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# **EDITED TRANSCRIPT**

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#### **PRESENTATION**

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

Okay. Great. Thanks for joining us, everybody. I'm Terence Flynn, the pharma analyst -- U.S. pharma analyst here at Morgan Stanley. We're very pleased to have Merck with us today.

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Joining us today from the company, we have Rob Davis, CEO; and Dean Li, Head of R&D. Thank you, gentlemen, for joining us today. Really great to be back in person, and great to have you here today.

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

Great. Thank you for having us. It's good to be back in person.

### QUESTIONS AND ANSWERS

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

For sure. Maybe, Rob, obviously, newly recently appointed CEO, maybe just help us think about where you've been spending the majority of your time in the role. I know you've been at the organization for a long time previously as CFO, but now in the CEO role, where are you spending your time?

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

Yes. Well, I appreciate the question. So it's been about a year and almost 3 months. It doesn't feel so new, but in CEO time, I guess, maybe it's still a little new. But if you look at where we are and maybe just to give you some context, I feel very good about where the business is today. We're performing and executing extremely well scientifically, operationally, commercially.

I feel very proud of what our Merck employees are doing in light of everything they've seen. And if you look at the business, it's strong. If you saw it in what we had in the second quarter, if you look at our full year guidance, we're delivering very strong growth.

And as you look forward with the key growth drivers we have, they're all intact. They're durable. And as a result, we remain confident that you're going to see strong growth from us as we look out to 2025 and beyond. And in fact, we're also going to continue to see margin expansion, and we've previously indicated with goal being greater than 43% by 2025.



So as you look at the business, things are progressing, we're doing well. And then finally, our pipeline is maturing. I would tell you sitting here 1.5 years in, a year and few months into my role, I feel better today than I did a year ago. I think we're making some great strides, and I'm sure that will come up here in a little bit with Dean.

So from all of those aspects, I feel like we're in a good place. But if you ask me, what am I doing? Clearly, I would really bucket what I see is the role I've been playing in 3 major categories.

First and foremost, it was ensuring that while we feel very strongly about the derisked assets we have to deliver quarter in, quarter out growth, I wanted to ensure we had operational execution to do that. I feel very good. I think we're showing the credibility that we can do that.

I spend time with the team on that. Obviously, Dean and I spend probably the most time thinking about how do you accelerate the pipeline, and importantly, how do you augment the pipeline. And that's really all about business development. And I feel like, as I said, I think we're making progress on the internal pipeline. And I think we've broadened some interesting assets externally. So we feel good there.

And then lastly, we know the world around us is evolving. We need to change with it. We're trying to drive a culture of urgency, one that understands we have to be more agile, more simple, more focused. That's why we did the spin-off of Organon. We're starting to reap those benefits.

And as we look, it's about how do you transform the way you engage with your customers with all of the players in the ecosystem. That's about how do we get better about data and analytics. So a lot of time on building the capability and the approach to transform the business.

So really, it's deliver today, drive the pipeline, transform for the future. That's where I've been spending my time over the last year. And I'm very optimistic, as I said. I think we're -- we've got all the building blocks in place. The fundamentals are there, and I'm quite confident that the team is going to execute against those.

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

Okay. Great. One big picture question. We've been spending some time on is the Inflation Reduction Act, which touches the whole industry, became law recently when President Biden signed it. It's going to be implemented but not until 2026. So there is some time here.

But maybe just as you think about the key components, recognizing a lot is still TBD, what is the impact on your business? And then how do you -- do you make any changes to respond to that as either on the R&D side, Dean, or as you think about business development opportunities, does it change the lens that you're looking at opportunities?

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

Yes. Well, maybe I'll talk specifically about Merck, and then we can talk more macro. If you look at it overall, the impact of this is -- for us in the medium term, is going to be manageable. If you take the different components of it, starting with the inflation cap, we have had a long practice of pricing at or below inflation.

So in fact, that -- nothing changes in our business going forward from where we've been. If you look at the Part D reform, that's something actually we're very much in favor of. I would argue and as industry representative, I wish more of the dollars freed up from this, from the drug industry would have gone back into reducing out-of-pocket costs. Only about 10% actually is going to reduce out-of-pocket costs. As an industry, we would have liked to have seen more.

But needless to say, we're supportive of what's happening with the Part D changes. And as it affects us, those rules don't come into effect until 2025. And for us, most of our products aren't big in Medicare Part D at that point. The one we have today is JANUVIA, and we'll have to see what happens with that. But really, overall, we should be in a good position.



