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MRK - Q2 2017 Merck & Co Inc Earnings Call

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## PRESENTATION

**Operator**

Good morning. My name is Darla, and I will be your conference operator today. At this time, I would like to welcome everyone to Merck's Q2 2017 Sales and Earnings Conference Call. (Operator Instructions)

I would now like to turn the call over to Teri Loxam. Please go ahead.

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**Teri Loxam** - *Merck & Co., Inc. - Vice President, Investor Relations*

Thank you, Darla, and good morning. Welcome to Merck's Second Quarter 2017 Conference Call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our Chief Financial Officer; Adam Schechter, President of Global Human Health; and Dr. Roger Perlmutter, President of Merck Research Laboratories.

Before I turn the call over to Ken, I'd like to point out a few items. You will see that we have items in our GAAP results, such as acquisition-related charges, restructuring costs and certain other items. You should note that we have excluded these from our non-GAAP results and provide a reconciliation of these in our press release. We have also provided a table in our press release to help you understand the sales in the quarter for the business units and products.

I would like to remind you that some of the statements that we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provision of the U.S. Private Securities Litigation Reform Act of 1995. Such statements are made based on the

current beliefs of Merck's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Our SEC filings, including Item 1-A in the 2016 10-K, identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck undertakes no obligation to publicly update any forward-looking statement. You can see our SEC filings as well as today's earnings release on merck.com.

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

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

Thank you, Teri, and good morning, everyone. Merck delivered sound operational results in the second quarter with growth on the top and bottom lines. We are confident in the underlying strength of our business, driven by our focused execution of key product launches, coupled with the continued contribution from our core businesses, which we believe position us well for the remainder of 2017 and the long term.

Changing gears for a moment. Let me speak briefly about the cyber attack on June 27, which, as you know, affected Merck along with many other global companies. The attack impacted our worldwide operations, including manufacturing, research and sales. However, the cyber attack did not have any appreciable impact on our second quarter results. Overall, full recovery from the cyber attack will take some time, but we are making steady progress.

Now getting back to the core of our business. We are excited by the just-announced oncology collaboration with AstraZeneca for a number of reasons. It expands our oncology leadership into the exciting targeted therapies of PARP and MEK inhibition as monotherapy and combination treatment, including with KEYTRUDA, which itself is a foundational treatment in both settings. It also gives us an opportunity to collaborate with our industry colleagues at AstraZeneca on a derisked basis on the development and commercialization of a first-in-class innovative cancer medicine, Lynparza, for multiple tumor types.

The deal structure is strong, with a considerable portion of the payment contingent upon the achievement of significant regulatory and sales milestones, and it enables us to maintain a healthy balance sheet with the flexibility to enter into additional business development deals. This oncology collaboration is an exemplar of the type of business development we find most attractive and will continue to look for going forward.

And now I'd like to turn the call over to our Chief Financial Officer, Rob Davis.

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**Robert M. Davis** - *Merck & Co., Inc. - CFO & EVP of Global Services*

Thanks, Ken, and good morning, everyone. Continuing on our momentum from the first quarter, we delivered another quarter of strong results in both our Human Health and our Animal Health businesses. Our continued product launch execution, coupled with effective expense management in the quarter, drove sales and EPS growth despite the continuing significant impact from generic competition.

Total company revenues were $9.9 billion, an increase of 1% year-over-year. Excluding the impact of exchange, second quarter revenues grew 2%. Our Human Health business grew 2% excluding exchange while our Animal Health business grew 7% excluding exchange. Animal Health growth was driven by continued strength in our companion animal business, primarily BRAVECTO, and the contribution from the Vallee acquisition.

Looking at the other parts of the P&L. Non-GAAP gross margin was 77.6% in the quarter, an increase of 190 basis points versus the second quarter of 2016. Favorable product mix, driven by KEYTRUDA and ZEPATIER, was the largest factor contributing to the year-over-year improvement. Non-GAAP operating expenses of $4.2 billion were 2% lower year-over-year, driven by a decrease in R&D, partially offset by an increase in marketing and administrative expenses. Decreased licensing costs drove the year-over-year decrease in R&D spend. Recall that our second quarter 2016 results included an upfront payment of $200 million for the Moderna licensing transaction. Adjusting for that transaction in 2016, R&D would have grown modestly. Taken together, we earned $1.01 per share on a non-GAAP basis, up 12% excluding exchange.

Now turning to the 2017 guidance. While we've had a very strong first half of the year, as Ken noted, we are still recovering from the cyber attack. As a result, we have been conservative in our guidance ranges, which we believe encompass anticipated downsides scenarios. Given the operational strength and the more favorable exchange environment, we are narrowing and raising our revenue range for the full year. We now expect revenues to be between $39.4 billion and $40.4 billion, which includes an approximately 1% negative impact from foreign exchange using mid-July rates. While we originally anticipated a moderate year-over-year increase in our gross margin percentage, we now anticipate some additional favorability to this rate, driven by favorable product mix and lower-than-expected discards.

We now expect our non-GAAP operating expenses to grow at a mid-single-digit rate compared to full year 2016, driven by continued investment in R&D, increased resources behind our ongoing launches, remediation expenses related to the cyber attack as well as additional R&D costs associated with our new oncology collaboration with AstraZeneca. We continue to expect the full year non-GAAP tax rate to be in the range of 21% to 22%, and we continue to project average diluted shares outstanding of approximately 2.75 billion for the year.

