Merck's CEO Discusses Q2 2013 Results - Earnings Call Transcript

Executives

Joe Romanelli - Investor Relations

Ken Frazier - Chairman and Chief Executive Officer

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Adam Schechter - President of Global Human Health

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Merck & Co., Inc. (MRK) Q2 2013 Earnings Conference Call July 30, 2013 8:00 AM ET

Operator

Good morning. My name is Andrea, and I will be your conference operator today. At this time, I would like to welcome everyone to the Merck's Second Quarter 2013 Earnings Call. All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question-and-answer session. (Operator Instructions)

I would like to now turn the call over to your host, Joe Romanelli. You may begin your conference.

Joe Romanelli

Thank you, Andrea, and good morning everyone. We would also like to say good afternoon and good evening to everyone listening outside the United States. Welcome to Merck's second quarter 2013 conference call. Before I turn the call over to Ken, I want to point out just a couple of items.

First, there are number of items in the GAAP results, such as acquisition-related charges, restructuring costs and certain other items. You should note that we have excluded those items in our non-GAAP reconciliation tables and you can see this in our press release in table two. This will give you a better sense of the underlying performance of the business. There are three tables in the press release. The first table is the GAAP results. Table number two reconciles our GAAP P&L to the non-GAAP results for the second quarter and table three provide the sales performance for the company's business units and our products, both on a recorded basis and excluding exchange.

During the call, we will refer to table two when we discuss the P&L and table three when we talk about revenue performance. Finally, I would like to remind you that some of the statements we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Such statements are based upon Merck's current beliefs of management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. The company's SEC filings, including Item 1A in the 2012 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 statements. Our SEC filings can be found on the website at merck.com. You can also find our earnings release and all the tables there as well.

So, with that this morning, I am joined by Ken Frazier, our Chairman and Chief Executive Officer; Adam Schechter, our President of Global Human Health, he will update you on our product and geographic performance; Peter Kellogg, our Chief Financial Officer, who will review our P&L and provide an update on our outlook for 2013; and lastly, Roger Perlmutter, our President of Merck Research Labs will provide you with an update on some of our key programs.

With that, I would like to introduce Ken Frazier. Ken?

Ken Frazier

Thank you, Joe. Good morning, everyone. It's a pleasure to be here again today to provide an update on our performance and to highlight some of the key events from the quarter. We continue to focus on our core strategy. In so doing, we will build shareholder value by prioritizing investments in our best commercial growth opportunities with key in-line products and in innovative R&D. Second, making disciplined decisions regarding the allocation of resources and managing our cost effectively, this approach is especially critical in a period when we are navigating significant patent expirations and adapting to the global healthcare environment.

This quarter, our business momentum accelerated while we continued to manage our costs. We believe these results more accurately reflect the strength of our underlying portfolio when compared to the first quarter of this year. We are still working hard to improve the competitive position and growth potential of key brands like JANUVIA, which will allow us to drive our top line growth in the future. In addition, we continue to managing our expenses and are maintaining our EPS guidance for the year. Peter Kellogg will provide more detail on our revenue and cost assumption. For the quarter, we delivered an EPS of $0.84. This reflected underlying sales growth of 3% excluding the impact of foreign exchange and patent expiries. The growth was driven primarily by our Global Human Health business, including strong performance from our diabetes, immunology, and vaccine franchises. In total, 7 of our top 10 products grew in the second quarter. As always, Adam will provide more detail on specific product performance. The fundamentals of our complementary businesses, animal health and consumer care remained strong. We continue to view these businesses as important components of our diverse portfolio.

In terms of geographic performance, we grew 10% in emerging markets in the second quarter, excluding exchange. In the past several months, I have had the opportunity to visit Brazil and Korea to see firsthand both the tremendous potential of these markets and the extraordinary enthusiasm of the MSD colleagues there. In Korea, for example, our diabetes and vaccine businesses are performing particularly well. The emerging markets now account for approximately 22% of our pharmaceutical sales with China continuing as a key growth driver.

Moving to the longer-term view, we remain committed to pursuing innovative science that translates into medically important products. To sustain our ability to do so however we are mindful that we must continue to find ways to improve our cash flow and build shareholder value over both the short and long term a commitment we also take very seriously. One way we demonstrate our commitment to building value in the short term is by returning cash to shareholders. Year-to-date we have returned nearly $9 billion to shareholders who both our dividend and stock buybacks. We have repurchased over a 120 million shares including our accelerated share repurchase in May.

