THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

MRK - Q2 2016 Merck & Co Inc Earnings Call

EVENT DATE/TIME: JULY 29, 2016 / 12:00PM GMT

OVERVIEW:

Co. reported 2Q16 revenue of $9.8b and GAAP EPS of $0.43. Expects 2016 revenue to be $39.1-40.1b, GAAP EPS to be $1.98-2.08 and non-GAAP EPS to be $3.67-3.77.

THOMSON REUTERS

CORPORATE PARTICIPANTS

Teri Loxam *Merck & Co., Inc. - IR*

Ken Frazier *Merck & Co., Inc. - Chairman & CEO*

Rob Davis *Merck & Co., Inc. - EVP & CFO*

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

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

CONFERENCE CALL PARTICIPANTS

Tim Anderson *Bernstein - Analyst*

Geoff Meacham *Barclays Capital - Analyst*

John Boris *SunTrust Robinson Humphrey - Analyst*

Mark Schoenebaum *Evercore ISI - Analyst*

Steve Scala *Cowen and Company - Analyst*

Chris Schott *JPMorgan - Analyst*

Colin Bristow *BofA Merrill Lynch - Analyst*

Seamus Fernandez *Leerink Partners - Analyst*

Jami Rubin *Goldman Sachs - Analyst*

Tony Butler *Guggenheim Partners - Analyst*

Gregg Gilbert *Deutsche Bank - Analyst*

David Risinger *Morgan Stanley - Analyst*

Alex Arfaei *BMO Capital Markets - Analyst*

Marc Goodman *UBS - Analyst*

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 2016 sales and earnings conference call. (Operator Instructions). I would now like to turn the call over to Teri Loxam. Please go ahead.

Teri Loxam - *Merck & Co., Inc. - IR*

Thank you, Darla, and good morning. Welcome to Merck's second-quarter 2016 conference call. Today I am 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 Labs.

Before I turn the call over to Ken I would 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 items in our press release. We've also provided a table in our press release to help you understand the sales results 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 US 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 risk 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 1A in the 2015 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 statements and you can see our SEC filings as well as today's earnings release on Merck.com. With that I would like to turn the call over to Ken.

Ken Frazier - *Merck & Co., Inc. - Chairman & CEO*

Thank you, Teri. Good morning, everyone. Thanks for joining the call this morning. Our performance this quarter reflects our continuing progress in advancing our priority products and programs. As we accelerate the launch of Keytruda around the world our researchers are continuing to study Keytruda with an extensive clinical development program that spans a multitude of cancer types. We are confident that Keytruda will be a key treatment in cancer for many years to come.

We also made good strides in the launch of Zepatier, our new hepatitis C medicine, during its full first quarter on the market. Our key in-line brands, such as Januvia whose sales are still growing nearly 10 years after its initial launch, also significantly contributed to our performance this quarter.

We remain committed to our innovation strategy and our mission of delivering important medicines and vaccines that address many of the world's foremost health challenges and global unmet medical needs.

Business development continues to be a priority and we are committed to finding the best external science to enrich our pipeline and portfolio. As I have previously outlined, we are taking a disciplined approach both financially and scientifically to identify and acquire opportunities at the right financial valuation.

In addition to acquisitions, we also are engaging in scientific and commercial partnerships to pair our best internal innovations with the best external innovation available.

As a recent example of our efforts, earlier this year we closed on the acquisition of Afferent Pharmaceuticals which will complement and enhance our primary care pipeline. Last month we began a new scientific collaboration with Moderna Therapeutics to develop personalized cancer vaccines by combining Keytruda with Moderna's vaccine technologies. Additionally, we recently announced our intent to acquire Vallee of Brazil to fortify our animal health business in Latin America.

In closing, our performance in the quarter positions us well for the second half of the year. Looking forward we will remain focused on executing on our launches and driving the performance of our strongest brands, as well as advancing and augmenting our broad pipeline to deliver a balanced and differentiated portfolio of valuable medicines and vaccines.

We believe this strategic focus will create long-term growth for the Company and sustainable value for both society and shareholders. And with that I would like to turn the call over to Rob.

Rob Davis - *Merck & Co., Inc. - EVP & CFO*

Thanks, Ken, and good morning, everyone. Our results in the second quarter reflect continued execution across the organization with our broad portfolio of products contributing to growth both on the top and bottom line.

Total Company revenues were $9.8 billion, an increase of 1% year-over-year. Excluding the impact of exchange, second-quarter revenues grew 3%. Our human health and animal health businesses performed well in the quarter delivering growth despite an approximately $210 million headwind from sales in Venezuela in the second quarter of 2015.

As you will remember, we scaled back our operations in Venezuela toward the end of last year and therefore recorded negligible sales from the country in the second quarter of this year.

Partially offsetting growth in human and animal health this quarter were lower contributions from our revenue hedge program and third-party manufacturing sales versus the prior year. While our revenue hedging program continues to contribute to the top line, it is expected to have a negative impact in each quarter this year on a year-over-year basis.

In terms of revenue guidance, we now expect full-year revenue of $39.1 billion to $40.1 billion including an approximately 2 percentage point negative impact from foreign exchange at mid-July rates.

Looking to the other parts of the P&L, non-GAAP gross margin was 75.7%, an increase of 30 basis points versus the second quarter of 2015. Foreign exchange and product mix both contributed to the year-over-year improvement as growth in higher-margin products such as Keytruda and Zepatier offset the declines in lower margin products such as Remicade.