Taken together, we continue to expect non-GAAP EPS to be $3.76 to $3.88. While we are leaving our EPS guidance unchanged, the strength of the business has allowed us to absorb the potential impact from the cyber attack as well as modest dilution from the AZ collaboration. Also, our range includes an approximately 1% negative impact from foreign exchange using mid-July rates.

In summary, our second quarter results demonstrate continued strong operational performance, driven by our ability to deliver value through prioritization of resources and execution on our launches that will contribute to long-term growth. While we work to fully remediate the temporary impact from the cyber attack, we remain confident that the underlying fundamentals of our business continue to be strong.

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

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**Adam H. Schechter** - *Merck & Co., Inc. - EVP & President of Global Human Health*

Thank you, Rob, and good morning, everyone. This morning, I'll provide highlights on the performance of Global Human Health for the second quarter, and my comments will be on a constant-currency basis.

Global Human Health delivered another solid quarter. Worldwide sales of $8.8 billion grew 2%, with contributions from launched products, including KEYTRUDA, ZEPATIER and BRIDION as well as our vaccine portfolio, more than offsetting the continued impact from LOEs. We also had another strong quarter outside of the U.S. with growth of 8%.

I'll highlight a few of our key franchises and product launches, starting with KEYTRUDA.

We continue to build our leadership position in immuno-oncology as we execute on the great opportunity we have with the launch of KEYTRUDA. In the second quarter, we added to our momentum with 4 new indications in the U.S. and an additional indication in Europe. Sales grew to just over $880 million, a very significant increase over prior year.

In the United States, KEYTRUDA sales continued to build across multiple indications, with lung cancer now contributing to roughly half of the sales. Sales in the fourth quarter -- or sales in the second quarter also reflect favorability of approximately $40 million due to the timing of customer purchases. In first-line lung cancer, KEYTRUDA is the only approved anti-PD-1 therapy, and we've seen a strong adoption of KEYTRUDA as monotherapy in high PD-L1-expression populations. And KEYTRUDA has quickly become standard of care in that setting. While still early days for KEYTRUDA-ALIMTA combination, feedback from oncologists has been positive following the FDA approval in mid-May. In fact, the combination was added to NCCN guidelines a couple of weeks ago as a recommended therapy in first-line non-squamous lung cancer regardless of PD-L1 status.

We've also started to see a greater contribution from lung cancer outside of the U.S. KEYTRUDA is now approved in the first- and second-line lung cancer settings in more than 60 countries. We continue to achieve reimbursement in more markets, and we are seeing a steady increase in patients being tested for PD-L1 status. In addition to momentum in Europe, we've also seen strong uptake in both first- and second-line lung in Japan. That follows our launch in the first quarter.

Outside of lung cancer, KEYTRUDA continues to be the leading anti-PD-1 therapy in metastatic melanoma in the United States and in many markets around the world. We've also seen strong launches across bladder cancer, head and neck cancer and classical Hodgkin lymphoma as well as early interest in MSI high, the first tumor-agnostic indication. We are excited about the continued growth of KEYTRUDA across indications. We believe our breadth of approved and future indications across tumor types will continue to establish KEYTRUDA as a foundation for the treatment of cancer.

In addition, we are very much looking forward to collaborating with AstraZeneca in oncology, as announced yesterday. We believe Lynparza can be a very important product in different indications over time, and the combination of our proven commercial success in oncology launching KEYTRUDA with AstraZeneca's strong experience will enable us together to make this product a tremendous success.

Moving now to JANUVIA. Global sales for JANUVIA franchise were $1.5 billion, a 7% decline, primarily driven by the U.S. In the second quarter, we saw solid volume growth of 3% in the U.S., but we also saw continued pricing pressure as we've discussed before. There was also lower inventory levels being held in the channel. JANUVIA continues to maintain DPP-4 leadership and to be a preferred add-on after metformin. We look forward to the opportunity to broaden our diabetes portfolio with the SGLT2 inhibitor monotherapy and in combination with JANUVIA partnered with Pfizer that has a PDUFA date at the end of this year.

Moving now to our vaccine business. Sales of $1.4 billion grew 11% due to strength in GARDASIL and approximately $70 million of sales from the terminated joint venture with Sanofi. In the United States, GARDASIL continues to see good underlying demand with very strong first-dose coverage rates. But we're starting to see some impact from the transition from a 3-dose to a 2-dose regimen. GARDASIL sales outside of the U.S. grew this quarter, primarily driven by the JV termination.

Moving now to Hospital and Specialty. Successful launches of ZEPATIER and BRIDION more than offset declines in CUBICIN, REMICADE and ISENTRESS. ZEPATIER sales reached nearly $520 million, driven by strong underlying demand in the U.S., Europe and Japan. We will continue to focus on expanding ZEPATIER's utilization globally, but recognize that uptake may be impacted by the ongoing decline in overall patient volumes in many markets and the increased competition. BRIDION had another good quarter with growth of more than 40%, driven by strong demand across ex-U.S. markets and the continued success of the launch in the U.S. The U.S. remains the largest opportunity for BRIDION moving forward.

In closing, we drove solid performance across many products this quarter, delivering growth despite a more than $800 million headwind from loss of exclusivity. We continue to execute well on our product launches, and we look for additional opportunities across our broad portfolio to drive growth through the remainder of 2017.

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

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Thanks, Adam. As Ken has outlined, the malware that infected our computational environment had a very substantial effect on our activities during the last few days of the quarter. However, in the following weeks, through very substantial efforts by both IT and MRL personnel, we've been able to maintain our clinical trial execution plan. And although there's still a great deal of restoration work to do, we continue on track to complete previously outlined priorities for the year.

