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MRK - Merck & Co Inc at JPMorgan Healthcare Conference

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PRESENTATION

Chris Schott - *JPMorgan - Analyst*

Good afternoon, everybody. I'm Chris Schott, pharmaceutical analyst at JPMorgan, and very pleased this afternoon to be introducing Merck. From Merck, we have Ken Frazier, the Company's Chairman and CEO. With that, I'll turn it over to Ken.

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

Thank you, Chris, and good afternoon, everyone. As always, it's a pleasure to be here at JPMorgan to provide you with an update on some of Merck's most recent accomplishments, and to highlight our strategic focus going forward.

Before I begin, I'd like to draw your attention to our forward-looking statement.

I'd also like to point out that all of my financial remarks will be through the third quarter of 2015. Accordingly, I will not discuss fourth quarter performance or provide guidance for 2016. As is customary, we will do that on our fourth quarter call in February.

Starting with a quick look at the external environment, the global healthcare market continues to evolve. As you know, demand for healthcare is growing around the world, driven by an aging population, an increase in chronic disease, and rising wealth.

In addition, many countries are implementing steps to significantly expand healthcare coverage with their populations. As a result, healthcare systems are being challenged and there's a greater emphasis on controlling cost, while maximizing population-based outcomes.

We believe new technology, combined with increased scientific understanding, will allow biopharmaceutical companies like Merck to operate more efficiently and enable further opportunities and breakthroughs in R&D, but these companies will need to adapt to this dynamic environment in order to succeed.

These external trends will drive the need for a sharper focus on innovation and value in all aspects of our business. Both innovation and value, fortunately, have always been fundamental to Merck.

Although using the technology, apparently, has not.

(Laughter).

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

As I was saying, Merck has a long legacy of bringing innovative products to patients with important, differentiated, and promotable advantages. In fact, this year marks Merck's 125th year in business.

Over our history, we have developed breakthrough antibiotics, such as Primaxin, discovered ground-breaking vaccines such as measles, mumps, and rubella, and GARDASIL, which was the first vaccine for preventing HPV-related cervical cancer, helped in the fight against cardiovascular disease with products like ZOCOR and VASOTEC, and battled the continuing global epidemic of diabetes with Januvia, just to name a few.

Most recently, we have been tackling cancer with immuno-oncology by bringing the first anti-PD-1 treatment to market.

These historic examples serve as reminders to us of what is still possible, if we keep unmet medical need as our North Star, and hold ourselves to the highest standards of scientific and operational excellence.

In today's challenging healthcare environment, we intend to sustainably pursue our mission of bringing new, innovative medicines to communities around the world, addressing the most significant global unmet medical needs in areas such as Alzheimer's, anti-microbial resistance, HIV, diabetes, and many more.

These are large markets, with significant unmet need, and we believe that payers will be willing to pay for innovation that creates value.

There we go again. I think I'm just going to use this. Thank you.

Merck remains committed to the goal of being the premier research-intensive global biopharmaceutical company. Given the evolving healthcare environment, and the significant unmet medical need that exists and that continues to emerge, we believe innovative biopharmaceuticals will remain one of the most attractive segments within the healthcare sector in terms of growth and margins.

Importantly, we believe that to continue to be successful, we need to have a balanced and differentiated portfolio that can weather competitive and payer pressures over time. We are dedicated to tackling the world's greatest healthcare issues, delivering the best medicines to patients globally, and, at the same time. providing substantial returns to shareholders.

Our focus is to innovate across our entire business, to pursue the most promising science externally through business development, and internally through our own research efforts, to execute in our labs and on our launches, as well as to deliver financial results by prioritizing resources to high-growth areas and key markets and customers, and, finally, to continuously adapt by developing an organizational culture and business model that evolve with the constantly changing landscape.

We've made significant progress in optimizing our organization, and executing on our strategy. We've advanced our late-stage pipeline, gained first-in-class approvals, launched new, innovative products, and delivered strong financial results.

As you may know, I asked Roger Perlmutter to rejoin Merck a couple of years ago with the express mandate to reshape and revitalize the Merck research labs, and to create a platform sustainable innovation for years to come.

We will continue to enhance our internal research capabilities, and actively produce the best external innovation, all while constantly challenging and reprioritizing our R&D portfolio in order to maximize shareholder and customer value.

We have streamlined our internal R&D governance, and strengthened our compliance and decision-making processes, which are enabling us to advance our pipeline in a more efficient and effective manner.

We've had several major product approvals in the past 18 months, including KEYTRUDA, GARDASIL 9, BELSOMRA, and BRIDION. We also submitted several new filings, such as BEZLOTOXUMAB for C-difficile and our Hepatitis C doublet, which has an upcoming PDUFA date in a couple of weeks on January 28th.