On a full-year basis non-GAAP gross margin is still expected to be roughly flat versus last year. Non-GAAP operating expenses of $4.2 billion increased 4% year-over-year with lower marketing and administrative expenses and an approximately 2 percentage point benefit from foreign exchange partially offsetting higher research and development expense in the quarter.

The increase in R&D reflects a $200 million upfront payment to Moderna for our recently announced collaboration on the development of personalized cancer vaccines as well as higher investments in our clinical programs.

We continue to expect non-GAAP operating expense for the full-year to be generally in line with the prior year. We anticipate incremental spend in R&D will be partially offset by lower marketing and administrative expenses.

Our non-GAAP effective tax rate this quarter was 19% primarily driven by the beneficial impact of orphan drug federal income tax credits for Keytruda recorded in the quarter. We continue to anticipate the full-year rate to be between 21.5% and 22.5% which includes the impact of the R&D tax credit.

Taken together we earned $0.93 per share on a non-GAAP basis in the second quarter, delivering 8% growth or 12% excluding exchange and another quarter of P&L leverage. On a GAAP basis we earned $0.43 per share in the quarter.

For the full-year we are raising the lower end of our non-GAAP EPS guidance, narrowing the range to $3.67 to $3.77 per share. We now expect foreign exchange to have an approximately 1 percentage point negative impact in mid-July rates. On a GAAP basis we now expect to earn $1.98 to $2.08 per share for the full-year.

Altogether we delivered growth both nominally and excluding exchange on the top and bottom line. We continue to have a number of opportunities in our pipeline with new product launches and with the potential for business development.

We remain disciplined in our approach to expense management recognizing the need to balance delivering in the short-term while making the appropriate investments to drive long-term growth. With that I will turn the call over to Adam.

Adam Schechter - *Merck & Co., Inc. - EVP, President 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 quarter of growth with sales of $8.7 billion or growth of 2%. We drove increases in core areas of oncology, diabetes, vaccines and hospital and specialty care which were partially offset by declines in Remicade and Nasonex.

I will now highlight a few of our key franchises and product launches and I am going to begin with oncology. This is an exciting time for Merck as a leader in immuno-oncology and as we work to make Keytruda foundational for the treatment of cancer.

We are launching our melanoma indication in more than 50 markets globally and we are preparing for launches in additional tumors. In the United States we are maintaining our strong position in melanoma and we are launching in second line lung cancer. And we are ready -- we are ready to launch imminently in head and neck cancer and we are preparing for the launch in first line lung cancer.

In the second quarter sales of Keytruda reached approximately $315 million on continued strength in the melanoma indication. In the US we are also seeing increasing sales contributions from progress we are making in second line lung cancer.

Importantly, PD-L1 testing rates continue to increase with approximately two-thirds of physicians now testing to determine which patients are most likely to benefit from PD-1 directed therapy.

This is very important as we prepare for a potential first-line indication where we recently announced that Keytruda offers an overall survival benefit compared to chemotherapy in patients whose tumors express high levels of PD-L1. Customers are eagerly awaiting the opportunity to treat lung cancer in the first line setting with Keytruda.

We also believe that all of the work we have been doing to drive testing for second line use will position us well in first line when we come to market. With a broad and deep clinical program that continues to grow and continues to generate positive monotherapy and combination data, we remain very excited about the long-term opportunity for Keytruda.

Next in primary care, the Januvia franchise grew 2% this quarter. In the United States we continue to drive TRX growth of 4% to 5%. As you recall, we saw 14% and 22% growth in the second and third quarters of last year respectively.

These tough comparisons had an impact on the year-over-year changes this quarter and will also impact year-over-year changes in the third quarter. But I continue to focus in the underlying TRX volume growth and it remains strong in the United States.

Outside of the US we generated strong growth in Europe and Canada and in emerging markets. We remain confident in our diabetes franchise for the remainder of 2016 and we are pleased with our continued strong access that we expect in 2017.

Moving to our vaccine business, sales of the vaccine portfolio reached about $1.3 billion. Growth of 7% came primarily from our pediatric vaccines, which was partially offset by Gardasil. Overall Gardasil sales declined 7%. In the US sales of Gardasil grew only 2% due to lower CDC buying. Outside of the US sales were impacted by the timing of public sector purchases in Brazil.

We are celebrating the 10-year anniversary of the launch of Gardasil. Real-world data that was recently published continue to show the benefits of HPV vaccination and we are seeing increased uptake and utilization of our HPV vaccine around the world. Also influential organizations, including the CDC, ASCO and the WHO, have expressed strong support for HPV vaccination.

It is worth noting that many markets are moving toward implementing a two dose regimen of Gardasil and there are discussions ongoing in the US as well. We anticipate this change to a two dose regimen could go into effect in the US by the end of 2016 or early in 2017.

Finally, in hospital specialty care, sales grew 3% to $2.1 billion. Growth in acute care and contributions from launch products were partially offset by declines in Remicade and Isentress due to competitive pressures that we expect will continue going forward.

We are making good progress with the Zepatier launch. We are having favorable conversations with payers and we have garnered some early wins in both the public and the private sectors for 2016 and 2017.

In the VA utilization of Zepatier is ramping up nicely and we have also started to see some advancement in Medicare Part D, in managed Medicaid and in commercial segments. Customers see the value that Zepatier can offer with high cure rates in a broad and diverse set of patients. It will take some time for Zepatier to ramp up as formularies come online, but we are pleased with the access that we have achieved so far.