During the second quarter, we had the opportunity to see the results of REVEAL, our 30,000-patient study testing whether anacetrapib when added to optimal care could reduce the risk of major cardiovascular events, composite of cardiovascular death, myocardial infarctions and coronary revascularization, as compared with the placebo control. The study was conducted by Oxford University and was distinguished by the long duration of the trial, permitting careful analysis of treatment effects over a period of years, and very complete follow-up.

As we announced earlier, the REVEAL study met its primary endpoint. The actual data will be presented at the European Society of Cardiology congress next month. We also plan to review the results of the trial with external experts, and we'll consider whether to file new drug applications with the FDA and other regulatory agencies.

Also during the second quarter, we obtained the results of our second Phase III study documenting that doravirine, when administered with lamivudine and tenofovir, was non-inferior to a similar Efavirenz-containing regimen with respect to the proportion of participants with HIV-1 RNA levels less than 50 copies per mL following 48 weeks of treatment. In addition, patients treated with doravirine reported fewer neuropsychiatric adverse events and had fewer abnormalities concerned with the protein profiles than did patients treated with the Efavirenz-containing regimen. These results strengthen our view that doravirine will represent an important new element of combination regimens for the treatment of HIV infection. We have a broad program in this area that includes interesting clinical candidates with high potency and long pharmacological half-lives.

I should note that doravirine is not the only important new antiviral in our arsenal. In addition, our cytomegalovirus-directed therapy letermovir, which has been studied for the reduction of CMV disease in patients undergoing hematopoietic stem cell transplant, has been assigned Priority Review status by the FDA with a PDUFA date of November 8th.

Turning to oncology. During the second quarter, we received U.S. approval for KEYTRUDA when used in combination with carboplatin and pemetrexed in the first-line treatment of non-squamous non-small cell lung cancer based on the KEYNOTE-021G study. This same data were also recognized earlier this month by the NCCN Compendia, as Adam mentioned, in guidelines for the treatment of non-small cell lung cancer.

We also gained approval for KEYTRUDA in second-line treatment of urothelial malignancies based on improved overall survival in patients treated with KEYTRUDA as compared with chemotherapy and in first-line treatment of such patients who are ineligible for platinum-based chemotherapy based on overall response rate and the durability of these responses. The Committee on Human Medicinal Products of the European Medicines Agency adopted a resolution in support of these indications earlier this week.

During the second quarter, we also received approval for a broad indication in patients whose tumors harbor an unstable DNA microsatellite profile suggestive of DNA repair deficiencies, irrespective of the underlying histology of the tumor. This approval represents to us a landmark in personalized medicine since it focused its attention on the mechanism of action of KEYTRUDA rather than correlating KEYTRUDA activity with a less predictive surrogate marker, tumor histology.

Separately, 2 late-stage studies of KEYTRUDA in patients with multiple myeloma, KEYNOTE-183 and 185, were placed on full clinical hold by the FDA because of unfavorable imbalances in overall survival that were detected during review by our independent data monitoring committee. While we have not had the opportunity to analyze complete datasets from these studies, we note that our clinical trials of KEYTRUDA often address the needs of desperately ill patients. In some of these situations, especially where novel drug combinations are used, unexpected toxicities may sometimes emerge.

We announced earlier this week that our second-line study of KEYTRUDA monotherapy in squamous cell carcinoma of the head and neck failed to meet its primary endpoint of overall survival. I cannot comment in more detail on this interesting and important study except to say that a detailed examination of the study results will be presented at an upcoming scientific meeting.

I have spoken frequently about the breadth of our KEYTRUDA program, which now includes more than 550 studies, including more than 300 combination studies. I note that we have now received 11 breakthrough designations for the use of KEYTRUDA in the treatment of malignancies, including 4 recent breakthrough designations for the treatment of renal cell carcinoma in combination with axitinib, primary mediastinal B cell lymphoma, Merkel cell carcinoma and for the treatment of high-risk early-stage triple-negative breast cancer in combination with new adjuvant chemotherapy. We are working closely with the agency to determine how best to advance these new indications.

Lastly, we are very excited about our new collaboration with colleagues at AstraZeneca on Lynparza, the leading poly ADP ribose polymerase inhibitor which they have advanced for the treatment of BRCA-mutant ovarian cancer. Recently presented data from their SOLO-2 study demonstrated a 70% improvement in progression-free survival in patients with platinum-sensitive, relapsed, BRCA-mutant ovarian cancer when Lynparza was used as maintenance therapy with a very manageable adverse event profile.

Similarly, data from the OLYMPIAD trial presented last month at the American Society for Clinical Oncology meetings demonstrated that Lynparza treatment improved overall responses in extended progression-free survival as opposed to traditional chemotherapy in women with hormone receptor-positive or triple-negative BRCA-mutant breast cancer who had received prior chemotherapy. Substantial preclinical data support the

view that PARP inhibition, by defeating one compound of the cancer cell's DNA repair machinery, can sensitize tumors to the effects of immune checkpoint inhibitors. Hence, we are very excited to be able to work closely with our colleagues at AstraZeneca, both to explore broader indications for Lynparza as monotherapy and as well as to examine the utility of Lynparza when used in combination with KEYTRUDA to improve the lives of patients suffering from malignant disease.

I'll now turn the call back over to Teri.

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**Teri Loxam** - *Merck & Co., Inc. - Vice President, Investor Relations*

Thanks, Roger. Darla, we're ready to move on to our Q&A portion of the call.