Longer term shareholder value is of course driven by innovative R&D and improving the return on R&D investments.

Roger will share his views in a moment but I would like to comment on why we believe innovation is the path to sustainable value and needs to remain the cornerstone of Merck's efforts despite challenges like the recent (inaudible) exit and Sugammadex delays. There is an increasing need for innovative treatments that offer meaningful differentiation of patients and demonstrate value to payers. This is true for chronic diseases like diabetes but also in areas of tremendous scientific opportunity such as cancer immunotherapies and neuroscience.

I'm excited about the program like our anti-PD-1 for oncology and our ACE inhibitor for Alzheimer's disease to have the potential to alter the course of medicine. With the opportunities we see before us I want to be clear that we intend to aggressively manage our costs in the short term and our fundamental cost space over the long term. We need to do this in order to preserve our ability to invest in our future and have the flexibility to respond to the opportunities and challenges presented by the global healthcare environment. In the second quarter we continue to take out cost and prioritize our investments. We're doing this while supporting future growth in core brands and in the pipeline.

Let me share two examples, first with Januvia, we continue making the necessary investments behind this franchise to ensure that we maintain our leadership position in the increasingly competitive diabetes market and maximize opportunities for future growth. Second with PD1 we have created a strong expert team which streamline decision making. We committed to making critical investments to ensure that we fully realize the potential of this important product and bring it to patients as quickly as possible.

In summary we're committed to driving top-line performance with key growth product and key geographies. Advancing and augmenting our pipelines and aggressively managing our cost base. By doing these things well we will preserve the ability to invest in our future, continue to generate strong cash flow and drive shareholder value and return over both the short and long term. I would like to now turn the call over to my colleague Adam Schechter. Adam?

Adam Schechter

Thank you Ken. Good morning everyone. This morning I will focus my remarks and the performance of our core products and our core markets. Let me begin with the overall performance. Human health sales declined 12% in the second quarter, our top-line results continue to reflect the loss of exclusivity a SINGULAIR, PROPECIA, CLARINEX and MAXALT and weakness in the yen, excluding sales in these products are underlying business grew 4% on a constant currency basis. Two contributors were Januvia and Janumet, Simponi and our vaccine business, only provide some more details. I'll start with the Januvia and Janumet franchise. The franchise has sales of $1.5 billion and 10% growth excluding exchange. The franchise grew 9% in the United States and 11% in International markets. In the United States, demand price, and inventory contributed to growth. With regard to demand we were able to maintain a 75% TRx share of the very competitive DPP-4 market.

Volume grew slightly by about 1% this quarter, regarding price we did see a benefit this quarter from price. We have increased price over the last year but we have also seen increase rebate and pricing pressures as competitors seek to improve their former position by increasing discounts.

Finally, on inventory, our customers increased their inventory levels by about $30 million in the second quarter. If we exclude this inventory benefit, we believe our sales would have grown by about 5% in the United States in line with our expectations. In the international markets, JANUVIA and JANUMET had good volume growth in every region around the world and retained market leadership with a 70% global market share.

Now, let me touch on our outlook for the rest of the year. We continue to expect mid-single-digit sales growth in the United States, which excludes channel movements that are difficult to predict. We also continue to expect low double-digit growth, excluding exchange internationally. In the United States, we continue to invest and change the current TRx trend. We have focused our resources on JANUVIA to drive demand and to defend our strong leadership position in a highly competitive market. Globally, there continued to be good growth opportunities in the diabetes market and we are positioned well with the market leading DPP-IV inhibitor.

So, moving now to ISENTRESS, ISENTRESS sales of $410 million, which represents about 5% growth? In the United States, we are maintaining our patients here despite new competition. Outside of the U.S., ISENTRESS continues to have good volume growth offset partially by pricing pressure in Europe and timing of emerging market purchases this quarter. In our cholesterol franchise, ZETIA and VYTORIN global sales were up by about 1% over the prior year. ZETIA growth was partially offset by decline in VYTORIN sales. We are currently launching LIPTRUZET, the combination of ZETIA plus atorvastatin in the U.S. This product reinforces the benefit that this family of products can provide to many patients who continue to have high LDL cholesterol despite the wide use of statins.

