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MRK - Q2 2019 Merck & Co Inc Earnings Call

EVENT DATE/TIME: JULY 30, 2019 / 12:00PM GMT

OVERVIEW:

Co. reported 2Q19 total Co. revenues of $11.8b and non-GAAP EPS of $1.30. Expects 2019 revenue to be $45.2-46.2b and non-GAAP EPS to be $4.84-4.94.

CORPORATE PARTICIPANTS

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

Roger M. Perlmutter *Merck Research Laboratories - President*

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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 the Merck & Co. Q2 sales and earnings conference call. (Operator Instructions)

I would now like to turn the call over to Teri Loxam, SVP, Investor Relations and Global Communications. Please go ahead.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thank you, Darla, and good morning. Welcome to Merck's second quarter 2019 conference call. Today, I'm joined by Ken Frazier, our Chairman and Chief Executive Officer; Rob Davis, our Chief Financial Officer; and Dr. Roger Perlmutter, President of Merck Research Labs, who will each have prepared remarks. In addition, I'm also joined by Mike Nally, our Chief Marketing Officer; and Frank Clyburn, our Chief Commercial Officer, who will be available for the Q&A portion of the call.

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 belief 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 2018 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 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. We have also posted a presentation via the Investors section of merck.com which includes some of the highlights from the quarter.

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

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

Thank you, Teri. Good morning, and thank you all for joining the call. Our science-led strategy, together with our clinical and commercial execution drove another quarter of accelerating revenue growth with strength across our global portfolio. Our results demonstrate the continued momentum of our business through the first half of the year and further show that our focus on the kind of innovation that significantly improves health outcome is paying off. As highlighted at our recent Investor Day, we are confident that our innovative portfolio of products and significant pipeline opportunities, supported by unparalleled R&D and commercial execution, will continue to drive strong growth while we invest in cutting-edge science to deliver breakthroughs over the next decade and beyond.

Over the past quarter, we continue to advance our pipeline and presented encouraging data across our programs, including 2 additional regulatory approvals and a filing acceptance for KEYTRUDA, 2 new regulatory approvals in infectious diseases as well as new clinical data on the V114 pediatrics trials, MK-8591 and many others. Our clinical and regulatory progress reflects Merck's unwavering commitment to biomedical research aimed at bringing forward products that can make a meaningful difference in the lives of patients around the world.

In addition, we continue to strategically invest in business development to strengthen our pipeline through value-enhancing external opportunities. This quarter alone, we announced 2 acquisitions that will bolster our oncology pipeline with Peloton Therapeutics and Tilos Therapeutics, respectively. We also successfully completed our tender offer for Immune Design and closed on the acquisition of Antelliq in Animal Health. We remain confident that our strategy, growth prospects, outstanding scientific and commercial talent and leadership team, together with our focus on execution will enable us to drive significant value for patients and shareholders this year and for years to come.

And with that, I'll now turn the call over to Rob to review the details of our quarterly performance. Rob?

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

Thanks, Ken, and good morning, everyone. As Ken mentioned, our performance in the second quarter is a clear testament to the strong momentum and growth potential of our business. Our results over the last several quarters continue to reinforce the confidence we have in our ability to drive sustained long-term revenue growth and meaningful operating margin expansion while maintaining a disciplined capital allocation strategy focused both on investing in the business and returning capital to shareholders.

Now turning to our results. Total company revenues were $11.8 billion, an increase of 12% year-over-year or 15% excluding the negative impact from foreign currency. This growth was led by our human health business, which increased 17% this quarter excluding exchange. Animal Health grew 9% excluding exchange. The remainder of my comments pertaining to sales will all be on an ex exchange basis.

The increase in human health revenues was led by key products in our oncology, vaccines and hospital businesses. In oncology, KEYTRUDA sales exceeded $2.6 billion this quarter, an increase of 63% year over year. Growth was driven by increased adoption globally in the first-line lung setting as well as uptake in recently approved indications. In the U.S., strong demand across all indications continues to drive performance. KEYTRUDA is firmly established as the standard of care for indicated patients in first-line lung and we continue to further penetrate segments of the population,

including low and non-PD-L1-expressing patients. In addition, we are encouraged by our recent launches in metastatic renal cell carcinoma and adjuvant melanoma where we are already seeing strong adoption by oncologists.

We are also excited about our opportunity in first-line head and neck cancer for which we received approval in June. With 20 indications currently approved in the United States, we are further establishing KEYTRUDA as a foundational cancer treatment.