On the commercial front, we are driving operational excellence, prioritizing resources to our highest growth areas, such as diabetes, oncology, vaccines, and hospital acute care, and focusing on key customers and markets.

We are developing new pricing and contracting models, innovative outcomes research and real-world evidence capabilities. We still have work to do, but we are well on our way to developing a commercial organization that can successful and efficiently flex and launch products regardless of the market or disease area we need to address.

Diabetes continues to be an important opportunity for Merck as macro trends support a global market that is growing, with hundreds of millions of patients having the disease.

Over the last year, we continued to grow the Januvia franchise globally, which is impressive, given that it has been on the market for almost a decade. Januvia has a strong leadership position in the DPP-4 market, and we will continue to invest behind this important product and defend our global market share. Notwithstanding the competitive dynamics in this field, we are going into the 2016 year with strong momentum and confidence in this $6 billion brand.

In addition, over the past year, we continued to invest behind our vaccines business with the successful launch of GARDASIL 9, our next-generation HPV vaccine, which improves the coverage against cancer-causing HPV to nearly 90%.

Vaccines remain an important part of our balanced and differentiated portfolio, both commercially, as well as in R&D, where we are working on bringing additional innovative vaccines to the market over the coming years.

We have also continued to deliver on our financial commitments, exceeding our $2.5 billion annual cost-savings goal by the end of 2015, and returning almost $10 billion to shareholders through dividends and share repurchases in the 12 months through the third quarter of 2015.

In addition, we had a very active and productive year on the business development front last year, which I will talk a bit more about in a couple of minutes.

But I can't talk about Merck's recent accomplishments and execution without highlighting KEYTRUDA. As many investors point out to us, Merck has not historically been thought of as an oncology company. This may be true, but, then again, before Januvia, we weren't a diabetes company either.

Like Januvia, KEYTRUDA is an extraordinary breakthrough, KEYTRUDA is also an example of unprecedented execution and focus across Merck's research, manufacturing, and commercial divisions. Just three and one half years after the first patient was dosed in the clinic, KEYTRUDA became the first anti-PD-1 treatment to be approved in the United States.

We have the broadest clinical program of any anti-PD-1/PDL-1, with over 200 clinical trials underway across more than 30 tumor types, and we are studying KEYTRUDA currently in over 80 combinations.

We now have approvals in first and second line melanoma. KEYTRUDA is the number one treatment choice across all classes for melanoma in the United States, and we are launching KEYTRUDA in over 40 countries.

KEYTRUDA is also approved in second-line, non-small-cell lung cancer, where we are off to a good start since launching in October. In effect, KEYTRUDA is a pipeline within a product.

In addition to KEYTRUDA, we also have over 10 internally owned I-O targets in our pipeline, with several of them expected to be in the clinic by year end. This reflects our commitment to the important and fast-developing field of immuno-oncology.

We have built an oncology business that has attracted top oncology talent from across the industry to Merck, and we already accomplished a great deal with KEYTRUDA, but we are still in the beginning chapters of the KEYTRUDA, and immuno-oncology story.

We believe KEYTRUDA will be a foundational treatment across many tumor types, and we expect to have additional mono-therapy data, as well as combination data across a number of different tumor types over the coming months and years.

We are also very focused on investing in other opportunities within our pipeline. We have more than 20 programs in Phase III, with another three programs under regulatory review as we speak.

These programs target many of the largest public health issues, such as Alzheimer's Disease. We continue to invest in advancing the treatment of HIV with more effective and better tolerated regimes, and despite effective treatments for atherosclerosis, there remains more than 60% residual CV risk for patients, meaning there is a significant opportunity for anacetrapib, our CETP inhibitor, if successful.

With macro trends demonstrating that diabetes remains a growing problem, we continue to invest in new mechanisms to help control this progressive disease.

We also have significant programs in Phase I and II in a variety of key disease areas, and, importantly, we're actively engaged in business development to constantly restock and reshape our pipeline.

Business development is a critical part of our strategy. We are looking to pair our best internal programs and inventions with the best external science and innovation to deliver a balanced and differentiated portfolio of medicines and vaccines.

We look to do this through collaborations and partnerships, as well as acquisitions, and we have been quite active over the past year. We have done several acquisitions, including cCAM Biotherapeutics, which expands our portfolio with early immunotherapy candidates, Idenix, which strengthens our HCV pipeline for a potential pan-genotypic short-duration regime, and Cubist, which augments Merck's strong foundation and opportunity in hospital acute care.

And just today we announced our acquisition of IOmet Pharma, which expands our immuno-oncology program with novel IDO1 and TDO inhibitors.