Finally, Bridion is growing well on strong global demand and early contributions to the US launch. In the US our teams are rapidly securing formulary access and initial indicators of use by physicians in the surgical suite are encouraging.

In closing, our teams delivered another quarter of solid performance. We have momentum in our four focus areas and strong execution for our key launches. This positions us well for the second half of 2016 and for 2017. Now I will turn the call over to Roger.

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

Thanks, Adam. During the second quarter we made significant progress in gaining registration for important new products and also advanced a number of new programs.

On the infectious disease front, in June the FDA antimicrobial advisory committee agreed on a vote of 10 to 5 with one abstention that substantial evidence of the safety and effectiveness of bezlotoxumab, now called Zinplava, in preventing recurrence of C. difficile infection in patients 18 years and older had been presented.

Subsequently the FDA has requested additional information to enable their review of the Zinplava file with the result that a new action date of October 23 has been set. We are working closely with the FDA and with other regulatory agencies to make Zinplava available to patients at risk for recurrent C. difficile infection.

Considerable progress has also been made in advancing curative therapies for hepatitis C virus infection. The European Committee for Medicinal Products for Human use, known CHMP, adopted a positive opinion regarding the approval of Zepatier for the treatment of chronic hepatitis C virus infection noting its high efficacy against HPV genotypes 1 and 4 including in patients with compensated cirrhosis and severe kidney disease.

This recommendation has now been ratified by the European Commission. I will remind you that Zepatier is not cleared by the kidney and can be used in patients irrespective of baseline renal function.

As I mentioned during the first-quarter earnings call, we are working to supply the European market. We have made good progress on this front and still expect that we will be able to launch Zepatier in the EU in the fourth quarter or at the latest in the first quarter of 2017. Reviews in other jurisdictions are also proceeding.

Meanwhile we are continuing to explore additional treatments for the more than 150 million people with hepatitis C virus infection around the world. Progress was made in advancing our triplet regimen incorporating MK-3682, a urogenital nucleoside polymerase inhibitor, along with a protease inhibitor Grazoprevir and a novel NS5A inhibitor, MK-8408.

We now have substantial experience with this combination with more than 1,000 patients enrolled in clinical trials. Results from our extensive Phase 2b program will be available later this year and will be presented at major scientific meetings.

Because of the favorable properties of MK-3682 we are also exploring a doublet regimen employing just this polymerase inhibitor along with MK-8408. Together we believe that these combinations can offer broad efficacy for HCV infected patients irrespective of HCV genotype and in a variety of clinical settings.

Lastly on the infectious disease front, I note that our V920 vaccine to prevent Ebola virus disease received FDA breakthrough designation and prime designation from the EMA, permitting close regulatory interaction to optimize development and facilitate review of this important potentially life-saving agent.

Turning now to oncology, this was an extremely active quarter for Keytruda, our PD-1 directed immunotherapy for malignant disease. I have said repeatedly that I expect that Keytruda, by virtue of the spectrum of its activity, will prove to be foundational in future cancer care.

At The American Society for clinical oncology meetings last month we presented data demonstrating the activity of Keytruda as monotherapy in 15 different tumor types. We also presented data from multiple studies where Keytruda has been used in combination with conventional chemotherapy, with targeted therapies and with immunotherapies.

In all we now have more than 300 clinical studies underway exploring the activity of Keytruda in more than 30 different tumor types. More than 100 of these studies employ Keytruda in combination with other agents.

In Europe the CHMP adopted a positive opinion for the use of Keytruda in the treatment of locally advanced or metastatic non-small cell lung cancer in patients who have failed at least one prior therapy and whose tumors express the PD-L1 biomarker.

We have championed the view that because patient outcomes in the treatment of non-small cell lung cancer are correlated with the extent to which PD-L1 is expressed on the tumor, it is important to assess the status of this biomarker prior to initiating therapy with a PD-1 directed agent.

The data supporting our dossier were derived from the KEYNOTE-010 study which showed that Keytruda treatment in populations with 1% or more of tumor cells expressing PD-L1 yielded superior overall survival compared with the results of traditional chemotherapy. These data are also under review by the FDA with an action date of October 24.

During the quarter we also reported top-line results of our KEYNOTE-024 study which compared Keytruda monotherapy to platinum-based chemotherapy in the first-line treatment of patients with locally advanced non-small cell lung cancer.

Keytruda treatment demonstrated superior progression free survival and superior overall survival in this setting. A manuscript describing these results has now been accepted for publication and hence should appear in the near future. We've also begun to work with regulatory agencies to enable supplementary filing of these data to our existing Keytruda labels.

Beyond treatment of melanoma and non-small cell lung cancer, we have pursued accelerated approval for Keytruda for the treatment of squamous cell carcinoma of the head and neck with disease progression on or after platinum containing chemotherapy. The PDUFA date for this review is August 9.

Based on our current trial enrollments we have several additional potential filings for Keytruda over the next 12 to 18 months, including bladder cancer, gastric cancer, colorectal cancer in the setting of microsatellite instability, and relapsed refractory classical Hodgkin's lymphoma, an indication for which we received breakthrough designation from the FDA in the second quarter.

Moreover, data continue to provide intriguing evidence of the broad spectrum of Keytruda activity. Earlier this month for example Julie and colleagues at the Oregon Health Sciences University published a preliminary report demonstrating meaningful responses in patients with castration resistant prostate cancer who had progressed on Enzalutamide.