Outside the U.S., KEYTRUDA sales grew 73% driven by lung as we continue to gain reimbursement for the chemo combo in more countries in the EU. In Japan, we are now the leading anti-PD-1 agent, which speaks to our execution and the breadth of our indications. And in China, we have seen very strong growth given the recent launch in first-line lung and continued uptake in melanoma. And our growth should continue as we reach more patients and expect to launch additional indications.

KEYTRUDA is changing the way in which cancer is being treated, and we are still in the early days of the KEYTRUDA journey. We remain very confident in the long-term growth potential given our established I-O leadership and our expectation for many additional approvals around the world.

Our results also reflect continued strength in both Lynparza and Lenvima products we market in collaboration with AstraZeneca and Eisai, respectively. Lynparza revenue more than doubled this quarter, driven by further uptake in ovarian cancer based on the results of SOLO-1 in the United States as well as strength in Europe, China and Japan. Lynparza continues to lead the PARP inhibitor class in the United States with nearly 60% total patient share. We look to further establish Lynparza as the PARP inhibitor of choice in additional chemotypes and in combination with KEYTRUDA.

Lenvima revenue also more than doubled as we continue to drive sales in HCC in the United States and China and launch in several other markets. We believe Lenvima will be an important product for our oncology portfolio and look forward to the potential for additional indications across our broad development program.

Turning to vaccines. Our vaccines business reflects strong growth in our pediatric portfolio as well as strength in GARDASIL, which was driven by public sector purchases and greater demand in the adolescent cohorts in the United States as well as continued demand across Europe and the emerging markets especially China. The hospital business benefited from 20% growth in BRIDION, which is annualizing at over $1 billion, reflecting strong performance in the United States as we continue to increase share within the reversal market.

Animal Health revenue increased 9% this quarter to $1.1 billion. Livestock grew 13%, primarily due to the contributions from the products acquired in the Antelliq acquisition. Companion animal sales grew 4% as volume growth in vaccines and insulin products were partially offset by the timing of customer purchases in the prior year from BRAVECTO.

Turning to the rest of our P&L, my comments will be on a non-GAAP basis. Gross margin was 75.4% in the quarter an increase of 100 basis points year-over-year. Recall that a sizable catch-up adjustment for an accrued sales milestone related to Adempas was included in the second quarter of 2018.

Operating expenses of $4.8 billion increased 9% year-over-year. R&D drove a large portion of the increase in spend and reflects higher expenses in support of our discovery and clinical development efforts as well as business development transactions during the quarter. SG&A also grew year-over-year reflecting continued investments to accelerate our key growth drivers and the launch of new indications.

The decrease in other income this quarter reflected the unfavorable year-on-year impact of mark-to-market income on equity securities as well as higher net interest expense. Taken together, we earned $1.30 per share, an increase of 25% excluding exchange. This growth demonstrates the continued momentum in our business as we drive strong top line growth combined with disciplined resource allocation enabling operational leverage.

Turning to our outlook for the year. Given the confidence we have in our strong continued performance, we are narrowing and raising both our revenue and non-GAAP EPS guidance ranges for the full year 2019. We now expect revenues of $45.2 billion to $46.2 billion, which represents 7% to 9% growth versus 2018 driven by strength across our key growth pillars. This range assumes a negative impact from foreign exchange of just over 1 percentage point using mid-July rates.

We expect OpEx to increase by mid-single digits primarily driven by investments in R&D. We now expect non-GAAP EPS to be in the range of $4.84 to $4.94, which represents growth of approximately 12% to 14% versus 2018. We now expect a slightly negative impact from foreign exchange. All other elements of our guidance provided in April remain unchanged.

In summary, we are operating from a position of strength as reflected in our second quarter results and our updated guidance. We are confident in our ability to drive strong revenue growth in the near and long term, and we remain committed to delivering a leveraged P&L while balancing the need to invest in innovation, all of which we expect will deliver significant and sustainable value to patients and our shareholders.

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

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

Thanks, Rob. The second quarter was a very important one for Merck Research Laboratories with meaningful progress made in every part of our organization. First, we received numerous approvals from the U.S. Food and Drug Administration including, as previously mentioned, supplementary approval for the use of KEYTRUDA both as monotherapy and in combination with chemotherapy in the first-line treatment of squamous cell carcinoma in the head and neck; and supplemental approval of KEYTRUDA as monotherapy for the third-line treatment of small cell lung cancer. We also received supplementary approval for ZERBAXA in the treatment of hospital-acquired ventilator-associated pneumonia caused by sensitive bacterial strain. This represents an important advancement in the treatment of a life-threatening illness especially when caused by, for example, resistant Pseudomonas species. More recently, we obtained approval of RECARBRIO, our combined imipenem, cilastatin, relebactam therapy for complicated urinary tract or interabdominal infections. Relebactam was specifically engineered to enable extended activity of imipenem against certain otherwise resistant bacterial species expressing a form of beta lactamase and is part of our effort to address the increasing threat of antimicrobial resistance.