Moving to immunology, the combined immunology business consisting of REMICADE and SIMPONI grew 11% in the

quarter, excluding exchange. The growth was driven mostly by SIMPONI. Sales of SIMPONI grew 60% to $120 million this quarter. We are continuing to see a positive impact in the launch in France and the reintroduction of the autoinjector in Germany. Last week, we received a positive CHMP decision for an additional indication in ulcerative colitis, and we look forward to potential approval later this year.

Moving to VICTRELIS, the global sales of $116 million this quarter. Growth in emerging markets was offset by continued contraction of the Hepatitis C market in many countries, including the United States.

Lastly, moving to our vaccine business, which had another strong quarter. GARDASIL maintained its strong performance with 20% growth year-over-year. Second quarter sales benefited from continued uptake of the male indication in the United States and timing of government purchases in Latin America. Those were partially offset by lower sales in Japan. In Japan, the government recently suspended the proactive recommendation of HPV vaccines. We anticipate this decision will have a significant negative impact on the rest of sales of GARDASIL in Japan. For reference, sales of GARDASIL were $140 million in Japan last year. We are working with and we are providing information to the government on the vast amount of safety and efficacy data available for GARDASIL. On the other hand, we are pleased that the Ministry of Health in Brazil recently announced the National Immunization Program with GARDASIL to begin in 2014.

Moving on to ZOSTAVAX, ZOSTAVAX sales were $140 million this quarter. As we had expected, sales in United States declined sequentially due to seasonality. We expect the second half of the year to be stronger than the first half and the strongest quarter will likely depend on the start of the flu vaccination season. We continue to see ZOSTAVAX as a key growth driver. In the United States, we estimate that a little over 20% of the population ages 16 or older have received vaccine to-date. So, there remains opportunity for growth. Internationally, we are just beginning launches in the few Asian markets, including Korea. And we continue to anticipate our first European launch in the UK this fall with additional markets in 2014.

Now, I would like to touch on our performance on a regional level. In the United States, Europe, and Canada, sales continued to be affected by the loss of exclusivity of SINGULAIR, MAXALT, PROPECIA and CLARINEX excluding these products U.S. sales increased by 7% and sales in Europe and Canada were flat in the second quarter. Japan's sales declined 4% ex-exchange that was due to an increase in the utilization of generic versus branded products and lower sales of Gardasil which I mentioned earlier. Emerging markets has another good quarter with 10% ex-exchange sales growth that includes 10% growth in China. Growth in the emerging market was broad-based that came from our base business, our new products and our joint ventures. And key emerging markets, our growth is outpacing the overall market and we expect to continue to deliver strong growth in 2013.

In closing the human health business demonstrated growth of our underlying portfolio of key brands. In August we will annualize the SINGULAIR expires in the United States but we also anticipate generic entry in the United States for Temodar, despite the significant number of patent expires we're facing this year. I'm confident that we can drive growth of our strong and our diverse portfolio. Now I would like to turn the call over to my colleague, Peter Kellogg.

Peter Kellogg

Thank you Adam and good morning. As you heard from Ken and Adam our core brands performed well this quarter. Furthermore we continue to manage cost effectively while investing for future growth; additionally we executed a significant capital initiative in the quarter. Our confidence and our future cash flows and the historically low cost of debt allowed us to return cash to shareholders in the form of $5 billion accelerated share repurchase. This accelerated repurchase is a key component of our goal to buyback $7.5 billion of shares within the first 12 months of our $15 billion repurchase program announced in May.

These results and actions demonstrate that Merck is committed to improving our performance in the short term, investing for the long term and continuing to allocate capital in a shareholder friendly manner. This morning, I will briefly talk about our performance in the second quarter and now I will discuss our outlook for the remainder of 2013.

My remarks will focus on our non-GAAP financials, starting on the bottom-line we're a $0.84 per share this quarter compared to a $1.05 in the prior year. On the top-line, total company sales declined 8% in the second quarter excluding an unfavorable exchange impact of 3%. As Adam said sales increased 4% in our pharmaceutical business if you exclude generic erosion and foreign exchange.