As Rob noted, R&D expenses increased this quarter in large part owing to the establishment of our business partnership with Moderna and the development of novel immunogens with the goal of further improving the efficacy of our immunomodulatory agents including Keytruda.

While we have, through the Moderna investment, as well as our funding of key clinical trials, increased our support for Keytruda in immuno-oncology, we continue to pursue other important new therapies. For example, this week we announced the closing of our acquisition of Afferent Pharmaceuticals which gives us access to a set of P2X3 receptor antagonists.

Their lead program, AF-219, is currently under study in a fully enrolled Phase 2b trial for the treatment of chronic cough and is also being investigated in a Phase 2 study for the same indication in patients with idiopathic pulmonary fibrosis. I look forward to updating you on this and other programs in the coming months.

Meanwhile we continue to support the development of ertugliflozin both as monotherapy and in combination with Januvia. We have presented important Phase 3 data on this program and will submit regulatory dossiers before the end of the year.

Also we expect to receive the adjudicated cardiovascular safety data from odanacatib from our external evaluators in the next few days which will then be analyzed over the next several weeks. It is my expectation that the US odanacatib file will be submitted in the fourth quarter. I will now turn the call over to Teri.

Teri Loxam - *Merck & Co., Inc. - IR*

Thanks, Roger. As we move forward with Q&A we would like to get in as many questions as possible this morning on the call, so we would appreciate it if you would limit yourself to just one question each. Darla, if we can move forward with Q&A please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Tim Anderson, Bernstein.

Tim Anderson - *Bernstein - Analyst*

I have a commercial question on the PD-1. So Bristol's first-line trial results coming up. In your opinion if they hit PFS and possibly OS in all PD-L1 expressors, not just the high expressors, how much of a benefit do you think that gives them commercially?

Already they are obviously much more penetrated in lung in the second line setting. They are already getting usage in first-line to some degree off label. And I am wondering if they were to hit in a broader population, if you think that makes a substantial difference?

And can I just clarify the comment about publication timeline for 024? It sounds like, if I heard you right, that has already been accepted. You said that would be published in the nearer-term. I am assuming that doesn't get published before ESMO, but ESMO would be the likely venue for a concurrent publication.

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

Tim, it is Roger. The manuscript was accepted for publication; I don't have a publication date so I can't really speculate on when it would be published vis-a-vis ESMO. But we have an accepted manuscript and I'll let Adam comment on the commercial question.

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

So, Tim, I think it is a very important question and I will walk you through how I think about it. The first thing is I will be very glad to be first to market, being first to market for a new indication matters.

I remember when we were first to market with melanoma people were asking if you have progression free survival, but you don't have overall survival, they come out with overall survival will it matter? And I kept saying I just want to be first. And as long as we have the studies underway to show that ultimately we can show overall survival that we should be okay.

If you look at first-line lung the first thing I would say is we are glad to be first. The second thing is the issue that we have right now with PD-L1 testing in second line where the competition has all comers, I think that will go away in first-line because everybody will be doing PD-L1 testing. So that obstacle that we face today goes away with first-line.

The second question will become not only what the indication is but what reimbursement occurs. And even today you start to see reimbursement occurring even where you don't necessarily have the indication.

And the good news is at the time of the first-line launch we should have data in second line showing positive results in the PD-L1 [+1] positive so we will have data in +1 to 50 for second line. So we still have to see how it plays out, but I am pleased to be first to launch hopefully and then we will see how the reimbursement works out over time.

Operator

Geoff Meacham, Barclays.

Geoff Meacham - *Barclays Capital - Analyst*

Good morning, guys. Thanks for taking the question and congrats on the quarter. Roger, you've downplayed the chances of achieving an OS benefit in the past. And now that you have it I was hoping that you can put it maybe in clinical context especially given the crossover.

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

I don't think I downplayed the possibility. I think it is always the case that it is uncertain what the results of clinical trials will be. I mean they are experiments and we don't know the answer in advance.

Certainly we are very pleased with the results that we saw in the 024 study. There is meaningful crossover of course as there is now in any such study. And the fact that we achieved overall survival even in the context of meaningful crossover I think gives a sense of how powerful the benefit is.

Keep in mind that we had a small amount of first-line data that we had obtained in the [001F] cohort, so we knew that there was benefit in that setting. And in that sense it is not surprising to see impressive PFS results. The overall survival obviously was something that we had hoped for and it is nice to see it come through.

Operator

John Boris, SunTrust

John Boris - *SunTrust Robinson Humphrey - Analyst*

Thanks for taking the questions. On the Bristol and Lilly calls they indicated that Opdivo was seeing up to 15% to 20% use in first-line lung. Can you comment at all, Adam, about use of Keytruda in first-line lung?

And then the tangential question to that one for Roger. It would seem that, based on the Checkmate 012 data, that an objection that your sales reps might be getting is that has Keytruda been studied in lung cancer across all PD-1 levels with a CTLA-4 type mechanism like a Yervoy.

Can you help me understand why a physician would use Keytruda in first-line lung or across second line lung if its next step is and it believes that it needs to go on to an IO/IO combo versus an IO/chemo compound? Thanks.

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

So, John, with regard to Keytruda, right now in the US about 70% of the uses still melanoma and then there is somewhere between 10% to 15% that we believe is in second line lung and then the rest is amongst a whole host of different uses. So the utilization in first-line lung right now is very low.