During the second quarter, we also had the opportunity to review exciting new data from our antiretroviral program including 48-week data from the combination of doravirine with our new nucleosidal reverse transcriptase translocation inhibitor, islatravir, for the maintenance of low viral burdens in patients infected with human immunodeficiency virus. These data, which were presented last week at the International AIDS Society meetings in Mexico City, were complemented by studies of a subcutaneous islatravir implant that might permit long-term, perhaps once yearly prophylaxis against HIV infection.

In the infectious disease space, we also presented data on the immunogenicity of V114, our new 15-valent pneumococcal conjugate vaccine in pediatric populations. We are very enthusiastic about V114 for which Phase III data from our comprehensive development program will become available beginning towards the end of this year.

Returning to the oncology space. Just yesterday, we announced that the Data Monitoring Committee supervising our KEYNOTE-522 Phase III study of neoadjuvant and adjuvant KEYTRUDA combined with chemotherapy found that KEYTRUDA treatment was associated with an improvement in pathologic complete response rates, 1 of 2 dual primary endpoints on the study as compared with chemotherapy alone.

I wish to make 2 key points regarding this study: First, neoadjuvant therapy occupies an increasingly important role in the treatment of breast cancer especially in the triple-negative subset which represents between 15% and 20% of breast cancers. In this setting, the use of neoadjuvant therapy can reduce tumor burden, permit less-aggressive surgical resection and provide improvement in long-term outcomes.

Second, achievement of a pathologic complete response in which examination of the surgical specimen shows that tumor cells have been eliminated has been repeatedly associated with improved event-free survival and overall survival in this often quite aggressive malignancy. Hence we are very encouraged by the interim analysis demonstrating successful achievement of this endpoint.

In this context, the KEYNOTE-522 Data Monitoring Committee recommended that the study continue unchanged until the data become mature enough to assess event-free survival. In the meantime, we look forward to discussing the KEYNOTE-522 data with regulatory authorities and to presenting our data in an upcoming scientific meeting.

Finally, I wish to note that we anticipate that the brisk pace of regulatory approvals in major jurisdictions that we have achieved during the first 6 months of the year will continue especially in the oncology space. I look forward to sharing these notifications with you in due course.

Now my colleagues and I will take your questions.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Roger. Darla, we'll turn it over to the Q&A portion. (Operator Instructions)

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question is from Terence Flynn with Goldman Sachs.

Terence C. Flynn - *Goldman Sachs Group Inc., Research Division - MD*

Ken, there's obviously been a more significant focus on larger deals in this space following some of the recent announcements. Would just welcome your latest thoughts here on Merck's capital allocation strategy. I know you touched on this a little bit at your Investor Day about a month ago but just wondering if you could provide us an update there.

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

Thank you very much for the question, Terence. We have watched some of the activity around us in the sector. I think each one of those companies is evaluating their own growth prospects over the next few years. We feel very, very confident in our growth prospects going forward. As we have said in the past, given all of that, we're not interested particularly in a large merger that we believe can be disruptive to the company including R&D. We continue to look at bolt-on deals. We do look across the spectrum in terms of size for bolt-ons. We don't divide it by a dollar amount. But at the end of the day, we think the operational complexity, the cultural disruption, the R&D disruption that has been associated with large mergers counsel that we should not go there particularly because we feel very confident about our ability to grow our company organically supplemented by bolt-on deals.

Operator

It's from Seamus Fernandez with Guggenheim.

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

Maybe just 2 very quickly. On the first one, some spectacular growth in pediatric vaccines across the board as well as GARDASIL. Could you guys just help us more fully understand the sustainability of the kind of growth that we saw this quarter? And then just incremental to that, if you could just comment on what happened with NuvaRing this quarter in particular.

And then the second question, just broadly speaking, for Roger, 8591, the data looks solid for the doravirine combination. Obviously the PrEP information is quite impressive and exciting particularly if you can get to annual dosing with the implants. But just wanted to better understand how you guys are working towards finding a better partner than doravirine for 8591. And if you're willing to work with other companies and collaborate on those programs. That was -- those were some concerns raised by physicians that other great products are out there and that unfortunately it doesn't look like the companies are collaborating with each other on that front. So just wanted to ask on that front.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. Thanks, Seamus. We'll start with Frank.

