, thank you.

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