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MRK - Merck & Co Inc at Cantor Fitzgerald Global Healthcare Conference

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

PRESENTATION

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

Hi. Good afternoon. Thanks for attending the Merck session here. I have Mike Nally, the CMO of Merck. And we're going to a fireside chat. But before we begin, I wanted to see if you had any opening comments or remarks.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

No. I mean it's just wonderful to be here. Thanks for the opportunity, and look forward to a good conversation.

QUESTIONS AND ANSWERS

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

Okay. Great. So the first question I had for you is there's a talk about leadership succession, and I'm curious, any comments from that front? And then the other thing that people ask me a lot is, is transformational M&A possible without a new CEO?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Well, I think your fundamental question is one that our Board of Directors are spending a lot of time on and given, obviously, very careful consideration. Ken has kind of come up on his -- what was previously his stated retirement age of 65. However, last year, the Board removed the mandatory retirement age and they did so largely because there's great momentum within the business. And in many respects, I think the feeling was having an artificial date for a transition was not necessarily the right thing for the long-term success of the business. And so by removing that, it allows them to make the best choice at the right time. Very clearly, they're considering both internal and external candidates. But I think what is a certainty is I think everyone feels good about where Merck is today and the opportunities that we have in front of us.

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

Okay. Great.

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

And do you want me to touch on the M&A thing as well?

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

Yes. Yes.



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Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

I think from the M&A side, as a team, we've spent a lot of time thinking about both the organic growth opportunity and the inorganic opportunities in front of us. And there is a general sentiment that right now our research labs are working really well. Over the last 5 years, and certainly since Roger joined the organization, a lot of focus and emphasis has been on getting discovery research working again. But also really fine tuning our ability to execute from a clinical development standpoint.

And the conversation we have within the company is, as you think about different M&A alternatives, there is a cost of doing a large transaction. We live through it in the merger of Merck and Schering-Plough. Often times, you're assigned to spend a couple of years prioritizing a portfolio. And often times, they spend a lot of time worried about what their job is post that merger. And we feel really strongly that the best use of our scientists' time is to develop the next-generation of breakthrough therapies.

And so we're probably less inclined on the bar scale transaction, but I think everything else is really fair game. And we spend an extraordinary amount of time trying to find the right assets where we think Merck can uniquely contribute from a scientific standpoint to create value for our shareholders.

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

Okay. Great. And then in terms of deal size, what's your appetite for bolt-on versus large-scale deals? Or you don't look at it like that? And then would you consider a large transformational deal during an election year? Or do you think that will draw too much political attention?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

We have the financial ability to do all ranges of transaction. So it isn't a question of the -- necessarily the size. All of it always comes back to the quality and does this help Merck create greater value going forward. And that's why, again, the large stuff hasn't made a ton of sense for us. But we look at everything else in between, and it's just a question of finding out the right asset at a fair price.

And I think the market reality that we've been looking at, Louise, has been one in which premiums that are being demanded by sellers are high. The access to capital for biotech is very easily accessible. And so in many respects, it's a question of do we see great science? If we see great science, we're not afraid to pay for great science. We just did so with the Peloton transaction we did earlier this year. But often times, finding that right interception is really important for us.

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

Okay. Any questions from the audience? Okay. Next question I had for you is, do you have any thoughts on what's on the table for what Trump could say tomorrow regarding drug pricing?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

I never make those sort of broad proclamations. I think the reality is as we go through this election cycle, there's going to be a lot of noise. We recognize that whether that be on the Democratic side, on the Republican side, within the executive office, drug pricing is a topic that catches voters attention. And when we look at the different initiatives that are coming out of Washington, clearly we've seen Pelosi's version, we've seen the Senate Finance Committee's version. We've heard a host of different things out of the Trump administration.

The thing that we orient to is the real true and fundamental challenge around patient out-of-pocket cost. And there is a real affordability issue within the U.S. And as a company, we are very supportive of anything that ultimately supports lower out-of-pocket cost. And when you think about

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our industry and the supply chain of our industry, the fact that the difference between gross to net prices for us is somewhere between 40% and 50% in a given year. There's a lot of value that isn't being passed on to the end user.

And a company like ours would be very willing to sit around the table to try and find a constructive solution that ultimately lowers those out-of-pocket cost.