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Sure, Seamus. Let me start with NuvaRing. No really new news there, no generic entry this quarter, Seamus. So we continue to promote NuvaRing as we have done in the past.

With regards to vaccines, a couple of things. Let me start with GARDASIL. GARDASIL had a very strong quarter, growth of 50% if you would exclude exchange on a global basis. We did see in the U.S., we did see CDC purchases in Q2 of this year which actually took place in Q1 of last year. So you do see some bumpiness with some of our vaccine sales. But I would ask to take a look, Seamus, on a year-to-date basis, vaccines for GARDASIL globally is up about 35%. So we're seeing very strong demand, especially in 11- to 12-year old cohorts in the U.S. and some in the 19 to 26 cohorts. We're also seeing very strong ex U.S. demand, as we talked about in the Investor Day in particular in China, in Europe in a lot of the gender-neutral programs that are rolling out. So we're still very confident in our growth prospects for GARDASIL.

The pediatric vaccines did also see a very strong quarter this quarter. That was driven by demand as well. There was some buying to the private sector within the U.S. this quarter based on some of the measles outbreaks that you read in the news. And we do believe that we'll continue to see growth for our pediatric vaccines going forward. So the durability of our vaccine business we feel very good about both for near-term and long-term growth as we mentioned just on Investor Day.

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

Thanks. Seamus, it's Roger. With regard to islatravir, MK-8591, I mean, first of all I would say again, the performance of islatravir is quite remarkable. And especially in the implant setting, the durability is remarkable and it's important to note the very long intracellular half life of islatravir and the very impressive resistance profile.

I would take nothing away from doravirine in terms of its capabilities. For many in the market, they're used to the previous non-nucleoside reverse transcriptase inhibitors, (inaudible) in particular, which had a lot of adverse events associated with them. Doravirine is superior to those and is a very effective agent. And I think the combination of islatravir and doravirine will be good. That said, we're also considering lots of other combinations and had lots of other conversations. And over time, you'll have the opportunity to see the broader impact of islatravir in a variety of different settings. Important thing to emphasize is that it can be administered on a daily, a weekly or monthly or even a longer duration regimen which offers great possibilities, I think, for changing treatment patterns in HIV-infected individuals.

Operator

It's from Andrew Baum with Citi.

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

A couple questions, please. Firstly, interested on your thoughts on the Senate proposal to fund catastrophic coverage given your exposure to Lenvima, Lynparza, JANUVIA and others.

Second, on islatravir, a question for Roger. Thinking about PrEP both with the implant as well as the once monthly, do you think the FDA is ready to accept anything other than traditional noninferiority trials? And what do you think that could do to the time lines in order to bringing islatravir to market as PrEP?

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

Okay. So let me just comment generally about what's happening with the various things that are going on and some of these proposals that were included in the Senate finance package. Let me start by saying that as a company, we are very supportive of the kinds of changes that will relieve patients in terms of their out-of-pocket costs. I think the catastrophic changes are a step in the right direction, but that's a very small number of people who actually progress through the system and get to catastrophic. So we continue to work with people as part of a legislative process and the administration because we support lowering costs for seniors at the counter and not just at the catastrophic portion. And so with respect to the impact on our own portfolio, I'm going to turn it over to Frank.

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes, so just on the oncology front, I think you heard from our colleagues at AstraZeneca, Lynparza for Part D is -- approximately 25% of our business flows through Part D. To remind everyone with regards to KEYTRUDA, that is reimbursed through Part B. So it is not a Part D product. So we feel as though we're balanced across our oncology portfolio going forward. Roger?

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

Yes, and Andrew, with respect to the PrEP regimen, I think it's a great concern to the community as a whole that if one has to do active comparator controls, because of (inaudible), that's understandable. The event rates are so low that you will need very, very large populations and very difficult to execute clinical trials. FDA and other regulatory agencies are not unaware of this. There have been discussions among a variety of sponsors and particularly in the very active patient community about this and what could be done. And we have a lot of ideas in mind. But thus far we don't really have a novel trial design that will permit more rapid registration. Watch this space. I mean we're very concerned about this issue.

Operator

It's from Chris Schott with JPMorgan.