But what is important as we are seeing PD-L1 testing start to occur more and more often. And I mentioned that two-thirds of physicians are now testing. And what we see is when physicians test they tend to use Keytruda and that is where we see the utilization of Keytruda for lung right now.

The good news is the work that we have been doing on testing I think is going to pay off for us as we get the first-line indication and the obstacle goes away for second line. So I am very encouraged and excited about the opportunity to launch in first-line for sure.

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

John, it is Roger. The truth of the matter is we really, as I have said, need to understand how well Keytruda works as monotherapy and for that matter Opdivo in order to be able to understand how to proceed with combination therapies.

The combination therapy work is all extremely early; we do not have any data that tell us that any combination provides superior overall survival versus monotherapy. Indeed, we have the first data in first-line lung that show that Keytruda is superior to traditional chemotherapy.

And again, it needs to be reviewed, but when people have a chance to look at the data that represents a real sea change in the way people treat lung cancer. Combination chemotherapy has been the mainstay of therapy for decades. So that is going to be a pretty big deal.

If you look at response rates, an imperfect indicator of course, the best response rates that we see are the combination of Keytruda with chemotherapy like [pemetraxate] where we reported a small number of patients, 71% overall response rate in the lung cancer setting which is obviously very provocative.

With time I think we will discover how best to use these agents in combination, whether that is an immuno-oncology combination with a CTLA-4 directed molecule, with other molecules -- we have 10 of them in development on our own -- or with chemotherapeutic agents time will tell.

Operator

Mark Schoenebaum, Evercore.

Mark Schoenebaum - *Evercore ISI - Analyst*

Thank you very much for taking my question. I appreciate it. I guess I'll follow-up on the last question, Roger, if I may.

When I think about the market for immuno-oncology what I always tell clients is lung is where the money is and if you can really figure out lung you will probably figure out the space. The other tumors -- lung is probably bigger than all the other tumors combined.

So, I imagine you are very focused on this too. So my question is specifically what do you think of the data that Bristol has put up on Yervoy plus Nivolumab? And that will be out next year. And what are you doing to hedge against that risk that that becomes the standard of care?

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

Well, Mark, a number of issues. First of all lung is not larger than all other tumors combined. It is an extremely important cancer, but again, I keep trying to point out that we are at a very early point in the evaluation of the use of PD-1 directed therapies in malignant disease.

Just again, as an example, the fact that we are seeing prostate cancer response -- remember that previously it was thought prostate cancer was refractory to PD-1 directed therapy, Opdivo treatment there were really no results. That shows you that we are still learning a great deal about how to use this as monotherapy.

Combinations, a lot of combinations appear to be showing early signs of signals, whether that is combinations with chemotherapy or combinations in the case of Opdivo, and us as well, with ipilimumab with CTLA4. Time will tell which is the best combination.

If it turns out that ipilimumab was the best combination then that would be the way to go forward and we obviously have studies using that combination as do others. Our combination studies with targeted chemotherapies and traditional chemotherapies are also very far along and that will be extremely interesting.

We will have a chance to see those data relatively soon. We will finish the first of those sets of studies in the third quarter, so we will have to see the data very soon.

Operator

Steve Scala, Cowen.

Steve Scala - *Cowen and Company - Analyst*

Thank you. Regarding the upcoming Keytruda PDUFA in head and neck cancer, should we assume approval will be only for third line PD-L1 positive patients given that was the population studied? Or should we expect a broader label than that? And how should we think about the size of the opportunity as well? Thank you.

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

First of all, with respect to the approval, I cannot comment on what exactly the label will look like but -- except to say that in general of course you get the label for the population that you studied and that is what we would expect.

So this is the first and it is an accelerated approval in the head and neck cancer setting. There's a lot of additional information that will be coming out from our other studies going forward. In terms of besides of the opportunity, I will let Adam speak to that.

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

So if you look at head and neck, it is a few thousand patients in the United States. But again, it is not about any one indication; it is about Keytruda becoming a foundational therapy.

And when you listened to Rogers introduction and you hear all of the different indications and the tumors and combinations that we are studying, it is going to be all those together that we are preparing for every day that is going to make Keytruda foundational for the treatment of cancer in our view.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Just switching gears a little bit, can you elaborate on the Zepatier launch thus far, any surprises that you are seeing? And when we think about market sizing over time for HCV, how do you see the number of patients treated annually trending from here? Do you think overall market volumes can increase or do you think we have hit a peak? Thanks.

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

Chris, this is Adam. So, we are six months into the launch of Zepatier and we are encouraged by the progress that we are seeing. Obviously the first thing we are doing is trying to secure access and, as I mentioned, we have early wins.

So in Medicare Part D for example we have United and Express Scripts where they have added us at parity to their Medicare Part D formulary effective July 1. In Medicaid we are making significant progress in not only getting our formulary but some of those Medicaid formularies have increased the number of patients that they are making eligible for treatment.

We are working very closely with our commercial customers and access is progressing. We still have some negotiations that are ongoing as we speak. And as I said, the VA continues to ramp up nicely. So, we are encouraged by the access that we are getting and now we have to work to build market share and that is what we are going to focus on as we move forward.

In terms of the overall market, it's a large market, there's about 3 million patients in the US that still need to be treated, so it is going to be a market that will be around for a while. We are currently seeing just about, just over 200,000 or so patients per year treated in the US. That is a lot more than if you would have gone back five years ago where there was somewhere between 120,000 to 150,000.

So, we have certainly seen an increase, but that increase I think has maxed out and I think we will see more of where we are as a steady-state as we move forward. And that really the size and the pace of the market is going to depend on getting more patients diagnosed and through the system as we move forward.