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

Okay. One of the other big questions that we get is how you expect to grow through potential generic competition for KEYTRUDA that's coming at the end of the decade?

And also if we should assume that oncology will continue to be your most important franchise going forward? Or could that change to some of the other products you have in your pipeline?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

I'm just glad that we're past the JANUVIA patent expiry question. I mean, in many respects, from a company perspective, we're extraordinarily blessed to have the KEYTRUDA opportunity in front of us. This is truly a once in a generation opportunity, where -- and every tumor type we seem to explore, there's a real clinical benefit. And in many respects, that is creating a huge bolus of investment, but the returns are considerable. And we're lucky to have a 10-year window before the first patent on KEYTRUDA expires.

So from a company perspective, we're trying to do what we do in all these sort of cases. We're starting with the science and we think we've got some fabulous opportunities. Certainly, not just with KEYTRUDA, but with our partnerships with Lynparza and Lenvima. There's been great opportunities for both in the PARP class and the TKI's. We have another 20 different novel mechanisms in oncology that we're looking in combination. In addition, within the 1,050 studies that are outstanding for KEYTRUDA right now, around 600 of those are in combination. And so we're seeing the breath of oncology and we're seeing where new promising ideas are sprouting up. And it gives us an opportunity to add those to the portfolio in the future.

But beyond oncology, we have a real great opportunity in vaccines. We have the opportunity with GARDASIL to continue to grow well beyond the key KEYTRUDA expiry. But also a rich pipeline with pneumococcal vaccines, RSV vaccines, CMV vaccines and dengue vaccines that we think will make a contribution within that window. And our HIV molecule that we're studying right now truly has the chance to change the underlying transmission dynamics in HIV.

And from a treatment perspective, but also from a prophylactic perspective, we think that will have a meaningful impact. And that's just kind of the stuff that we see today. If we go back 7 years ago, we wouldn't have been talking about KEYTRUDA in this way. And so one of the great things about a company like Merck is, our basic research sites are as productive as they've ever been right now. And there's a lot coming through those sites today and we think that also helps carry us forward. But on top of that, we'll also be active externally, and we recognize that all the science in the world isn't happening within Merck and we'll stay active and vigilant on the business development front.

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

Okay. Great. How do you view competition to KEYTRUDA from upcoming trial readouts in 2020 and beyond? And how hard is it for this data and new potential treatment to take share away from KEYTRUDA?



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Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Well, I think as we saw just this past weekend, right, I mean, there are going to be a lot of trials and a lot of trial readouts in the I-O space over the next decade. There's this much investment going there as anywhere and KEYTRUDA has a big target on it, but it also has a very high barrier to entry. The wall of data that has been generated around KEYTRUDA is quite substantial.

In lung cancer, 5 studies with positive overall survival data creates a really big competitive barrier. It becomes a lot harder to do studies because the emerging standard of care is no longer chemotherapy in many of these tumor types. It actually is KEYTRUDA. And so we feel that we're not resting on our laurels. We continue to prosecute KEYTRUDA in a number of different settings. A big opportunity for us is to move earlier in the treatment continuum and you're seeing that with some of the neoadjuvant and adjuvant data. But we're also still exploring many of the most significant tumor types like prostate cancer with KEYTRUDA. And then in novel combinations, we think there's a lot of room to go.

But I think the thing that gives us the best competitive positioning is oncology is a data-driven market. The data for KEYTRUDA has been remarkably consistent and reproducible across tumor types. I think ultimately that gives us the best competitive position.

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

Okay. Any questions from the audience? Okay. Another question I had for you is on China. So how do you think regulatory changes there could impact the competitive landscape? I know you're not as much involved in generics, but there's also the NRDL. They're going to make it more frequent. How do you expect it to play out for you from a pricing perspective there? And what are your -- some of your big products that you're excited about?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Yes. So we've been one of the prime beneficiaries of kind of the modernization of the regulatory processes in China. Very clearly, as we've seen regulatory reform and harmonization to much of the Rest of the World, the Merck portfolio has disproportionately benefited.

We joke internally sometimes. It took us 10 years to get GARDASIL 4 approved in China. It took us 9 days to get GARDASIL 9 approved. And while that's the extreme case in terms of the regulatory changes, it's something that we're seeing more consistently that the time lines between introduction in the United States or Europe and China are contracting.