Animal health sales increased 1% year-over-year excluding exchange driven by companion animal and poultry businesses. In consumer health we had a onetime unfavorable adjustment to sales this quarter excluding these adjustment consumer health sales would have been up 4% on a constant currency basis. Moving to other revenues we

saw an increase in supply sales to AstraZeneca in the second quarter. Despite this we continue to expect the supply sales will decrease as we approach the May 2014 U.S. patent expiration for Nexium.

At the PGM line as previously discussed generic erosion of high gross margin products also created 2.5% headwind on the gross margin this quarter. As a result our non-GAAP gross margin declined on a year-over-year basis to 75.7%. As we indicated previously we expect the full year gross margin ratio to be about 1% lower than 2012 due to this mix shift in our sales. Turning to marketing and administrative expenses, our second quarter SG&A expenses were about $60 million lower year-over-year excluding foreign exchange benefits and some onetime corporate charges, we reduced our SG&A spending by about a $100 million this quarter. Similar to last quarter we continued to proactively reduce spending.

As a result of our cost reductions we continue to expect SG&A spending in 2013 will be lower than 2012. Moving on to R&D, research and development expenses in the second quarter were a $144 million lower than prior year. However we recall that last year we had a significant upfront payment of a $120 million for our agreement within the site excluding this R&D expense would have been relatively flat.

Other income and expense was about a $100 million higher year-over-year primarily as a result of foreign exchange losses and interest expenses. In the month of May we concluded a $6.5 billion debt offering at a blended average interest rate of less than 2%. This debt offering funded our accelerated share repurchase and we now have new interest expense and lower shares outstanding

Moving to tax, our non-GAAP tax rate was 21.9% in the second quarter. We are maintaining our estimated full year tax rate to be in the range of 22% to 23%. The tax rate for the second half of the year will be considerably higher compared to the rate in the first two quarters.

Now, turning to the 2013 outlook, on the bottom line, we are reconfirming our 2013 non-GAAP EPS guidance range of $3.45 to $3.55. On a GAAP basis, we expect to earn between $1.84 and $2.05. Now, for additional color on the outlook for the rest of the year, let's start with revenue. During the second quarter, the U.S. dollar continued to strengthen against many global currencies. If today's foreign exchange rates persist, we would expect full year 2013 sales to be negatively affected by about 3 percentage points, which is greater than we had previously anticipated.

Given our performance in the first half of 2013, the continued strength of the U.S. dollar and select product trends, we have adjusted our full year revenue expectations. We now anticipate that total company revenue will be 5% to 6% below 2012, including the negative impact of foreign exchange. While we have adjusted our sales guidance, we are maintaining our EPS guidance through cost management and SG&A and R&D. Accordingly, we now expect R&D expenses in 2013 to be lower than 2012.

Moving to the quarters, as we think about the back half of the year, we see improvement in EPS performance compared to the first half of the year. Additionally, we anticipate that the fourth quarter will be higher than the third quarter from an EPS perspective. So, in conclusion, this was a solid quarter, where we successfully executed a major capital initiative to return cash to shareholders. We also drove growth in our key brands while managing costs and we continue to step up our efforts on our key R&D programs. Thank you.

Now, I will turn the call over to Roger who will provide an update on MRL. Roger?

Roger Perlmutter

Thanks Peter. During the second quarter, we made steady progress in clarifying the registration process for Merck's next wave of products and advanced our clinical trials in important areas. For SUVOREXANT, our first-in-class orexin antagonist for the treatment of insomnia, the FDA has provided a clear path to registration through their complete response letter, which we received at the end of the quarter. We are making good progress in preparing 10 milligram and 5 milligram SUVOREXANT dosage forms to enable initiation of therapy at lower starting doses, which was the principal change requested in the FDA's review.

We hope to be able to begin stability testing of these materials in the very near future with a goal of submitting definitive data in response to FDA's requests in the first half of 2014. As was demonstrated at the FDA Advisory Committee Review in May, SUVOREXANT has distinctive therapeutic properties, which we believe will enable it to become an important treatment for patients suffering from insomnia.

Turning to other regulatory actions, two weeks ago, we announced that the FDA had postponed its Advisory Committee Review of SUGAMMADEX, our parenteral agent for the rapid reversal of certain types of neuromuscular

blockage during surgery. This still enable the FDA to complete audits of certain U.S. and European study sites that were involved in generating data contained in our submission. We are working closely with the FDA to facilitate these audits and will have more to say about the registration timeline for SUGAMMADEX once the FDA has completed this review. As you know, SUGAMMADEX is already registered in more than 40 markets around the world.