Operator

Colin Bristow, Bank of America.

Colin Bristow - *BofA Merrill Lynch - Analyst*

Thanks for taking the questions. So, on Keytruda in first line, (technical difficulty) question. Just given the lack of PD-L1 testing harmonization and therefore the need to test for the drug you want to use, if Bristol does show a PFS and OS benefit across a broader PD-L1 expression population what would drive physicians to test for Keytruda given it would carry a lower probability of a positive result?

And then just a follow-on for Keytruda. Could you just give some details around the current performance in terms of share in each indication? Thank you.

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

So let me start. First of all, the label says for Keytruda that it is based upon a PD-L1 test by an FDA approved test. It doesn't have a specific test assigned to Keytruda versus Opdivo. So I am not concerned and frankly most of the commercial labs that are measuring PD-L1, and/or the individual institutions that do it themselves, are not having designated tests for designated products, so that's not a concern frankly.

In addition to that, with first-line lung I believe everybody is going to start to measure PD-L1 right from the start. So, even for the competition I think they're going to be advocating the importance of measuring PD-L1 moving forward. So that obstacle will go away.

Then ultimately I believe it is going to come down to the market share that you are able to achieve within the lung segment and therefore I am very pleased that we will be the first one to launch.

If you look specifically at our share of our business, about 70% of our business is in melanoma, 15% is in lung, and then the rest is in all other indications. And then you can kind of extrapolate that if you look at -- we have about, if you look at the dollar sales reported, about 30% of the dollar sales in share right now.

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

And Colin, it is Roger. The Blueprint Project demonstrated that the PD-L1 diagnostic test that is used by Bristol-Myers for Opdivo and our diagnostic tests are actually very similar in terms of their results and can be used almost interchangeably.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - *Leerink Partners - Analyst*

Thanks for the questions. So just a couple of quick ones. Number one, can you just remind us again what the benefit on tax was this quarter? It seems quite a bit lower than I would have anticipated this quarter.

The second question is -- as it relates to the manuscript that is in place, obviously we don't know the timing, but one would presume that that could impact NCCN guidelines and obviously uptake in the front-line setting. So am I thinking about the commercial impact of that publication?

And what would be the second publication to sort of validate the effect that obviously you're going to see an overall survival benefit in that patient population?

And the last question is relative to the transcript; obviously you don't want any surprises with the FDA filing an evaluation. So one would presume that the filing in fact could be with the agency at this point. Would that be a separate filing per se or is it possible that that could be incorporated into the existing filing for KEYNOTE 010?

We have seen the agency move in that way before, but should we think of this as a separate and distinct filing or is it possible that it could be incorporated into the KEYNOTE 010 filing? Thanks a lot.

Rob Davis - *Merck & Co., Inc. - EVP & CFO*

Good morning, Seamus. It is Rob, I will answer the tax question and then turn it over to Roger.

What the benefit relates to is the IRS allows you for orphan drug clinical trials. So if you have a drug that has a validated orphan status from the FDA the clinical trial expenses related to that drug can be taken as a credit against your tax, that is what we refer to as the orphan drug tax credit.

This relates to certain indications and stages within malignant melanoma that did receive a designation, I think we got it back in 2013. And then we spent the majority of the time since then accumulating the data and validating the expense and that led to the accrual you saw in the quarter. So that drove the vast bulk of the onetime benefit we saw in the quarter.

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

It is Roger. With respect to the manuscript, as you say, the first manuscript which describes the results of the 024 study, you asked about what would be the second publication. And there will be a number of publications that will come out of the study, although it is not an enormous study, there's still a lot of data there.

The first thing is to step through the primary and secondary endpoints and the characteristics of the treatment results. And thereafter there will be a lot of color and shading that will be added in other publications.

It is important data to get out there. My view looking at the data is that they are potentially practice changing and that it's important there be a chance to review that. Those data of course wouldn't be available for review by NCCN or other agencies until such time as publication takes place.

Then you also raised a question about our interaction with regulatory agencies. And all I can say about that is we've begun our discussions, we're working closely with regulatory agencies to understand the basis for filing supplements in the context of having multiple reviews.

And maybe if I could elevate just a little bit, I would say that the workload for regulatory agencies, given the very large number of studies that we and our competitors are doing in this field, is quite substantial. And how best to manage that workload and evaluate all these new data that are coming in is something I think that FDA and other regulatory agencies are wrestling with.

Operator

Jami Rubin, Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. Just a couple of questions. First, you talk about the advantage of being first, which I agree with, in front-line lung. But do you expect that there will be off label use for Keytruda in patients with less than 50% PD-L1 expression? And when are those trials -- the all comers or the over 1% expressers and above, when are they expected to read out?

Then I have a question for Ken. On almost every conference call or meeting you have hinted at the desire to do deals, business development, the importance of that to your long-term strategy, yet we really haven't seen much in the way of deals this year. The deals have been relatively small in nature.

Is that what the hint is today, that the types of deals you are likely to do are likely to be like the Moderna deals or the smaller deals? Or should we still expect that Merck is likely to announce a major transaction, which is something that I think you kind of signaled earlier in the year?

And when you think about the Company's outlook over the next five years with a number of LOEs, how important is a large transaction to your growth strategy? Thanks very much.

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

This is Adam. So first of all, being first to market does matter and, as you said, I think it is an advantage. We will only obviously be able to promote it based upon the label that we have and therefore be in expresser greater than 50%.