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## QUESTIONS AND ANSWERS

**Operator**

(Operator Instructions) Your first question comes from the line of Alex Arfaei with BMO Capital Markets.

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**Ardalan Alex Arfaei** - *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

A couple on diabetes, if I may, for Adam. How should we think about the rate of price erosion for JANUVIA? And just overall, in terms of your strategy, you developed -- you had biosimilar Lantus approved in Europe in January, and you haven't launched it yet. You developed as a once-weekly JANUVIA but you didn't proceed with it. So I guess, we're all waiting for ertugliflozin. Just help us understand how we should think about how you plan to position that drug given the substantial lead by Jardiance on their cardiovascular benefits data.

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**Adam H. Schechter** - *Merck & Co., Inc. - EVP & President of Global Human Health*

Yes. Sure, Alex. So if you look at JANUVIA, the IMS TRx volume growth in the U.S. was strong. It was about 3%. However, it's not as strong growth as what we experienced last year, which was about 4.5%. I've been saying for a couple of years now that each year, the pricing pressure gets a little bit harder than the year before. And this year is harder than last year, and I expect next year will be harder than this year. It's not discounts on new orders. It's just continuous pressure that builds in the channel, particularly in the United States. As we look forward, we're excited about the SGLT2 and the SGLT2 combination with JANUVIA. I believe that JANUVIA will continue to be the first choice for add-on therapy after metformin, and I think that will remain the case around the world. But a lot of patients still don't get to their HbA1c goals even with metformin plus JANUVIA. So there are many patients where they look to add on an additional oral agent, of which the SGLT2s sometimes are the right product to add. Therefore, I believe having a combination with an SGLT2 with, by far, the market leader in the DPP-4 class will be a competitive advantage for us, and that's why we look forward to launching that with a PDUFA date in the United States later this year.

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**Operator**

It's from the line of David Risinger with Morgan Stanley.

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**David Reed Risinger** - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

I have 3 questions. The first is, could you please provide a little bit more color on the downside scenarios that you factored in for the cyber attack in the second half of the year and also, what guidance would have been if not for the cyber attack? Second, with respect to KEYTRUDA-chemo combo in lung, could you talk about expectations for ex-U.S. approval and launch timing? And then finally, could you discuss the 15-valent pneumococcal vaccine and your level of enthusiasm for that and when we will see data later this year?

**Teri Loxam** - *Merck & Co., Inc. - Vice President, Investor Relations*

Why don't we start with Rob on the cyber modeling. Rob?

**Robert M. Davis** - *Merck & Co., Inc. - CFO & EVP of Global Services*

David, so as you look at the cyber attack, we are still assessing the full impact. And we do not have a specific estimate at this time, so I can't give you the specific downside related to that. But I will tell you we have anticipated there will be temporary delays in fulfilling orders, and we will incur expenditures related to the remediation efforts. However, based on what we know today, we have considered all of those scenarios into the range of guidance we provided, both sales and EPS. So we feel like we've captured the anticipated scenarios in what we've told you. And I think it's also important to point out that despite the temporary challenge of the cyber attack, our operational momentum is strong, which has enabled us to raise our revenue guidance, and we did maintain EPS guidance for the year while absorbing both the impact from cyber as well as the dilution from the AZ collaboration. And then with your second question, would guidance have been higher but for cyber, the answer is yes.

**Teri Loxam** - *Merck & Co., Inc. - Vice President, Investor Relations*

Over to you, Roger.

**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Right, okay. So David, a couple of questions. First, KEYTRUDA-chemo combo in lung outside the United States. Obviously, we're pursuing the registration of the 021G data in a variety of jurisdictions. Haven't provided any updates on this. We are going through the usual motions, and as more information becomes available, we'll certainly let you know. And we're very enthusiastic about V114, our pneumococcal conjugate vaccine. We have already data from a variety of studies, some of which we've had a chance to present, and we hope to be embarking on registrational studies with V114 in not too long a time. So things are moving along extremely well in that area.

**Operator**

It's from the line of Steve Scala with Cowen.

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

Would you provide an estimate of the percent penetration for KEYTRUDA and ALIMTA in first-line lung cancer? And secondly, similar to the deal Merck is doing with AstraZeneca for Lynparza, did you consider doing a similar deal for tremelimumab? And if not, perhaps you could tell us why.

**Teri Loxam** - *Merck & Co., Inc. - Vice President, Investor Relations*

We'll start with Adam.

**Adam H. Schechter** - *Merck & Co., Inc. - EVP & President of Global Human Health*

Yes. So with regard to first-line lung cancer, a couple of things are important. First of all, we are certainly seeing a strong uptake overall. And in the United States, KEYTRUDA is now the leader in terms of market share in first-line lung cancer. With regard to the combination with ALIMTA, we're certainly starting to see some uptake, but it's still too early to give any specific market share for that portion of the business. But as I mentioned on the call, with NCCN recommendation and reimbursement, we think that will continue to be helpful. So we are very pleased right now. About half

of the sales for KEYTRUDA in the U.S. are in first-line lung, and that was the largest increase in terms of a percent of our sales. So we continue to believe that KEYTRUDA will be a mainstay for the treatment of lung cancer first line.

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

And as far as our deal with AstraZeneca goes, we really like the PARP inhibitor and the MEK inhibitor, and that was our primary reason for wanting to engage them in terms of a potential deal. We have our own CTLA-4 in development, and I'll turn that over to Roger for any more comments.