And then really, the big piece of this is about Medicare price negotiation, as you know. And as we look at it, to the key assets we have, I would start with KEYTRUDA, as we look out to the loss of exclusivity in 2028, really, we feel like we're in a good position there. And then GARDASIL, one of our other big products, given the fact it's not really a Medicare product, it largely is unaffected by this. So all in all, we see this as very manageable.

And as you look at how we've built our long-range plan, and I think this is important, we have over the last several years talked about our confidence in our long-term growth. I can tell you as we've built our models, we always assumed we were going to see price pressure in the United States.

In fact, I think in a lot of other settings, we've said that. I've said that. So we had dollars in assuming something would happen. Now we know what it is, but importantly, as a result of that, our long-range outlook doesn't change. It, in fact, we already covered what's happened. So I remain confident in our growth prospects and our margin expansion.

We've been working to prepare our business for this for some time. So we're well positioned. That being said, if you step back and look at it from an industry perspective, this -- as an industry and as part of pharma, we are concerned. I do think this will have a chilling effect on R&D long term.

If you look at what's happening here, it is going to impact how you think about business development. It is going to impact how you think about development of drugs. How specifically? It's too early to tell because -- and also, I think it will be very fact specific to the individual drug, to the individual company.

But I think it is easy to say that overall, the hurdle rates you're going to have to achieve both in internal R&D and external R&D have gone up because your window of return has gotten smaller. And so how all of that plays through, we're going to have to see.

I actually as a large company with still -- obviously, we can talk about KEYTRUDA, but overall, still a fairly large diversified company, strong cash flow, strong balance sheet. We're going to -- we'll come through this.

I'm not worried about that. I'm confident of that. I do think, though, to some of the marginal companies, the smaller companies, this could have an impact. And as I said, I do think it will impact ultimately the way people think about how they develop drugs. So a lot more to be said.

This is still only law. We don't know the regulations, and we need to see how these translate into the actual administrative rules. But I don't think, overall, it's -- this was a good day for pharma from that perspective primarily because it's going to impact our ability to deliver for the patient.

Now I worry about the patient who is waiting on the innovation that maybe they don't get it as quickly or in the same way they would have. And over time, I think as people understand that, there still maybe will be an opportunity to see this adjusted over time to give more of that value back to the patient out-of-pocket cost and preserve innovation the way we think it should.

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

Yes. Does it change that mix? Like some people have suggested maybe it shifts more towards biologics away from small molecules or again, disease area focus? Or is it still too early to kind of make those broad generalizations?

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

I think it's too early to make those broad generalizations. I do think the fact that we have a shorter window before you have negotiation for small molecule relative to large, that's real. We're going to have to understand that. How does that affect the way you think about development of small molecules, I think it still depends on what is the asset you have in hand and what's the pathway to develop it. So I don't know how it's going to affect it, but I do think that dichotomy is interesting and could have unintended consequences.



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

Okay. So stay tuned. As one of the areas you mentioned where you're spending your time, Rob, is augmenting the pipeline via business development. One of the first deals that you guys did was the Acceleron transaction to kind of move into PAH build out your cardiovascular portfolio.

So again, maybe just give us a mark-to-market in terms of how you're thinking about the forward strategy here on the business development side. And is Acceleron kind of the example deal? Is that the kind of deal that you'd want to do on the forward here as we think about future business development opportunities?

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

Yes. Well, so if you look at the way we think about BD, and I think Acceleron is a good example of this, it starts with where do we see an unmet need where there is a scientific approach starting to go after it that we think is intriguing.

And in particular, if we can find one that then overlaps with where we believe we have particular capabilities or where we can expand into new capabilities that get us interested and frankly, I look to Dean and all our employees and partners in our business development and in our R&D organization, where the R&D teams get excited, I get excited.

So it starts with the science and the opportunity for the pipeline. We then look and understand what does it mean to the overall portfolio. In a perfect world, I would like to see us, all things equal, more diversified than less.

So we do take that into consideration. It doesn't drive us. The science drives us, but it is -- but it does inform us. And then finally, it's about where you see value creation. And I believe you have to still believe that you're going to drive long-term value through it.

If I sit back and I go back to what I introduced the discussion to the day, I sit here today at year-end feeling like we're making progress. We have more to do. We have not done everything we need to do, but we are definitely putting runs on the board. We're definitely making progress. I feel more confident today about our pipeline.