Whether there is off label use we will have to see what NCCN decides and what individual physicians decide. It wouldn't surprise me if they decide that but, again, it is nothing that we would have ever tried to encourage or promote.

Ken Frazier - *Merck & Co., Inc. - Chairman & CEO*

And on business development, thank you for the question, Jami. What I am signaling is that business development remains a very important priority and we are very actively engaged in trying to find the best scientific innovation.

Our main focus is to continue to augment our Phase 2 and early stage pipeline. We remain very active with the partnerships and collaborations and we are also looking actively for bolt-on acquisitions in key growth areas.

From our perspective I think it is important to remember that for us a bolt-on acquisition is not defined by size. When we talk about a bolt-on we are focusing more on finding the right assets that can augment our pipeline as compared to doing a large deal just for, for example, cost synergies.

So, all that being said, we are looking very carefully, we are taking our time and we are being diligent in seeking out the right assets at the right valuation. And I think that is what you should read into this.

And I think if you look across what has happened in the industry, there has been a re-rating of certain assets, but those boards and management teams are also taking time to assess what they actually think will happen going forward in their future.

So, I wouldn't read anything into it other than the deals we have done are the ones that we think can add value. And we will continue to look at all kinds of deals going forward.

Operator

Tony Butler, Guggenheim Securities.

Tony Butler - *Guggenheim Partners - Analyst*

Excuse me, good morning. Roger, brief question. In the Julie Graff data, did she actually see responses in prostate cancer patients who were PD-L1 negative and/or was that what informed you to decide to do three cohorts in the 199 trial?

And then briefly, Adam, on Zepatier, can you say to date what percentage of sales are from government channels versus those from commercial channels, realizing that may change over the next six months? Thanks very much.

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

Tony, it is Roger. The Graff data are -- it is a very small study and you are talking about just a handful of responders. It is unknown in each one of these settings whether the PD-L1 biomarker -- and this is part of a larger set of biomarkers that we look at, whether the PD-L1 biomarker is relevant to that particular tumor type.

And if it is whether the relevant index is the tumor proportion score or more broadly the combination of both tumor cells and inflammatory cells. So still a lot of work being done in the area of biomarkers and how predictive they are.

Stay tuned. I think the important thing to note is in a tumor type that was previously believed to be refractory, that is where an immuno-oncology would provide no benefit, there is clear evidence there could be some.

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

And Tony, this is Adam. So we saw the $112 million of Zepatier for the quarter and, again, we are still early into the launch. I mentioned that we have some Medicare Part D wins that start July 1. Obviously you won't see a lot of sales from those in the quarter.

Most of the sales in the quarter came from the VA and some other segments where we had utilization for patients with renal insufficiency. But as we move forward I would expect that the mix is going to change substantially. And as Medicaid -- I'm sorry, as Medicare Part D commercial ramps up I think you will see a very different mix.

Operator

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

Thank you. Adam, do you have any comments on Remicade dynamics and that rate of erosion and how you have chosen to play defense there? And maybe you could comment on how that experience so far shapes your view on the potential for biosimilars for Merck from an offensive standpoint.

And Rob, since we don't have the 10-Q, would you are mind providing cash flow from ops and receivables, if you have those handy? Thanks.

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

This is Adam. With regard to Remicade, our strategy all along has been to try to hold onto as many existing patients that were currently treated as we can. I think we have done a very good job with that.

Most of our loss of revenue came from reference pricing due to lower prices from the biosimilars. However, we are certainly starting to see that we are not only losing new patients but there are some countries in Scandinavia and even some other larger countries that are beginning to think about substituting therapeutically even existing patients.

So, I do believe that we are going to continue to see erosion for Remicade, that the biosimilar impacts, they are accelerating and they are going to continue as we go through the year.

As I think about biosimilars in the future, I think the key is going to be what your order of entry is into the marketplace and being first or second in the marketplace will matter. Each market molecule is going to be different and we will deploy different strategies based upon those different markets.

You see different strategies, for example, that you might use in the UK and France versus Germany. And we will have to be very specific by market how we launch our biosimilar portfolio.

At the same time what I would say is Symphony grew 16% ex exchange. So even the seen an impact on Remicade you haven't seen that go over into the other anti-TNFs and therefore we expect to continue to see good growth from Simponi.

Rob Davis - *Merck & Co., Inc. - EVP & CFO*

Gregg, this is Rob. We don't have the specifics for cash flow and the working capital you are asking for this morning. We are still finalizing some of those parts. But in general we tend to continue to see strong trends in cash flow and continue to see overall working capital improving across inventory and payables.

And then on the receivable side there is a little bit of a swing back, but then part of that is due to just as we are launching new products the mix of the receivables on those relative to what we see on the others. But there is nothing new or significant continuing trends and you will see the exact numbers when you see the Q.

Operator

David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. I was hoping, Ken, that you could paint a picture of how you see the next couple of years unfolding. Obviously you don't provide long-term revenue guidance, but you have some big growth drivers in Keytruda and Zepatier. And at the same time you will be experiencing the patent expirations of Vytorin and Zetia and Cubicin.

And so, I guess I am asking could you help frame for us how you see the evolution of Merck's revenue base and what other key revenue contributors you see to help offset the patent expiration pressures? Thank you.

Ken Frazier - *Merck & Co., Inc. - Chairman & CEO*

Well, obviously, we are not in a position, as you suggested, to give any 2017 guidance yet, but we are actively looking across our portfolio at the best ways, as Rob said, to balance the near-term investments while continuing to drive long-term growth.