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Yes. I mean, the Lynparza situation and our partnership with AstraZeneca was a very special transaction that reflects the genuine alignment of the 2 companies. With respect to CTLA-4, we have an interest in CTLA-4. We do believe quite strongly that there will be opportunities for a range of different combinations with KEYTRUDA that will improve -- we hope will improve outcomes in individual patients, and it will become very personalized. But we do have our own CTLA-4 antibody, MK-1308. And so there's really no reason under the circumstances for us not to pursue -- we've put a lot of work into developing that molecule. No reason not for us to use that one if that turns out to be the right agent.

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**Operator**

It's from the line of Andrew Baum with Citi.

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

Two questions, please. Firstly, for Roger, could you just outline your longer-term commitments to HIV? It seems that you have many of the building blocks, the legacy business, the Organon business and several promising interesting molecules, such as EFdA. Could you outline the overall strategy there, in particular the plans for EFdA for both treatment and prep? And then second, could you address the question of PD-L1 cutoff for the combination with CTLA-4? When I look at the 021 data with the pembro and YERVOY, it seems to be an inverse relationship, if anything, in terms of efficacy and PD-L1 expression. So how are you thinking about that as you develop your own CTLA-4 for combination with KEYTRUDA?

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Right. Thank you, Andrew. First of all, we see a lot of opportunity to improve therapeutic options in HIV. Of course, I've spent some time talking about doravirine, and we published those data. And we've also put quite a bit of effort into developing, as I mentioned, potent long-acting molecules, which potentially could be given with -- in an unusual formulation, whether that's Depo or something else, to provide a mechanism for infrequent dosing. For EFdA or what we call MK-8591, that molecule has very unusual characteristics. We had the opportunity to present some of the data at the Paris meetings just earlier this week. And first of all, it's enormously potent, but secondly, even single-dose data results in dramatic suppression of viral load that can persist for a long period of time. We actually have the sense that we may be getting at something very important there in terms of the reservoir of HIV infection, but that's for the future for us to investigate on. I just -- I think we're very enthusiastic about the totality of the portfolio to provide better therapy for HIV infection. And with respect to PD-L1 cutoffs, frankly, in the 021 study, the sample sizes weren't large enough to be able to look at different PD-L1 levels and try and infer from that which patients would benefit most. And as you know that -- the data that have become available from others -- including ourselves but also Bristol-Myers from other studies -- have been a little confusing about how best to use the combination of a CTLA-4-directed therapy and a PD-L1-directed therapy. Nevertheless, we continue to study that and to try and develop better indices for which patients would benefit most. The agents are quite different. They have different activities. They have different adverse effect profiles. And we're hopeful that we'll be able to define a patient population that will benefit especially from such a combination.

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**Operator**

It's from the line of Seamus Fernandez with Leerink.

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**Seamus Christopher Fernandez** - *Leerink Partners LLC, Research Division - MD, Major Pharmaceuticals and Biotechnology*

Just a couple of quick questions. Roger, can you talk a little bit about the competitive environment that you see in first-line lung cancer more from an additional data perspective? We know there's a lot of additional clinical studies coming. But just wondering if you could give us your thoughts on the prospect of showing a survival benefit in the KEYNOTE-189 study and its relative importance in the overall landscape. Is it something that you think is likely to be demonstrated and perhaps not demonstrated by other studies? And then separately, Adam, it's our understanding, again, that the first trial coming from the competitor Roche is actually using an Avastin-based regimen. Could you just help us understand a little bit the commercial dynamics that you -- that could either impact KEYTRUDA or perhaps have that be a somewhat understated potential regimen if that trial is successful?

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Right. So Seamus, with respect to the competitive environment, there will be a lot of data coming out for various combination studies -- chemo combination studies, combinations with other biologic agents, et cetera -- in lung cancer. I think the general comment, and just be aware of this, but just to be sure that we highlight it. The general comment is that it becomes increasingly difficult over time to show overall survival differences comparing KEYTRUDA or any other PD-1 or PD-L1-directed agent with chemotherapy because of the crossover problem. In essence, because of the known activity of KEYTRUDA, in particular in the lung cancer setting, patients who would fail a chemotherapy regimen will likely be crossed over. And indeed, one has to -- it is always ethical to pursue studies of a new agent versus standard of care, but the dataset is becoming extremely strong with respect to lung cancer and the power of KEYTRUDA. So that's going to make it difficult over time because patients will be crossed over where studies began some time ago, and we expect that. On the other hand, when you look at what we have achieved previously, for example, KEYNOTE-024 and in other areas, but the hazard ratios for PFS and for OSR are so impressive that there's a real chance that nevertheless, we'll succeed. So we're optimistic about those trials going forward, but we recognize that it does become over -- harder over time because of the crossover phenomenon.

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**Adam H. Schechter** - *Merck & Co., Inc. - EVP & President of Global Human Health*

And this is Adam. So I feel very good about our position in first-line lung cancer today. And if you look at the data that we have, not just as a monotherapy but also in combo with ALIMTA, it's very, very strong. And if you think about the utilization, it's not just in academic centers for treatment of first-line lung. It's also in the community-based physicians. There, they're very comfortable using chemotherapy. So I think the combination of KEYTRUDA plus chemotherapy with the strong efficacy data that we have will continue to be a very strong position for us. Obviously, we have to see what data comes out and what the results would be. But as Roger said, the bar is very high with the data we have, and I feel good about our position in lung today and as we move forward.

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**Operator**

It's from the line of Tim Anderson with Bernstein.