I would use the example, use Acceleron. If you look at our total cardiovascular or cardiometabolic space, we've now indicated we think we have 8 new launches coming by 2030 that could have revenues in excess of \$10 billion by the mid-2030s. I wouldn't have said that a year ago.

Those -- that's new, how that portfolio has matured. So we remain focused. We remain urgent in what we think we need to do. I no way believe that we shouldn't be on this issue of trying to bring the pipeline and to continue to drive for sustainability. We do that with focus and urgency but by no means desperation.

We are doing it in a disciplined way. We're going to hold to the discipline. We're going to show that we can create value. And I'm confident that there are enough runs to be had out, there's enough shots on goal that we're going to be a sustainable growing company for the long term. I'm very confident of that, and that guides us, and that's really how we think about it.

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

Okay. Maybe 2 follow-ups. One is, you mentioned your entrenched position with KEYTRUDA. And I think in the past, you guys have talked about how that gives you an advantage in terms of looking at combination data sets, maybe you get a read on those earlier because you're running those trials in parallel with other companies.

So when you think about kind of that plus your existing SG&A infrastructure, how does that all impact your kind of ROI calculation on some deals, especially in cancer as you think about there is a big opportunity set there. Again, you already have some of these existing maybe advantages over the competition.



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

Yes. Well, I mean, clearly, the -- we see what KEYTRUDA gives us as leverage. It clearly is leveraged. It's leveraging our internal pipeline through our ability to understand the biology and the science of oncology and to determine where to go next. You've seen that consistently with the business development deals we've done where we've leveraged that. WELIREG is a great example of that, which is off to a great start here as its earliness launch.

So that is advantage, and I do think that synergy that comes from potentially combining with KEYTRUDA or what we learn from KEYTRUDA is something that brings value to us. But that's not -- oncology is not the only place we see it. I mean, we go back to the example you used. Acceleron is leveraging our position in the cardiovascular space.

Merck has a long history in cardiovascular disease. We had a deep and growing pipeline in cardiovascular disease. It wasn't well-known externally, but we knew about it. That's what drove us to Acceleron was early learning around the PAH space and what we were seeing with our own internal assets.

So there are many areas where we see that expertise, and we can leverage it. And I'll give you one more, and this is something I know that Dean often comments about. You think of immuno-oncology as strength of oncology, but we forget about immunology, the first part of immuno-oncology. We are leveraging our immuno-oncology experience now to start to make decisions about how to move into immunology.

We did a deal for Pandion last year specifically driven off of that. There are other areas as Dean often says. On the one hand, you look at something that you turn on in the battle against cancer. When you turn that same thing off, it operates somewhere else in the system, in the immune system.

So immunology is another area where we have expertise. That breadth of experience, I think, gives us multiple areas where we can leverage synergies. But clearly, I also want to take advantage of the strength we have in oncology as an important one as well.

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

Okay. Makes sense. And then the other question we get a lot is just flexing the balance sheet. So as you guys think about that, KEYTRUDA could be one of the largest, most successful drugs ever, \$30 billion in revenue.

You have your internal pipeline, but obviously, as you talked about, you're looking externally to bring additional assets in. But as you think about levering up to essentially do deals to fill that \$30 billion hole, how do you think about the right amount of leverage on the balance sheet and using equity for deals as well? I think that's a high-level question. You guys have fielded (inaudible), too.

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

Well, clearly, I would start with we believe we have the financial capacity, both in terms of the cash we have on hand and the strength of our balance sheet to, frankly, pursue any opportunity or frankly, a series of opportunities that we want to pursue. So that's not a determiner for us.

We have been clear. For the right strategic opportunity, we would be willing to potentially lever up, but nothing's changed in that fact. And as we look forward, it's something we're there.

Equity is a use in funding. Again, we have the luxury right now is we can do things with cash we don't need to do. And as we think about a lot of the smaller things we would look at, you don't need it per se, but obviously, that's something that's always open to us. But we'll do what makes the most economic and strategic sense based on the deals we're looking at.



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

And then, I guess, one more just on the FTC side. You guys touched on this on your 2Q call, but I think there's been a focus on how does the FTC think about health care deals, larger health care deals? Do they want to basically stop all deals from happening? Like how aggressive are they going to be on that front? So from where you sit, do you think deals still can happen in this environment? And how do you think about FTC as a risk to future business development opportunities?

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

Well, I definitely think the FTC environment right now makes it more complicated. But for the right deal, and if you're smart about how you plan it, I still think deals will get done. So I don't think it's going to stop deals from happening, but definitely, the path towards getting deals done is definitely more complicated.