Also during the second quarter, we had the opportunity to present encouraging data on MK-3475, our monoclonal antibody directed against PD-1 for the treatment of malignant melanoma at the American Society of Clinical Oncology meeting in Chicago. This immunomodulatory approach for the treatment of malignant disease is also under study in patients with non-small-cell lung cancer. We hope to present preliminary results observed in such patients in October at the International Association for the Study of Lung Cancer meeting in Sydney. Our data thus far have encouraged us to begin a Phase 2/3 study in non-small-cell lung cancer for which enrollment is just beginning.

We are also continuing to study responses in patients with other malignancies before we believe treatment with MK-3475 may be beneficial by itself or in combination. New studies have recently begun in patients with hormone receptor negative breast cancer, neuroepithelial tumors, head and neck cancer, and in certain patients suffering from colorectal cancer. In the plenary's presentations at the ASCO meetings in Chicago, it was noted that immunomodulatory agents offered great promise for the treatment of desperately ill patients suffering from malignant disease. Our portfolio includes not only MK-3475 but other immunomodulatory agents which have emerged following a systematic evaluation of cell surface proteins involved in immune regulation. With respect to MK-3475 OU will recall that we have received breakthrough designation from the FDA for this therapy and we're in very close communication with the agency regarding requirements for an viable data set in the setting of advanced melanoma.

Meanwhile our MK-8931 program, a small molecule inhibitor beta secretase for the treatment of Alzheimer's disease continues to enroll patients and advance of a safety review which we believe we will complete at the very end of this year.

Satisfactory completion of this review will permit expansion of the study for formal efficacy testing, in this pivotal study patients with mild to moderate Alzheimer's disease will be evaluated for the effect of MK-8931 on a cognitive performance and activities of daily living: following 78 weeks of treatment as compared to placebo.

Finally, during my first few months in this role at Merck I found much to be proud of in terms of the quality of our programs and our people. However, I see the clear need for changes that will strengthen the return on investment in R&D. My review is focused on each critical area of performance, programs, processes and people and I have begun to make adjustments along each dimension.

From the programmatic point of view we're moving to narrow our focus to make certain that products with unambiguous clinically meaningful advances receive our complete attention. With respect to process the governing structure has been flatten considerably removing some layers of decision-making. Much has already been achieved here, but more will be required to improve our efficiency in providing resources to leading project. Finally, with respect to people we're moving quickly to build our leadership in R&D and specifically brought our licensing, business development function into my senior leadership area. As for all large bio pharmaceutical companies, licensing plays a key role in the development of breakthrough therapies. I expect Merck to participate fully in this area.

Additional details of our revised R&D strategy will be the subject of future reviews. I'm very much looking forward to sharing this information with you. Ken?

Ken Frazier

Okay so thank you Roger and thank you and I have thank you letter and thank you, Andrea (ph). So before we move into Q&A, I just remind you that we're going to try to get to as many questions as possible. If you could keep your questions to one or two and if you have additional questions if you can rejoin the queue this way we can get to as many calls as possible. So Andrea you can go ahead and open up the first line for questions.

Question-and-Answer Session

Operator

(Operator Instructions). Yes sir, your first question comes from the line of Marc Goodman with UBS

Marc Goodman - UBS

Couple of things, first can you comment a little bit more about animal health and consumer both very seem to be a

little weak even consumer excluding that one time change you made. You talked about add products for immunotherapy can you talk about how quickly you can get those in demand? And then R&D, can you talk about some of the changes that allowed you to take spending down for the quarter. Thanks.

Ken Frazier

Let's start with the animal health and consumer question. So, I would say that overall reflecting on this quarter it was an okay quarter for those businesses but if you step back, you'll see that they grew low single-digits and we look back beyond the third quarter we think both are performing well. So I would not let one quarter be the answer for those two businesses, as I've said we continue to think of them as being complementary businesses that will help us over the longer term contributing to our top and bottom line growth.

Adam Schechter

I would add I think in the animal health business they are in the middle of rolling out the Activel (ph) product line which we're very excited about as well as SUPRIVA rather and I think I reminded you that last year in the second quarter we actually had some very strong performance as we picked up some business where there were other stocks some of our competitors, so we're probably are in the animal health business slapping a pretty strong prior year. For the other questions maybe I will pass it over to Roger.