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**Timothy Minton Anderson** - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Analyst*

Can you confirm the timing of KEYNOTE-189 data? Are you confident that we'll see the top line release before the end of the year? And is there any chance that we'll see the full data release in 2017? Second question is going back to your development question -- your development plan with CTLA-4 and with YERVOY specifically. Earlier in the year, you seemed to be leaning towards initiating pivotal trials with a KEYTRUDA-YERVOY combination, and I'm wondering if you've disposed with that or put that on ice. I understand you have your own internal CTLA-4, but it's a

YERVOY-specific question. And then on 021G, is there pushback in the prescriber community just based on the fact that, that's Phase II data? And do you think the Phase III is really needed to open the floodgates in terms of broad utilization?

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**Teri Loxam** - *Merck & Co., Inc. - Vice President, Investor Relations*

Why don't we start with Roger?

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Okay. Tim, with respect to KEYNOTE-189, the -- as always, these are event-driven trials, so as time goes on, we look at events and we ask ourselves when we think the data are going to become available. We do our best to update clinicaltrials.gov and give our best estimate. Our expectation is, based on what we're seeing, that the 189 top line will become available this year. I would think it would be difficult to get the full data out in a scientific meeting just because of the time required, once the top line is available, to actually prepare the material for presentation. But I can't say. It's just -- it's event-driven. And with respect to the KEYTRUDA/YERVOY combination, yes, you're right, I mean, we had -- we've done quite a number of studies and published them with respect to the combination, and we have a -- had discussions with regulatory agencies about a KEYTRUDA-YERVOY combination. Haven't pulled the trigger on it in part because we continue to accrue additional data from others as well as ourselves. And also, as you can appreciate, we've just got an awful lot of studies going on, and we have to prioritize among those in terms of starting time. So that one is on the block, but we haven't yet pulled the trigger on it.

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**Adam H. Schechter** - *Merck & Co., Inc. - EVP & President of Global Human Health*

And then, Tim, this is Adam. So anecdotally, we're hearing very positive comments, and we're hearing the comments on 021G not just from academic centers and physicians but also in the community-based area. And the key is that we have an approved FDA indication and we have NCCN recommendation. So I don't have data yet to support anything other than what we're hearing from the field, but everything we're hearing is positive at this point. And I would expect that the combination will be used increasingly more often as we move forward.

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**Operator**

It's from the line of Chris Schott with JPMorgan.

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

Just 2 here, maybe -- and maybe both for Roger. First, on the PARP deal, can you just -- I appreciate the comments about how you see PARP fitting into the IL landscape. Any tumors in particular where you see the strongest rationale to pursue a combo there with KEYTRUDA? My second question was just on the MYSTIC failure and just some of your thoughts here. KEYTRUDA was obviously able to show a PFS and OS benefit in high expressers. We didn't see that signal with your competitor. Just any thoughts here of this as a trial design issue, PD-1 versus PD-L1 issue or just something more specific to the molecule? Just any comments there would be much appreciated.

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Thanks, Chris. First of all, with respect to Lynparza, as I indicated, the data already for Lynparza are quite robust in the ovarian cancer setting and the recently presented data at ASCO in lung cancer. They have now -- and I guess I should say we have since it's the 2 of us together, 10 ongoing registrational trials in a variety of different areas in 14 different tumor types that are being pursued. There's more than 120 studies, many of which are investigator initiated, but nevertheless, a lot of studies on clinicaltrials.gov. So a lot to pursue. I think one of the things that impressed us in our conversations with our colleagues at AstraZeneca is how well they've thought through the issue of DNA repair defects generally. And as we know, the expectation is that, in tumor cells that have crippling mutations in various parts of the DNA repair process, they should accumulate mutations

which are potential targets for immune cells to recognize. And so the logic behind the combination is as compelling as we see. The interesting thing is that using the kinds of analyses that they've done, we can sift through tumors more directly and ask which ones are more likely to have impediments in DNA repair as a result of PARP inhibition and hence, which ones are more likely to be those that we could benefit by adding KEYTRUDA as well. My sense is that this will once again turn out to be something that is less about histology and more about molecular definition of tumor type, and to me, that's the really exciting part because, again, it represents further personalization of therapy. And then with respect to the failure of the MYSTIC trial, we learned about it at the same time that you did, and we have access to the same material that you have, which is just what has been presented in terms of study design and clinicaltrials.gov. I really -- I have -- I really don't know what the nature of the patient population was in detail. I don't really know what the data looked like, and hence, it's not fair for me to comment. Suffice it to say it was not what they had hoped for in terms of a progression-free survival result, but it's impossible for me to explain why that happened. As you know, when you look at the KEYNOTE-024 data in the first-line setting in a PD-L1-enriched population, the hazard ratio for progression-free survival was 0.5 with a p-value that had 2 zeroes to the right of the decimal point. So that indicates that there's quite a lot of power in that study. And so to really understand it -- and it's not so different from trying to sort through what exactly happened in other studies that haven't been successful, you really need to look very carefully at the patients that were involved, and what their characteristics were, and I'm sure we'll be hearing a lot more about that as the data are presented.

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**Operator**

It's from the line of Umer Raffat with Evercore ISI.

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**Umer Raffat** - *Evercore ISI, Research Division - Senior MD and Fundamental Research Analyst*

Perhaps, first, maybe for you, Roger. I just wanted to zoom in on any important differences in trial conduct, so conduct specifically between 021G and how KEYNOTE-189 is being conducted, perhaps things like whether patients are having to give fresh biopsies, their prior radiation exposure, time from diagnosis to first dose, smoking history, that sort of thing. I just wanted to understand that, number one. And then secondly, on the AstraZeneca deal, a couple of follow-ups. One, how did you think about the Astra PARP versus some of the other unencumbered PARPs in the marketplace? Just wanted to understand your thought process behind finalizing this specific one. And secondly, just for our housekeeping, could you just help explain what will be the biggest trigger of the $6 billion-plus in milestones just so we understand and model the cash flows appropriately.