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

Okay. Maybe, Dean, over to you on some of the combination opportunities here for KEYTRUDA. Obviously, protecting that franchise is one of the front and center question for the company.

And so you guys had some data at ASCO. You're working on more combinations, but maybe from your kind of current view, what are you most excited about on the combination opportunity set here? And what should we be focused on forward as we think about that opportunity for the company?

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

So I would just emphasize, we're excited about the combination area. And we think it's important to have multiple bets within the combination area. I would actually emphasize that one of the most important combinations is pembro with surgery. So the push of pembro into earlier stages is going to be very important.

You see a lot of new data that's coming out. There's actually new data coming out in relationship to ESMO about that. That will drive the demand for innovation in how do you administer pembro using 2 active agents, how do you move from an IV setting at a cancer center to something that's more convenient.

Also in the IO-IO spaces, we have a number of checkpoint inhibitors. We have cytokines, and we also have vaccine readouts that should be coming out as well.

In the non-IO sort of space, I would just emphasize, we have Lynparza, Lenvima, but for example, Lenvima, we look at our WELIREG as a way to sort of ask ourselves wherever -- what we learn from Lenvima, how does that position us for WELIREG. What we learned from Lynparza today, how do we think about other DNA repair recombination as well as second-generation PARPs.

And then, for example, in relationship, RAS, what you've seen is the issue of combination for RAS and the combination of a pembro, the person who can make a really good molecule that can combine with pembrolizumab is going to be in a treasured position, not necessarily the first position, but the treasured position. And we're very confident in our RAS program that is advancing in clinic.

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

Okay. One follow-up is just confidence in your anti-TIGIT antibody given the recent Roche data. I know you talked a little bit about this at ASCO. But maybe just high-level thoughts there? And again, when are we going to see the next set of data from your program?



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

Right. So there's 2 points I would emphasize. When people think of TIGIT or any of these other checkpoint inhibitors, there's always a question of how do you position a pembro plus another checkpoint inhibitor.

I would comment that there has been movement in that. For example, PD-1 in LAG-3. So that might make you think there's a better chance of a checkpoint inhibitor with another checkpoint inhibitor.

In relation specifically to the pembro, the details make a difference. The details of -- it is my personal opinion, but also scientifically, there's a different screen of PD-1 and a PD-L1, and not all PD-1s are the same. I would say the same thing in relationship to TIGIT. Our anti-TIGIT, vibostolimab, we're very confident from preclinical and our early clinical studies and what it does and its ability to differentiate from other compounds.

So those data are coming through. I think some of the data are going to be coming through in the late-stage Phase III trials. I think they're somewhere in the 24, 25, 26 range.

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

Okay. Got it. Okay. And then, I guess, just pivoting a little bit over to sotatercept. Probably you touched on this, the importance of that deal for the company. I think we're expecting the first set of Phase III data for that asset later this year, early next year.

So maybe just, Dean, any update on time lines there? And then what are going to be the key -- other than safety, what's the key focus for this first Phase III trial that we're going to do?

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

Always it's safety, but really, it's -- this would be the first disease-modifying drug that is out there. And our effort is to demonstrate that. So the first trial with STELLAR with this 6-minute walk, that is the fundamental primary endpoint. And that is a registrational endpoint.

So we're interested in getting that out there. We'll have other signals and relationship to that, that will inform our other trials. In our other trials, we, for example, try to go into later stages and show time to clinical worsening. So that's very important.

And we also try to go into earlier lines. Right now, we're after a whole bunch of medicines, where we're going to try to go earlier lines. So that first trial is registrational. It will get sotatercept to the PAH, but it will allow us to build off of that. And that data should be coming, as you said, this half of the year with registration if it's positive to early next year.

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

Okay. And would the earlier line trials are -- I know you have 2 more Phase IIIs going on. Are any of those in earlier lines? Or this would require a different -- you'd have to do another Phase III to get to the earlier lines?

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

I'm sorry. So one of our trials is in the same class of people with Class 2 and 3, and it's putting it first line. So that's recruiting extremely well. There's an enormous excitement in the community of physicians and the community of patients. I sometimes use my ability to recruit as what the unmet need. And all of our trials in the PAH space have recruited faster than what we would have imagined.



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

Okay. Maybe, Rob, back to you. I mean, you touched on kind of the margin expansion story here between now and '25. I think a big part of that is the roll-off of the royalties on GARDASIL and KEYTRUDA. So maybe just remind us of kind of the targets? And then how much beyond the royalty roll-off are you able to kind of leverage the profile?