We've also been active in partnerships and collaborations, with more than 40 executed across our portfolio last year. For instance, we signed key collaboration agreements with Moderna for rights to use Messenger RNA therapies, with NGM to discover, develop, and commercialize novel biologic therapeutics, and with Bayer to develop and market potential new treatments for cardiovascular disease, to highlight just a few.

Our main focus, going forward, is to continue to augment our Phase II and early-stage pipeline. We expect to remain very active with new partnerships and collaborations, and we are actively looking for bolt-on acquisitions in key growth areas.

However, we remain open to looking across the entire spectrum of assets and companies in terms of size and stage of development to create the strongest portfolio we can, consistent with our goal of long-term value creation.

As we look forward to this year, we have many key catalysts. In oncology, we're expecting data from several registration-enabling studies, including data from our first-line lung trial with KEYTRUDA, initial GITR data and additional combo data, a label expansion for KEYTRUDA in second line lung cancer, based on the results of the KEYNOTE 10 study, which we filed in the U.S. at the end of the year, as promised, and the potential for additional filings for KEYTRUDA in several tumor types.

In Hepatitis C, we're getting ready for a potential approval and launch of our HCV doublet, as well as advancement into Phase III for our triplet.

In diabetes, we are expecting potential filings at the end of the year for ertugliflozin, our SGLT inhibitor that we partner on with Pfizer, as well as a potential label update for Januvia to include the positive TECOS results.

We also anticipate filing Odanacatib and several biosimilar filings, a potential approval for BEZLOTOXUMAB in C-difficile, and many other key catalysts our portfolio.

As you can see, we have a very busy year ahead. We'll remain dedicated to innovating, executing, and adapting across our entire business to ensure we continue to deliver breakthrough medicines that address significant unmet medical need in the most efficient manner possible.

We will continue to reshape our labs, diligently look for good business development opportunities, advance our pipeline, and focus on our commercial launches, all while delivering financial results and shareholder returns.

Over the past couple of years, I believe our management team has done a great job streamlining our operating model and reducing our costs, while at the same time building a new oncology business unit and increasing our investment behind Januvia and other key brands.

We've done this by strategically reallocating resources behind our most promising research programs, products, and markets. We will continue this strategy going forward, with the goal of having costs grow slower than revenues so that we can continue to deliver a leveraged P&L.

Beyond 2016, we are looking forward to the completion of our Phase III program for anacetrapib, as well as the Phase III mild-to-moderate study of our novel BACE inhibitor in Alzheimer's, both of which are expected to read out in 2017, as well as additional data and milestones for KEYTRUDA and many other compounds in our portfolio.

In summary, this is an exciting time to be Merck. While we have significant strides in our strategic initiatives and accomplished ground-breaking milestones in our R&D labs, we have a lot to look forward to, both in 2016 and the years to come.

I thank you very much for your generous listening, and now I'd be happy to take whatever questions you may have.

QUESTIONS AND ANSWERS

Chris Schott - *JPMorgan - Analyst*

Okay, mic is on here. Maybe we have time for one question here. Ken, one of the topics, I feel like, for the pharma group that a lot of investors are grappling with is the price dynamic. Certainly we've been seeing a lot of political headwinds. It's an election year.

How do you see Merck, and the industry more broadly, kind of adapting or responding to some of this noise that we're hearing on the pricing front?

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

So, I think there's two distinct areas that I think you need to focus on with respect to price, once of which is the political dynamic that you describe. The other one is, frankly, the consolidation of payers around the country.

And I think that, with respect to the political dynamic, I think the most important thing, and I try to do this in my role as head of PhRMA, is I think the industry needs to communicate better with the outside world to help people understand, for example, the difference between list prices and effective prices in the market.

I also think that people need to focus on the fact that as a result of insurance benefit design, patients often pay more than 20% of the cost of their pharmaceuticals through co-insurance and co-pays, while they pay, let's say, 4%, 5%, 6%, 7% of what they have to pay in terms of their in-patient bills, and maybe 8% of their outpatient bills, so that that disparity in the amount of insurance effectively creates a huge issue for patients when they present at the pharmacy counter.

So, I think we have a huge amount to do as it relates to communicating about the structural dynamics of pricing as well as to help people understand, of course, the real benefit of drugs, which is the value of reduced hospitalizations, and longer, better lives.

I think with respect to the consolidation of payers, I think what we're also seeing in the marketplace is the same kinds of pressures that are happening under the Affordable Care Act in the United States are driving a lot of the insurers together, and we continue to deal with that issue by continuing to come forward with innovative products that actually have value, which is why I think our strategy is the right one.

At the end of the day, only those products that actually bring real value to patients and the healthcare system are going to be reimbursed in the world in which we're going into.

Chris Schott - *JPMorgan - Analyst*

Thanks very much. I think we're going to continue our discussion across the way in the breakout session.