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

Just 2 here. Maybe first, elaborate a little bit more on the China dynamics driving that 51% growth. I guess what products in particular are behind this? And can you remind us the overall size of your China business at this point.

My second question was just KEYTRUDA in RCC. Can we just get a quick update in terms of uptake you're seeing so far? Where in the market you're seeing the most traction with the data, et cetera? Just -- I know this is obviously an important new indication for you guys.

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Chris, it's Frank. On China, China is about $725 million this quarter. And it grew, to your point, 50%. It's really being driven by a number of products. As we mentioned, we pivoted to innovation, so our oncology portfolio, Lynparza, Lenvima, KEYTRUDA is driving growth. GARDASIL has had a significant uptake in China. We have NRDL listing also for JANUVIA. So it's a broad-based, innovative portfolio that is driving that 50% growth, and we believe that will continue in China.

With regards to RCC, we're very excited, Chris, about where we are to date. As we mentioned when we rolled out the data for RCC, it's important to note that KEYTRUDA plus axitinib shows a benefit across all 3 risk groups, which differentiates us from the competition. So we're seeing uptake across all 3 risk groups, and it's really based on the strong overall survival, progression-free survival and very strong response rates. 80% of our targeted accounts in the U.S. have adopted this regimen into their guidelines, which I think is a very strong early indicator. And we're seeing and

hearing very strong feedback from both community and academic physicians. So I feel really good, Chris, about RCC in the U.S. And as you know, we also plan to be rolling that out around the world. So we see this as a key indication, key growth drivers for us going forward.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. And Roger on 522 -- sorry, my bad. I misheard the question, apologies.

Operator

It's from Navin Jacob with UBS.

Navin Cyriac Jacob - *UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic*

Two. Sorry, if I missed this. But will it be possible to quantify how much of the U.S. GARDASIL public sector buying pattern was? If you could actually quantify that amount, that will be helpful.

And then just on KEYTRUDA plus Lynparza in first-line lung, can you remind us where those trials are? When we could expect to see readouts there? And as a corollary to that, KEYTRUDA in prostate cancer, you were going to be starting a -- 3 Phase III trials there as well. Wondering when we could hear updates from those trials as well.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Let's start with Roger.

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

Great. Okay. So as we have discussed, and we've showed some data from our Investor Day, there's quite a large opportunity for combinations of KEYTRUDA with Lynparza. And in one of those cases, it's prostate cancer. We have indicated that we will be starting registration-enabling studies for those. And as the studies move forward, obviously they take some time to conduct, we'll then have a chance to update you on the results. But we're enthusiastic about the opportunity of the combination and believe that there will be many circumstances.

I should point out that not only the Lynparza combination but the Lenvima combination as well, where we just received breakthrough designation for the hepatocellular carcinoma first-line indication, too. So there's an awful lot going on in combination studies with both agents.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Frank?

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. And on GARDASIL, as I mentioned, we have a CDC purchase in Q2, which was not purchased in Q2 of 2018. It was actually purchased in Q1 of '18. So the way in which I would characterize GARDASIL is in the U.S., year-to-date we have grown 20% when you look on a 6-month basis. I think that's the best way to look at it from a GARDASIL perspective. So think of the U.S. growing about 20% right now versus prior year for the half year mark. Because you are going to see different timing with regards to CDC purchases.

Operator

It's from Umer Raffat with Evercore.

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

I have 2, if I may. You mentioned low complexity as being a key consideration for bolt-on you're looking at. And in that vein, I guess my question is are you open to therapeutic areas like orphan? And also if there's a company with, let's say $50 billion market cap or value, is that still a tuck-in as long as the complexity is low?

And secondly, on gross margin, so I see 2 big drivers going forward, 1 of course being KEYTRUDA's Bristol-Myers royalty reduction in 2023. But also, anything you may be baking in on pricing reform? I was curious if you could add numbers around each of those.

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

Well, I'll start with the BD question. Thanks, Umer, for your question. I don't think the size is the issue necessarily for complexity. I think it has to do with whether or not the 2 companies overlap and whether or not we're spending a lot of our time integrating IT systems, manufacturing systems. So if it's a true add-on, a separate kind of business, a true bolt-on, I don't think the size drives the complexity at all.

As it relates to orphan versus other kinds, our preference is to do the most good for the most people. But having said that, we are not against the right kind of therapy, even including orphan indications or orphan approaches to therapy. What we care about is are we getting good science that we can leverage together with our internal efforts to actually create value for shareholders as well as patients.