And so our portfolio is rapidly skewing toward an innovative portfolio and I think that's what differentiates us from many of the other competitors in China, between GARDASIL, between KEYTRUDA, between the recent NRDL listing for JANUVIA that's what's fueling our growth. In the second quarter of this year, we sold roughly \$750 million in China, and the business is growing 51%. And a lot of that is fueled off of the introduction of GARDASIL, the introduction of KEYTRUDA, broader access for JANUVIA.

And I think with -- you've maybe even seen this morning, KEYTRUDA monotherapy in first-line lung was just approved. And so we're seeing the steady drumbeat of new approvals that gives us a lot of hope for the future. And the GQCE dynamic, to be honest with you, is exactly what we would want from any global healthcare administrator, free up room for innovative medicines by squeezing the later life cycle off patent medicines. And so that is ultimately the lifeblood for an innovative company like ours.

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

Okay. Another question I had for you is how do you think you can effectively garner share from local players? A lot of them also have less expensive products than you. What have you seen so far there?



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Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Again, the most important thing in China is data matters. In a therapeutic area like cancer, the fact that we have this robust data set that has consistently shown overall survival benefit and then I think when you look at the heterogeneity of the data across other players, people with the ability to access KEYTRUDA, want KEYTRUDA because of that data.

And so our best form of defense is to make sure people understand the survival benefits that we've been able to generate and compare those relatively to everyone else's data that's been generated. And the challenge that many folks are having is that as time goes on, as the standard of care changes, it's going to be harder to run these trials because the standard of care is changing. And so for us, in China or in any market, the quality of our data is going to be our best defense.

Unidentified Analyst

A lot of companies have exposure to the biosimilar markets. What are your thoughts on the biosimilar markets and Merck's exposure there or lack thereof?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Well, we have a partnership with Samsung for biosimilars. And again, I think much like my comments on QCE, the reality is, is that a vibrant biosimilar market ultimately is a good thing for an innovative company like Merck. Clearly, we are a company that is very balanced in our view of the biosimilars, where we want robust intellectual property protection during the patented segment. But ultimately, we believe that for markets to be vibrant, there is a time. And then, ultimately, you want to see uptake of competitive alternatives. And so we take a very balanced view. We recognize that the fundamental challenge facing health care globally is a sustainability challenge. Health care spending as a percentage of GDP in every market around the world is growing too fast. And biosimilars provides an alternative to create headroom for the next wave of innovation, which will ultimately be the lifeblood of a company like ours.

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

Any other questions? Okay.

Unidentified Analyst

Just talk about how you guys are looking to adjuvant markets broadly? And how big the adjuvant market is relative to current market potential?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Yes. Well if you look across most major tumor types, the vast majority of diagnosis occurs in earlier stage disease. And so for us, this is a natural evolution of kind of the studying of KEYTRUDA. And for us, right now, we have over 100 trials underway in the adjuvant and neoadjuvant space across most of the major tumor types. We're looking at KEYTRUDA in combination with existing standard of care, and we think it's going to be a very sizable opportunity for us.

You saw the data over the weekend in the triple-negative breast space where we're showing a real substantial improvement in PCR, which is a very good signal for our longer-term survival. And so for us, the real benefit of going into adjuvant and neoadjuvant therapy is, ultimately, if you're able to get to cancers earlier, you radically change survival rates.

And so we see this as a natural extension, but one that is additive to the kind of current business in the metastatic setting.



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

Okay. Another question I had for you is what makes vaccines an attractive asset for you? And what kind of investments are you making behind vaccine?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Well, I think the vaccine market is something that Merck has had a long-standing history in. And one of the things that makes vaccines attractive is, ultimately, if you can prevent disease, you have a very attractive proposition to health care authorities around the world. And our organization, historically, under the leadership of a gentleman named Maurice Hilleman, came forth with basically the majority of the ACIP recommended immunization schedule. And the work of Dr. Hilleman saves millions of lives a year around the world.

And so one of the things that really is attractive about this business is, clearly, the public health impact is enormous. But beyond that, the characteristics that are really attractive is the competitive intensity is fundamentally different. The barriers to entry are substantial. The capital intensity is huge. And ultimately, if you can find that standard of care, these are long-lived assets.