We do anticipate some headwinds from several LOEs, as you suggested, Zetia, Vytorin, Cubicin and Nasonex. But we are also pleased that we are maintaining the steady growth of Januvia as a foundation to launch these products like Keytruda and Zepatier.

Beyond that, as you know, we have things that are coming out of our pipeline. Roger made reference to building onto our diabetes franchise with ertu as well as odanacatib. And next year we are looking forward to being unblinded with respect to our BACE inhibitor and anacetrapib. So those would be some of the internal things.

And then as I mentioned in response to an earlier question, we continue to look at business development and inorganic growth as an important critical part of our strategy going forward. As I sit here today, obviously I haven't anything new to announce to you, but I just want you to know that we are actively pursuing value creating inorganic growth opportunities.

Operator

Alex Arfaei, BMO Capital Markets.

Alex Arfaei - *BMO Capital Markets - Analyst*

Good morning, folks, and thank you for taking the questions. Adam, I know you are well aware of the significant price erosion in the hep C market as a result of increased competition. As you look at the immuno-oncology market, how comfortable are you with long-term price sustainability there as the number of treatment options increase over the next few years? Thank you.

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

I would look at them as separate and distinct markets and I think the big difference is Medicare Part B versus the way in which the hepatitis C products are reimbursed. I think there is different dynamics in those two markets.

With that said, as you look forward and you think about combinations of potential immuno-therapies or combinations with other therapies we have to find additional ways to think about contracting with customers and working with customers differently than the way in which you do today.

It is remarkable when you think about the number of indications that we are studying Keytruda for and we think about how we are building this huge wall of data, it is going to be real hard for followers to match us with the data that we are going to have over time.

And we are going to have to find ways to work with payers so that they can really find the right way to ensure the patients that need our monotherapy or our combination therapies in the future have access to it.

So, we are going to continue to think about the right ways to do pricing and contracting. I feel pretty confident as I sit here today that we will be able to maintain good contracts and access as we move forward.

Operator

Marc Goodman, UBS.

Marc Goodman - *UBS - Analyst*

Good morning. Adam, can you talk about the emerging markets, broadly what is going on there with your products, obviously excluding Venezuela which we know is going on.

And then secondly, can you talk about the Januvia/Janumet franchise overseas and just give us a flavor for how those products are doing relative to all the changes going on in the broader diabetes market. Thanks.

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

First of all, with regards to emerging markets, ex Venezuela -- ex foreign exchange we grew about 6%. So we continue to have good growth in the emerging markets. And if you look at China, we had 11% growth ex foreign exchange. So, the growth albeit not as good as it was a couple years ago it continues to be robust.

With that said, lumping emerging markets together today is not a good idea, because you have very different dynamics in terms of what is occurring in a market like China versus what is occurring in a market like Russia or what is happening in Argentina.

So we really do focus market by market what our opportunities for growth are. And then we titrate our expense base in those markets based upon the opportunities. But I do believe that the emerging markets will provide growth going forward and remain an important opportunity for us as we move forward.

With regards to Januvia outside the US, we continue to see good growth in Europe and Canada and that growth is coming from volume and the volume growth in most of those markets is very strong.

I would say the biggest issue we are facing is the fact that our market share is still high in countries like Germany, that it is hard to grow market share. So we have to continue to find ways to grow from sulfonylureas and ultimately from metformin.

But there is hundreds of millions of patients that need to be treated outside the US. If you look at the emerging markets we have strong double-digit growth of Januvia. I think that is going to continue over time. And we really have not gotten NRDL approval for Januvia in China yet. So once that is achieved I think that represents another opportunity for us for growth of the Januvia franchise outside of the US.

Operator

Andrew Baum, Citi.

Operator

Pivoting towards HIV, from the data you recently presented it looks like you have once daily Isentress. Could you talk to both the [sensor] properties of having that molecule given the erosion of that integrated market from Gilead and GSK or (inaudible) as we've seen historically? But also can you talk about the potential offensive strategies given you now have a base for a single tablet once a day regimen? Thank you.

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

So, as you look at our HIV franchise, obviously we have been losing dollar, share and volume based upon what is occurring in the competitive set in the marketplace. So we are really glad that we are going to have a QD Isentress and I think it will be very helpful for us.

The key is generally speaking we don't give guidance at a product level, but it is unlikely that the introduction of QD Isentress is going to be able to return the franchise to growth. I think it is going to enable us to be able to compete better within that marketplace as it exists. But I wouldn't look for very strong growth moving forward based upon that product for the franchise.

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

And if I could just say -- it is Roger. We have quite a number of compounds that we have developed that have intriguing properties with respect to HIV therapy that are all in early development. I haven't had a chance to talk about those in an earnings call setting but will hope to as more data becomes available.

Ken Frazier - *Merck & Co., Inc. - Chairman & CEO*

Okay, let me just close by saying this was a strong quarter. We continue to execute on our innovation-based strategy. And we continue to look for the best opportunities for long-term growth with respect to things like Keytruda and Zepatier. But we are also eager to find the best opportunities that will create long-term value for our shareholders both inorganically and organically. Thank you very much.

Teri Loxam - *Merck & Co., Inc. - IR*

Thanks, Darla. That concludes the call.

Operator

Thank you. This concludes Merck's Q2 2016 sales and earnings conference call. You may now disconnect your lines.