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

This is Rob. To your question, just to remind everyone, for gross margin, over time as we indicated at the Investor Day, we do expect to see gross margin generally flat. Because while we do see product mix benefits flowing from products like KEYTRUDA and our vaccines business, we also, as we mentioned, have assumed negative price going forward.

The impact of royalties, you've hit obviously the one with KEYTRUDA that does step down in 2023 and the impact of the collaborations which in the near term will be a drag on margin, although long term would become accretive, we haven't given specific dollar numbers to those. And frankly, we don't want to get that specific in guidance. But clearly how those interplay will determine whether you see our product gross margins slightly up, slightly down or flat over the period with most of what's driving our operating margin expansion, as we've talked about, coming from reducing growth in operating expense relative to sales.

Operator

It's from David Risinger with Morgan Stanley.

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

I guess first I'd like to start with actually the last comment. And I know that this was mentioned previously at the analyst meeting. But in terms of Merck's projection of negative price going forward, that's a bit different than some of your peers. I think some of your peers talk about flat pricing. So maybe you could provide some more color regarding what you see as the biggest downward pressures on price for Merck going forward.

And then second, could you just provide an update on the growing meningitis concerns? I jumped on the call late, so I don't know if this was addressed, but wanted to hear about that topic and then also the durability of Merck's PROQUAD, M-M-R II revenue line strength.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. Let's start with Rob.

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

So thanks for the question. With regards to pricing, again, I think the important thing to focus on is how we see the mix going forward. And I can't speak to what our competitors are implying. But if you recall, we've actually seen negative price quite some time outside the United States, so that's not a new phenomenon. We've been absorbing headwinds in price outside the United States for several years. Historically, that was offset by price increases in the United States. As we look going forward, we no longer see the benefit of those price increases in the United States because of obviously the changing dynamics. And so as you look in total, we do continue to believe we're going to see declining price, as we look forward, impacting our margins.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks. And Frank on the pediatric vaccines?

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. On the pediatric vaccines, we are continuing to see very good demand within the pediatric vaccines. And clearly, the measle outbreak has driven some of that demand, especially in the private sector. We also did see buy-in this quarter in Q2. We do anticipate that some of that buy-in will come out in Q3 and Q4. But as I mentioned before, we see our pediatric vaccine business as a very strong part of our growth story. And we see it as a very durable business going forward.

Operator

It's from Tim Anderson with Wolfe Research.

Timothy Minton Anderson - *Wolfe Research, LLC - MD of Equity Research*

A couple of questions. A longer-term question on KEYTRUDA. We published an analysis a while back claiming that cancer drugs, very often, ultimately sell much more outside the U.S. and in the U.S. as they mature to the tune of 50% more or so. When I look at how we and the analyst community at large models KEYTRUDA, and other PD-1s for that matter, knowing everybody really thinks that ex U.S. even surpassing the U.S. And I'm wondering if you can tell us what your long-term model assumes in this regard. Could the ex U.S. markets eventually kind of blow away the U.S. market over time? It could be blowing the dollars more potentially.

Second question, recent -- Bristol recently top line part 1 of 227 as positive, which I think was a surprise, can you remind us where you are with your CTLA-4 combination program? Specifically, what are the latest stage trials and in what tumor types? My guess is you may have kind of backed off this initiative that you started maybe a couple of years ago.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Let's start with Frank on KEYTRUDA.

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes, for KEYTRUDA, we look long term. We do see significant opportunity outside the U.S. in particular markets, like China especially when you look at some of the G.I. malignancies and the actual prevalence there. We are seeing obviously very strong uptake in Japan as well. Not going to give a specific number, but we clearly do see the ex U.S. opportunity as very significant. And in fact this quarter alone, we sold $1.1 billion outside the U.S. It grew 73%. So we see both ex U.S. and U.S. KEYTRUDA opportunities. But clearly, China is the one I would highlight as significant potential growth for us going forward.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

And Roger.

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

Tim, with respect to CTLA-4-directed therapy, our interest has been in demonstrating or assessing whether or not adding CTLA-4-directed therapy actually has an impact over KEYTRUDA alone. That is powering the study to see whether CTLA-4 plus KEYTRUDA is in fact superior to KEYTRUDA in any setting. And we have done that, both with ipilimumab and also with MK-1308, our own CTLA-4-directed therapy. And so registration-enabling studies are going on in both setting and with both kinds of combinations which includes, for example, the KEYNOTE-598 study and a couple of others. And we can go through the details with you quite easily on clinicaltrials.gov.

Operator

It's from Jason Gerberry with Bank of America.