Roger Perlmutter

Yes just Marc just a couple of things with respect to the immunomodulatory agents there is a whole set of different cell surface molecules that involvement as checkpoint regulators if you will that control the response of limfositosis too stimulus and we have had the opportunity to inventory, we use to develop antibodies directed against the whole set of them and to look at them in pre-clinical setting. We hope to be advancing those into the clinic relatively soon you'll see them come up on clinicaltrials.gov and I have more to say on them in subsequent quarters. With respect to expense there is no single category of expense control that we can point to, but there are whole variety of things that I have been able to do in terms of reassigning resources and in that process have pulled back on some of the spending levers, which enabled us to reduce our expense now and will going forward as well.

Joe Romanelli

Okay, great. So, next call?

Operator

Your next question comes from the line of Chris Schott with JPMorgan.

Chris Schott - JPMorgan

Thanks very much. Just had two questions. The first is on JANUVIA, obviously you saw a rebound in reported 2Q growth, but it looks like prescription volume growth left in the U.S. is still fairly low. I guess my question is do you believe you are seeing a benefit from the additional resources you put on the franchise earlier this year? And maybe more broadly you talk about the overall DPP-IV market at this point? I guess, as we start to annualize the TVD benefit, do you believe you can reaccelerate growth for this category? My second question which was going back to some of the comments that Roger had made about the licensing of assets. I guess, I am thinking kind of little bit more, should we think of this as a greater focus on M&A from Merck that we have seen in the past and is that focused more on early stage assets or those that have achieved proof-of-concept? Thanks very much.

Ken Frazier

Okay, let me start with the second one first. I just would say, Chris that for us, when we think about capital allocation strategy, one of the most important ventures Roger said is to augment the pipeline. And that means looking for the best technology that we can find, the best opportunities we can find that are value-creating opportunities and that will remain a major priority, and I know for Roger, it's even a greater priority. So, why don't I turn it over to Roger?

Roger Perlmutter

Chris, just let me emphasize as I think I did at the first quarter earnings call, that I am really interested and really focused on products. And so it is to me less important that we consider at this stage and more important that we consider what is the potential value of this new therapeutic entry? Does it have unambiguous meaningful clinical

impact that can change the practice of medicine and bring important benefit to patients suffering from grievous illness, that's the critical point? And I am prepared to go after those wherever those exist, and I know Ken and Adam and Peter are completely onboard with that.

Ken Frazier

And with respect to your JANUVIA question, I will turn it over to Adam, but again we are pleased that we saw the product perform better this quarter versus the first quarter, we think it's rebounding and we are continuing to provide tremendous support behind it. So, with that, I will turn it over to Adam.

Adam Schechter

Yes, hi Chris. Let me give you some additional context in the U.S. and also give you a little bit of more color outside the U.S. Now, we are thinking about outside the U.S. So, as I discussed in the U.S., we had 9% growth and I tried to give you some context of that by breaking it down, where we had 1% that was volume, 4% was inventory, and the rest was price. The real key is changing this TRx trend, and that's what we are frankly focused on. The real issue Chris is that we have a 75% market share in the U.S. despite a very significant number of competitors. So, it's not about time to gain more market share, it's really about getting sulfonylurea use over into DPP-IVs of which we have the lion's share.

Typically, with multiple new entrants in the market, you see a lot of class growth. We don't see a lot of class growth despite all the new competitors that have come into the marketplace. So, the way for us to change the trend is really to focus on the switch from sulfonylureas. And sulfonylureas still represent about 35% of the patient days of therapy. So, there is still a big opportunity there for us to go after. So, what we have done is we have increased our focus. We now have dedicated sales force and thereafter they are promoting they are engaged. In addition to that, we have increased our promotion spending and our print direct-to-consumer advertising. All of our focus now is on the sulfonylurea utilization up until the first quarter this year most of our focus is on the TVD opportunity, that's no longer there. So, it really is about sulfonylureas.