We're celebrating the 35th birthday of Pneumovax. We're talking about 40 years with M-M-R. These things have long life cycles that provide lasting and substantial revenue streams for a company like ours.

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

Any questions? Okay. Maybe following on that. Just on GARDASIL. Where do you see additional growth opportunities for this asset? And how long do you think this growth will persist? Is it the next 3 years, next 5 years?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

We're just scratching the surface with GARDASIL. When you look globally of the eligible cohort for HPV vaccination, we're roughly at about 5% coverage. And so when you think about all of the data and what we're learning around HPV vaccination, the data out of Australia has spoken loud and clear to public health agencies. When you're showing real reductions in precancerous markers across different cancer types that account for roughly 5% of global cancer cases, you've got a really strong proposition. And the fact that GARDASIL 9 protects against 90% of cancer cases -- of HPV-related cancer, I should say, gives us a real strong play to vaccinate both men and women against HPV-related disease. In many parts of the world now, there's a recognition that the head and neck cancer cases for men are surpassing cervical cancer cases. That's in the developed world.

And so gender neutral vaccination is coming to the fore as well as this general longer-term shift from GARDASIL 4 to GARDASIL 9. And so when we think about the aggregate opportunity, we're still very much in the early days. There's still a long way to go. And every market around the world maybe save a couple, the coverage rates are far too low. Gender-neutral vaccination is only in a handful of markets right now. And so we see a huge frontier for GARDASIL. And what we're really trying to balance is this tremendous opportunity with a very real capacity constraint. The market had stagnated where the aggregate dose output was roughly flat for about 5 years.

Upon the publication of this Australian data, the market took off. We're maxing out our existing facilities to serve as many people as possible around the world, but we're also investing carefully in additional facilities. We think we'll be able to grow GARDASIL over the next couple of years. But when the new facilities come on in 2023, we hope to have capacity to serve the world's needs.

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

Okay. And then another question here, also on vaccine, is PCV. It's one of the largest vaccine markets. And I'm curious, your 114, 116, what's your go-to-market strategy in light of the fact that there are other people looking to enter the market as well with new vaccines?



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Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Yes. I mean very clearly, we have a very formidable competitor in the pneumococcal market, right? That market has been built and shaped by a very well entrenched competitor. We believe that V114 offers protection against some very important additional serotypes that will broaden the utility over the current standard of care.

We recognize there are other potential entrants, but what we really focus in on is, do you generate a very balanced immune response that confers a level of protection against all of the serotypes within your vaccine? And we've been able to successfully do that in both the pediatric and adult market with V114. We'll wait and see what our competitors data set shows. But we recognize that given the huge potential around the world, this is a very attractive opportunity. And it's just our first foray into the conjugated space because we'll have follow-on vaccines in both the adult and pediatric markets that will extend our coverage even more completely.

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

I also wanted to ask you something that people come to me a lot on is, do you feel that you have all the assets and R&D that you need to bring you into the next decade? Or do you think M&A is a necessity for Merck?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Well, the fact that we only comprise less than 1% of global R&D spend, we'd be foolish not to think that there's a lot of great science occurring outside of our walls. Very clearly, no one entity will ever be able to kind of create an armamentarium that would dwarf the rest of the world. And so we recognize that partnership is a fundamental tenant to our strategy.

Last year, we did 60 different transactions with external partners from a business development standpoint. Some of those brought in more sizable assets, later-stage assets. A lot of them are early-stage technology partnerships. But in addition, as I mentioned earlier, one of the great things about something KEYTRUDA is we're studying now with everything else. And so we're getting really good insights in terms of what's working and what's not working in the oncology space.

And so we very clearly will be doing a sizable number of transactions going forward. It's about -- always about finding the right opportunity, but we recognize we're not going to advance the scientific agenda on our own.

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

Okay. Any other questions from the audience? Okay. I had a question for you on Animal Health. It seems like you're one of the few large-cap pharma companies that finds it to be a core asset for you. And why does it remain important to you? And what would change your mind about keeping Animal Health within the organization?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Well, I think the Animal Health business for us -- the question we ask ourselves consistently is, is Merck the best owner of a given business? And can we regenerate market-leading returns for a given business? And I think with our Animal Health business, we've shown that, in Merck's hands, our business has grown faster and has had a margin structure that is among the best of any Animal Health company. And within that, a lot of it is based on some of the synergies that flow from the pharma to the Animal Health side, and vice versa.