Jason Matthew Gerberry - *BofA Merrill Lynch, Research Division - MD in US Equity Research*

First is a follow-up on the Bristol Opdivo, Yervoy data. Just curious, Roger, how do you think oncologists are going to benchmark the CheckMate-227 data against the already approved either Merck combination or KEYTRUDA monotherapy in the PD-L1 greater than 1% populations?

And then my second question, maybe just for Frank. Can you frame the importance of NRDL listing for KEYTRUDA in the lung setting? And what I'm specifically curious about is the percent of the market accessible with and without the listing.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Let's start with Roger.

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

Well, Jason, it's really hard to comment on the data from the CheckMate-227 program because we haven't actually seen it. We have the top line announcement that one part of it with -- in the PD-L1 greater than 1% did succeed in the combination with ipilimumab. But we don't know what that success will look like in overall survival. We don't know the hazard rates those would look like. And there's a -- it's a complicated study, as you appreciate, because the study was broken down into multiple parts. And a part of it was predicated on a tumor mutational burden analysis and then subsequent PD-L1-directed subset. So without actually seeing the data, pretty hard to know how oncologists will respond. With time, the data become available, and I think people will want to have a look at it and understand what the meaning of that might be.

I -- our own data, I think are extremely strong, of course, with KEYTRUDA and the combination of KEYTRUDA plus traditional chemotherapy with typically on the order of doubling of overall survival. So there is important value that can be gained there. And we're optimistic that we're going to continue to be able to advance therapies that will improve overall survival in this disease.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Roger. We'll go to Frank on the NRDL.

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. And just one addition point to what Roger was saying. Commercially, with regards to lung, I do believe we're in a very strong position with our data. And as you mentioned with monotherapy, on the PD-L1 high population with very strong overall survival as well as KEYNOTE-189 reducing the risk of death in half, that data is playing very well around the world, and it has helped us to penetrate now 8 out of every 10 new eligible patients in lung. So we feel as though -- there'll be a lot of data readouts here from competition, but we feel as though our data positions us well in lung today and in the future.

NRDL. We are waiting to see if we'll be invited to actually participate for next year. It is an important potential listing. It does expand the population in China fairly significantly. There is 500,000 to 600,000 lung cancer patients in China. There's probably 300,000 of those that are part of our labeled indication. And NRDL gives us a chance, if invited, to expand into that patient population.

We'd also like to highlight, we expect to expand our label in China. China is going to be important for us, not only for 2020, but 2020 and beyond. And we are also seeing good self-pay market uptake in China as well. But clearly, we'll keep you informed as the NRDL process unfolds.

Operator

It's from Steve Scala from Cowen.

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

A couple of questions both for Roger. If you could clarify your KEYNOTE-522 comments. I think you said you needed EFS to file but that you would share the pCR data with regulators. So were you implying you would seek to file and potentially garner approval on pCR that is why you're going to share it in the first place? Or are you saying you absolutely definitely need the EFS?

And then secondly, if Bristol's 227 delivered a percent of patients alive greater than the 69% that KEYNOTE-189 reported at 12 months, just wondering how Merck would respond. Or do you think that, that is extremely unlikely?

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

Thanks, Steve. So with respect to KEYNOTE-522, the goal in discussing the data with regulatory agencies is to ask whether or not they think that represents a finding of sufficient importance to consider making the drug available for patients in that setting. So that's the reason to do it. As I indicated, pathologic complete response is associated with favorable outcome particularly in the breast cancer setting and as have been repeatedly demonstrated, to have that impact in the triple-negative breast cancer setting. On the other hand, this is something that agencies have to look at in regard to the totality of the data. So that's basically where we are there.

And with regard to 227, pretty hard to respond to hypothetical without actually seeing what the data look like. I really -- I don't know what to say about that. I think there's some interest in seeing what the subset data look like. Obviously, the flip side of that was that, maybe unsurprisingly, but in light of what we've seen, beginning with CheckMate-026, I mean, the combination of nivolumab plus chemotherapy was not successful in

Part 2, which for us, KEYTRUDA plus chemotherapy obviously gives impressive results in terms of overall response rate, progression-free survival, overall survival as we demonstrated repeatedly in non-squamous and squamous small cell non-small cell lung cancer. So these are behaving differently in these settings for whatever reason.

Operator

Your next question is from Louise Chan with Cantor.

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

My first question is on KEYTRUDA in China. Just curious, if you will disclose sales there? We get that question a lot. Just seeing if you can provide any color. And then how will you compete with the local players that are much less expensive on a price basis, at least for now?