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

Yes. And I addressed this in the opening, but just to restate it. So by 2025, we do expect to see our operating margins to be north of 43%. That's the number we've had out there for a while. We continue to believe we're on track for that.

And in fact, if you look at where we've been over the last couple of years, you have -- and even what we're seeing in '22 based on the guidance we just gave in the second quarter for the full year, you are seeing continued growth in our margins. So in reality, both product mix as well as continuing to drive manufacturing efficiencies and overall simplification is driving margin expansion.

And that's happening independent of what's happening with the royalties. What you're referring to is that we do have 2 important royalties that are going away at the beginning of 2024. The first is on KEYTRUDA. Currently, we pay a 6.5% royalty. That's going to step down to 2.5. And then a few years after that, it will go away. But that big move from 6.5 to 2.5 will have a benefit in the year 2024.

And then separately, we have a 7% global royalty on GARDASIL that goes away at the beginning of '24. So those -- then add on top of what you see is the other benefit we're seeing is the normal shift in our business.

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

Okay. Maybe back to Dean. The other area you guys are involved in is a TROP2 ADC for lung cancer. So there's some combination trials you guys are doing with Astra and Gilead. And then you announced a partnership with Kelun-Biotech here. So where would this drug or combination fit in the lung cancer paradigm as we think of (inaudible)?

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

Well, first of all, I think you emphasized the combinatorial benefit of pembro is one that we use to advance our programs. So our partnerships with Daiichi Sankyo and Gilead allows us to understand what you need in the molecule.

The second is we did announce Kelun, that partnership, but that's a partnership that has been going on for the last 2 to 3 years. In relationship to your specific question about TROP2 and antibody drug conjugates, one can look and say, one would first put it in second line. And then as you had it in second line, you would look at that data and ask at what point do you put it first line?

The second-line data will inform you about the first-line data, but you would not just advance it in terms of second line to first line. There are many other places where TROP2 expression is high in tumors and low in other tumors. So you may [at least] to think about breast cancer and many other cancers. So it's not just about going from second to first line in lung. It's about broadly looking at your opportunity.

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

And how quickly could you guys advance the Kelun program into a U.S. Phase III trial? I know they have some data in China in Phase III. But how quickly could you move to Phase III?



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

We are in the middle of discussing that with the FDA. But by standards of what we've seen in others, we would imagine that, that could happen in the next year or so.

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

Okay. Got it. Okay. I guess the other pipeline asset, which, again, there has been a lot of focus on, again, unfortunately, had some safety issues, but you're still moving forward. And my interpretation from your 2Q comments on islatravir are that you still see a forward path for the drug here, Dean, maybe more so in the treatment setting.

So maybe just give us an update on kind of where those discussions with the FDA are at and then how you're thinking about the opportunity for this drug on the forward here and compare it to where you were maybe thinking about the year...

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

So let me just reemphasize. We have islatravir and other compounds in the NRTTI space. When I was answering that question, it was specifically to islatravir, and we have been working with the FDA.

We envision there is a path. We understand what the effect that we've seen. We've been in conversations with the FDA. I do not want to get ahead of the FDA. But we have had very productive conversations with the FDA, and our partner, Gilead, has been part of those conversations.

The question that you asked me in terms of a path forward in relationship to prevention, it doesn't mean that we're not interested in prevention or that we don't have a path forward in prevention. The question that I was answering is, would I take islatravir or would I take my other compound to prevention. And it may be that I will have to make that choice. And there are many reasons I might take another compound instead of islatravir to prevention.

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

And when would we get a more definitive update on the final decisions?

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

I would say that we would have a discussion with the FDA. We would have a discussion with Gilead. But it's really when there was a decision to restart the Phase II and Phase III trials with islatravir. And I would imagine that, that would be a public announcement.

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

Okay. Maybe just in the last minute, Rob, one more on business development. Just biotech valuations have come back off the lows now. As you think about valuation opportunity set, how are you thinking about it now versus maybe 6 months ago where, again, more depressed valuations? Has there been any change in kind of seller mentality out there?

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

Short answer is no. I mean, I think the seller perspectively, what we're seeing still is an expectation for a premium valuation. And we'll have to see how that plays out over time, but we're not seeing a big shift in the expectations of sellers as of right now.



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

Okay. Well, with that, we're up against time, but, Rob, Dean, thank you very much.

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

Thank you.

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

Great to see you both in person, too.

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

All right. Thanks.

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