And we see that business as a business that we can continue to be a privileged owner of, and which we think we'll continue to have kind of industry-leading growth prospects and cash flow generation prospects. We believe that the innovation in the pharma side helps Animal Health --



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the innovation in the Animal Health side helps businesses like our vaccines business because there's a sizable vaccines business in Animal Health. And as a result, over the long-term, we think it's a really good fit for our portfolio.

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

Okay. Okay. I had a question for you on MK-8591. How do you expect to differentiate yourself in a market that seems somewhat crowded? And what would your go-to-market strategy be for this asset?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

Well, MK-8591 is just an amazing, amazing compound. This is going to be a very unique offering in the HIV space and what is really unique about it is it's extraordinarily potent. It penetrates the tissue in a deep manner. And ultimately, we believe it will help in terms of forgiveness as well as be very amenable to long-acting formulations in partnership with other molecules. We think it will have utility in both the treatment and the PrEP space.

And as a result, our focus is on finding the right partner molecules especially in treatment. It's thinking about the right delivery systems in terms of the long-term prophylactic use. But very clearly, if you look at the existing HIV market, one of the things that I think you're alluding to is that, in a clinical setting -- clinical trial setting, it's very difficult to improve on efficacy. But what we do know is in the real world, a substantial number of patients do not take their medicine on a regular basis. Given the fact that most individuals diagnosed with HIV are between 20 and 40 years old and they've got 50 to 70 years potentially of ongoing treatment, missing doses could create major issues from a resistance standpoint or from a disease outcome standpoint.

And so because of 8591's characteristics, we think we addressed some of those fundamental issues that may show better real world efficacy than existing regimens. And also avoid some of the liabilities of the existing backbone therapies.

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

When -- from a timing perspective, when could we see some more announcements from partnership?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

We're working on it on a daily basis in terms of the clinical program. I think we think there are probably some unique internal assets that we can partner with it. We aren't opposed to finding the right external assets. It ultimately comes down to -- the first entrant will be with doravirine, our NNRTI, but we're also looking at different integrase combinations as well as different delivery systems.

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

Okay. Maybe in the last few seconds I just wanted to ask you, as you look out into 2020, broad strokes, what are you excited about? What should we be looking for? What's the focus of the company next year?

Michael T. Nally - *Merck & Co., Inc. - CMO & Executive VP*

I think we're really excited about the innovation agenda that's occurring. The momentum that we're seeing with KEYTRUDA, all of these new tumor types is a real strong foundation. We see the partnerships continuing to perform very well with Lynparza and Lenvima. Our Vaccine business continues to have great momentum. Our Animal Health business is strong. And so we see a really good momentum.



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At the same time, we see huge opportunities within our clinical space to invest. We are still riding this enormous wave of opportunity from a clinical development perspective, that with very good investment choices, we're going to make those right choices that will ultimately help us drive the long-term growth profile for the company.

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

Okay. Any final questions for Mike?

Unidentified Analyst

(inaudible) competitor say [above 400 million] is Merck. The question is how (inaudible) development of drugs against the prices you have reached, which companies have to charge, is so high. Do you see any developers there in terms of -- I mean price of the new drug, which is very expensive, to development?

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Well, I think you're hitting on one of the fundamental challenges of our industry, right, is the cost of developing a new drug continues to go up, and yet the -- in reality, the amount of return for any new molecular entity is going down.

I think from our perspective, what we're focused on is trying to find molecules with differentiated attributes that allow us to add differential value to the overall health care system. And then finding what is the right fair share for Merck to receive in that context?

And as I said earlier, in the United States, we've got to find a way to lower out-of-pocket costs for consumers. That is something we speak with government authorities on a daily basis about. And it's something that if we don't solve, the industry will continue to be under great scrutiny well beyond the current election cycle.

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

Anything else? Okay. Great. Thank you very much Michael.

Michael T. Nally - Merck & Co., Inc. - CMO & Executive VP

Thanks, Louise. I appreciate it.

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

Thank you.



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