And then second question is just on potential competition for KEYTRUDA from some of the upcoming trial readouts in second half '19 and beyond that will be in non-small cell lung cancer, RCC and melanoma.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Frank?

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. So we don't intend to actually share our sales numbers for KEYTRUDA in China. As far as competing with the local players, we feel as though oncology is a data-driven market. There clearly are local players that are entering the market at a lower price. They are penetrating into some segments of the market. However, we're continuing to see very good penetration and very good growth in China. There are clearly patients that are in the self-pay markets where we compete today that can afford KEYTRUDA. We have our patient assistance programs, and we have a very strong commercial presence in China. So I feel really good that we'll be able to compete with the local players going forward.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Great. And then the KEYTRUDA positioning in the U.S. given peer trials?

Frank K. Clyburn - *Merck & Co., Inc. - Chief Commercial Officer & Executive VP*

Yes. I think as we mentioned, there's going to be a lot of competitive data readouts in lung and across many different cancer types. What I would say is right now, we are in a very strong first-mover advantage in many of those cancer types. When you think about 20 indications across 12 different tumors, we right now have built a wall of data that we feel very comfortable with. And in fact, many of the community oncologists are getting significant real-world experience using KEYTRUDA. So we'll have to see how the data unfolds with the competition. But as Roger and I have just mentioned, we feel as though our data right now, strong overall survival across many different cancer types, bladder; renal cell carcinoma; I haven't even spoken about adjuvant melanoma, which is a very important launch for us right now; head and neck, the teams are just launching that indication off a strong overall survival in the first-line setting. So we know it is going to be competitive. We feel as though we're very well-positioned based on our strategy and the data that we have as well as what you heard in our Investor Day, the significant amount of data to come, not only in the metastatic setting but also in the neoadjuvant and adjuvant setting going forward.

Operator

It's from Mara Goldstein with Mizuho.

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

(technical difficulty)

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Mara, we can't hear your -- we couldn't hear your question. If you wouldn't mind repeating that?

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

Sure. I have 2 questions, and the first is on the KEYTRUDA plus Lynparza trial in non-small cell lung cancer. And I'm just wondering what the expectation is in terms of expanding patient population based on that clinical trial.

And then the second question is one around regulatory strategy in Europe. Just understanding that yesterday or the day before, we learn that the CHMP had removed accelerated status for Novartis' Zolgensma, but we've also seen this is not an isolated incident with other drugs, and in particular oncology drugs being taken off that accelerator track. And I'm wondering if the company can share any thoughts around this dynamic and any potential impact on your own regulatory plans in Europe.

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

Right. Mara, the underlying logic behind KEYTRUDA plus Lynparza in a whole variety of settings is that where there are defects in DNA repair and there are -- those include a whole variety of different defects not just the BRCA1, BRCA 2 indications but a whole variety of different molecular defects. The effect of Lynparza can be to increase the representation of epitopes that potentially could be recognizable by immune cells, and release of constraints with KEYTRUDA in combination with that should be beneficial. That's the hypothesis that's being tested in a whole variety of different settings and quite broadly. So we're enthusiastic about it. We're encouraged that this could be extremely important.

One of the things I would point out with respect to Lynparza is it's extraordinarily well-tolerated. People stay on it for years, and the ability to maintain the treatment effect as has been shown, for example in the ovarian setting is really quite remarkable. So that's extremely promising.

With regard to EU strategy, the regulatory strategy really hasn't changed there. The EU has a PRIME program for -- within CHMP in order to permit more rapid review in general. The good thing about EU reviews is that they go along a very well-define time line, which we understand extremely well. And at this point, we're moving forward with those EU reviews as we've announced even just this week. So all of that is going very well for us.

Teri Loxam - *Merck & Co., Inc. - Senior VP of IR & Global Communications*

Thanks, Roger. And we were able to get to all of the callers' questions. So I'll turn it over to Ken for some closing comments.

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

Okay. I want to thank you again for joining us today. As you can see, our strong second quarter results reinforce why we're so confident in our ability to deliver sustained strong growth not only this year but beyond. And as we mentioned in Investor Day, we have a derisked portfolio of innovative assets. Together with our differentiated scientific, commercial capabilities and our ability to execute, we believe that uniquely positions Merck to deliver strong results for patients and shareholders well into the future.

So thanks, again. We look forward to joining you in the future.

Operator

This concludes the Merck & Co. Q2 sales and earnings call. You may now disconnect.