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**Teri Loxam** - *Merck & Co., Inc. - Vice President, Investor Relations*

Okay. So we'll start with Roger, and then we'll end with Rob on that question.

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

Okay. First of all, with respect to trial conduct of KEYNOTE-189 versus 021G, not a lot to comment on there. I mean the study is pretty straightforward. It's a substantially larger Phase III study but once again focusing, in the same way as we did before, on all-comers in a comparison of carboplatin and pemetrexed with KEYTRUDA combined. So it's -- they're fairly similar kinds of studies in terms of what we're looking at. I don't think there are major differences in terms of trial conduct, but -- to should draw your attention. With respect to the AstraZeneca deal, the question you asked is which PARP and why we want to look at one PARP or another. So let me just tick down that. With respect to Lynparza, let's talk about what we know. What we know is they gained approval, first of all, with their capsule formulation some years ago in a fourth-line setting in mutant -- BRCA-mutant ovarian cancer and have gone on in the SOLO-2 study to show that the new formulation of Lynparza has really a very profound effect. And when you look at that with the central review, a hazard ratio of 0.25 in the maintenance setting for these BRCA2-mutant ovarian cancer patients, that's a very impressive, really very impressive result. And in many cases, because now the molecule has been on the market for some time and has been studied for some time, you have a lot of evidence of durability in that patient population with many patients who've been on for a lot of years. And again, when you look at the OLYMPIAD data, which they presented at ASCO, that the effects in breast cancer were also very powerful. And so when I look at the total weight of data, what we know about the molecule and the ongoing studies, to me, it was just an extremely -- we're

going to -- if we're going to choose a poly ADP ribose polymerase inhibitor to study in combination with KEYTRUDA, it's an extremely attractive molecule and that's, of course, what drew our attention. And I guess, now we have to talk about the triggers, Rob.

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**Robert M. Davis** - *Merck & Co., Inc. - CFO & EVP of Global Services*

Yes. Umer, so if you look, the contingent payments in the deal were about $6.15 billion, and as Ken mentioned in his prepared remarks, we see this as a derisked structure from our perspective. And to that end, if you look at the $6.15 billion, about 2/3 are tied to sales milestones across various sales levels and 1/3 are tied to approval milestones across multiple tumor types.

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**Operator**

It's from the line of Jami Rubin with Goldman Sachs.

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**Jamilu E. Rubin** - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Just a few. Rob, firstly, you posted a $0.14 beat this quarter, yet you didn't raise guidance and understandably due to the uncertainty around the cyber attack. But if you could just kind of share with us what proportion of the absorbing the $0.14 beat for the year relates to the onetime cyber attack and what proportion relates to additional expenses or second-half comparisons or competition that we should be aware of. Secondly, Roger, we now have a handful of PD-1/PD-L1 drugs on the market, and specifically in lung, there are 2 PD-1s and 1 PD-L1. Are you seeing at all or do you believe there is a difference between these 2 agents? There have been interesting -- we've had different outlooks or different results from some of these different trials, some of which have been surprising, some of which haven't been. But just wondering if you could share with us your perspective on whether or not you see a clinical difference between PD-1 and PD-L1? And then just lastly, if you could give us an update on when you plan to initiate your Phase III IDO inhibitor with KEYTRUDA in front-line tumors, including lung. And what would be the comparative -- what are you going to compare that combination with? And does the MYSTIC failure help to guide that decision in any way?

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**Robert M. Davis** - *Merck & Co., Inc. - CFO & EVP of Global Services*

Jami, thanks for the question. I don't want to get into specifics because, as I said in answer to the prior question, we're still assessing the full impact. But what I would say is as we prepared our guidance and, in effect, maintained the EPS guidance while raising sales guidance, we did it looking at a variety of downside scenarios. It's important to note that we have both an anticipation that there will be some expenditures for remediation costs as well as the fact that there could be some sales impacts due to the temporary delays in fulfilling orders for certain products in certain markets. And those are only the items that we have factored in. But beyond that, I don't want to try to split it up because it is really range bound. I would end with just saying we're confident that the guidance we've given should encompass what we see of those anticipated scenarios.

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

And Jami, with respect to the difference between antibodies directed against PD-1 and those directed against one of the ligands, PD-L1, as you know, there are no head-to-head studies, and without head-to-head studies, it's extremely difficult to reason from one to another, as you point out. The clinical results have been variable even in any particular class and, in fact, even for a particular agent. So it's very difficult, I think, to draw general conclusions about is one better than the other. My sense is that there -- it would be not surprising that there were differences just because of the different patterns of expression and because of the fact that there is promiscuity in terms of the ligand relationship, so PD-L2 binding for PD-1 and, similarly, PD-L1 having other ligands besides PD-1. So it would not be surprising, but I don't see clinical data that tell me unambiguously that one is different from the other. Various people sum over the results of the different trials and try and draw conclusions. I think, without head-to-head information, it's hard to know. And secondly, with respect to the IDO1 inhibitor , again, we do have an ongoing Phase III study in melanoma that's been going on for some time. We're continuing to pursue that combination. And the central issue in the -- the central question is, okay, does adding epacadostat actually improve outcomes in a KEYTRUDA-treated population or not? That is the question, and that's the central question that we are addressing in all these other studies. We have, as you know, a lot of small, relatively early studies that suggest that, indeed, it

will. We love the fact that epacadostat is relatively well tolerated and it has a good adverse effect profile, which enables it to partner well. We have good Phase III study designs. Our Phase III study designs will not be affected by the MYSTIC data, which, of course, we've only seen the top line. Because they're already complete, we reviewed those Phase III study designs with the FDA and with other health authorities, and we've begun to socialize those designs with clinical trial sites and get to work on the whole issue of clinical operations and site feasibility and how we actually engineer these things. So we're expecting those studies will be starting very, very soon.

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**Operator**

It's from the line of the Geoff Meacham with Barclays.

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**Geoffrey Christopher Meacham** - *Barclays PLC, Research Division - MD and Senior Research Analyst*

For Adam, just a couple. For first-line lung in the U.S., can you talk a little bit about share and testing trends for monotherapy KEYTRUDA? I suspect that most of the sequential uptick was 021G. But I wanted to check that versus broader adoption from 024. And then, Roger, with all the tumor types you're exploring in KEYTRUDA, is there something specific on myeloma that makes IO less attractive as a strategy? I guess more color on 183 or 185 will be helpful.

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**Adam H. Schechter** - *Merck & Co., Inc. - EVP & President of Global Human Health*

Yes. This is Adam. So if you look at first-line lung, first, let me give you a sense of testing. Right now in the United States, we believe that more than 3/4 of patients are being tested. If you look at Europe, we believe that it's 2/3 of patients are currently being tested, where a country like the U.K. is about 90%, Germany is about 65%. So there's no doubt that we are seeing on a global basis, including Japan, significant increases in testing, and it's really becoming standard of care to test patients for their status. With regard to first-line lung, we are the leader right now in first-line lung for new patient starts, and we have about a 26% overall share, which is higher than any of the other products in first-line setting. And the majority of it, I believe, is based on 024 because we're just in the midst of launching the 021G results.

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**Roger M. Perlmutter** - *Merck & Co., Inc. - EVP & President, Merck Research Laboratories*

And Geoff, it's Roger. With respect to myeloma, probably not too much additional color I can add beyond what I mentioned in the opening remarks. I mean, certainly, we were very sad to see the -- to hear it first from our Data Monitoring Committee and to review the information that was then shared with FDA on the imbalance in deaths seen in the 183 and 185 studies. That, of course, flew in the face of earlier information that we had from Phase I studies in melanoma, which we presented at the American Society for Hematology meeting, suggesting that adding KEYTRUDA to immunotherapy could be very effective. Without having a chance to really look at the data, which -- of course, now we're cleaning and locking databases and we'll really step through all of that. Without being able to see those data, I can't explain what happened. I -- we haven't given up on the idea that there will be opportunities in myeloma, but clearly, the -- we have to look carefully at the accumulated adverse effects that occurred in the context of this combination therapy that's an aggressive therapy used in a very brittle patient population with advanced multiple myeloma.

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**Operator**

Your final question is from Tony Butler with Guggenheim.

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**Charles Anthony Butler** - *Guggenheim Securities, LLC, Research Division - MD and Senior Equity Analyst*

Adam, you alluded to in MSI high for KEYTRUDA that there was initial interest. And I'm really asking if you could just explore what initial interest means. Because it seems like such a broad indication, I would think that a number -- initial interest would be met quite handsomely with open arms. But I'd love for you to explore that and, more importantly, what testing really is on that front, much like for PD-L1. And then Rob, just briefly,

on the expenses related to cyber, are those onetime in nature? In other words, do you have that as a fixed cost for effectively the rest of the calendar year? Or does it actually leak into '18? Would you know that?

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**Adam H. Schechter** - *Merck & Co., Inc. - EVP & President of Global Human Health*

Okay. So let me talk about MSI high just a bit, Tony. So first of all, we're really working hard to increase awareness for MSI testing and the value of KEYTRUDA across the tumor types. And after the June approval, there's certainly health care professional awareness that we're hearing, but it's too early to see that translate into sales. It's really been detected across a lot of different cancer types, some that are uncommon like biliary tract cancer and some that are very common like colorectal cancer. If you look, MSI high, it really is an established biomarker, and it's used often in something like colorectal cancer or endometrial cancer, but it's not really done in many of the other tumor types. So we have still a lot of work that we have to do to educate the importance of testing for those other tumor types. And I would expect, over time, that this will continue to be an interesting and important indication, but it's going to take time to build frankly.

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**Robert M. Davis** - *Merck & Co., Inc. - CFO & EVP of Global Services*

Great. And Tony, thanks for the question. The majority of the expenditures are onetime in nature remediation costs, although I would say that as we move into '18, 2 things. One, the timing of which we're able to get everything remediated is still being worked through, so I think we can't rule out that it could bleed into '18 at this point in time. We just don't know. We'll give more information on that as we move forward. And then, secondly, while the majority of the costs are onetime, I do expect that we will see incremental investment in IT going forward that could drive our expense in that area up a little bit. But I don't see that in a magnitude that would materially change the way we'd look at our overall expense base, and certainly we'll manage that as we look at total expenses and be able to give more guidance on that as we get to the end of the year, looking at 2018.

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

Okay. In closing, we are really pleased with the operational strength that our business has shown in the first half of the year. We think we have great momentum, particularly with our product launches, and we think that positions us very well for the long term.

So thank you for your interest. We look forward to speaking with you in the future.

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**Operator**

This concludes today's conference call. You may now disconnect.

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