The good news is that we have maintained our strong managed care access in the U.S. So, we have access to our products in over 80% of the patients we have preferred access. And now it really is about executing on the sulfonylureas strategy in the United States. Outside the United States, we still have a very significant opportunity in every region outside the U.S. had strong volume growth. The one thing I think is important that although we had 11% growth X effects. The big difference between X effects and FX was the yen. We have a very significant amount of our sales in Japan for JANUVIA. In Japan, you may recall the DPP-IV class is the number one class of oral diabetics in Japan. In Japan, it's ahead of metformin, it's ahead of sulfonylureas, and we have by far the leading market share. At the same time on every other quarter we get supply sales from our co-marketing partner which happened this quarter, so when you look at our success in Japan, plus the supply sales coming in lumpy you can see how the yen would have a very significant impact on our sales when you don't adjust for exchange that's the difference primarily for the underlying business performance being very strong but what you see including foreign exchange.

Outside the US, we continue to anticipate low double-digit growth, and we see that we're getting that volume and I think the opportunity remains very strong there for us.

Joe Romanelli

Okay thanks Chris. And Andrea can we have the next question?

Operator

Your next question comes from the line of Tim Anderson with Sanford Bernstein.

Tim Anderson - Sanford Bernstein

On the new guidance changes this is the second time this year that you're kind of changing guidance albeit here you're not changing earnings guidance and the revenue guidance that speaker is not just foreign exchange, which is something that's out of your control, Ken you first took over at Merck you withdrew long term guidance that was standing at the time, so my question is that kind of a higher level here what's happening within the company such that numbers are assuming to move around as much as they are and then going back to outlook for mergers and acquisitions historically Merck did not do big mergers until it did Schering-Plough back in 2009 what's the outlook for M&A from here in terms of deal sizes, are you going to revert back really only looking at bolt-ons or are you considering mid-sized targets as well or what exactly?

Ken Frazier

Let me just start by saying we of course maintained our EPS guidance and so I want to make that very clear. In terms of what's happening with the sales you heard, Adam talk about the foreign exchange but there also have been during the course of this year we took on some I think at the beginning some pretty ambitious revenue targets given the fact that we were facing major patent expires that's how we try to deal with the situation last year that was undertaking this year. We have seen some things that have impacted product trends this year and including Januvia happened and what have you heard out without warning, saying it would also have been arguing the court this year we took on them. I think in the beginning. This is readily talking. Given the fact that we were facing major, naturally, but I would try to deal with the situation last year. That was not undertaken this year we have been found things that have impacted product this year, including Januvia we have seen the, we're housing an is unique. We are helping HCV (ph) just to pick up couple of major growth drivers that we have seen an impact on this year. So I just want to just underscore that we take our guidance very seriously during the course of the year as you know we have seen negative impact on four year sales of about 3% for foreign exchange but we have also seen some other impacts that it us like this quarter there was a onetime charge for MCC and I would also point out that if you look at our overall you can see that we're managing cost in order for us to continue to deliver our bottom-line EPS guidance which again I take very seriously.

Peter Kellogg

On the M&A front, so Tim I guess you kind of went through this chronology of Merck for long time I hadn't done any really big M&A deals I guess and then (inaudible). I think as we go forward really in many ways we're thinking a lot about the product portfolio in the business we have I think we reiterate a lot of what Roger commented on relative to making sure we have great two products and really exciting products and if that ends up leading as to business development deals or joint ventures or M&A I think we're comfortable with any of those. I think as Ken commented earlier we really do talk about our capital structure as having the number one goal of supporting strategic needs of the business and so we're certainly, all we maintain a position to be able to do that that said we also don't want to build up inefficient balances on the balance sheet so that's why we had a more proactive capital structure program recently. But no ways that could say we wouldn't be doing the right things to build the pipeline and we're always on the prowl looking for the right things the great assets that are out there.

Ken Frazier

I will just underscore what Peter just said I think from our standpoint looking for M&A deals that would be sensible value creating bolt-on deals is something that we will be very interested in doing but we have tried to become and remain a very discipline company when it comes paying for assets so that we can actually create shareholder value with them over the longer term. So deals is the number one priority that we can create value, we have enhanced our share repurchase, we obviously remain committed to our dividend but in the long term it's product that drive this business and that's why we're going to continue to look for sensible opportunities to augment our pipeline whether it's licensing or bolt-on M&A deals.

Joe Romanelli

Great, thanks and thanks for the questions. Andrea, next caller?

Operator

Your next question comes from the line of Jami Rubin with Goldman Sachs.

Jami Rubin - Goldman Sachs

So, Roger, a question for you, we – Merck issued a press release about a month ago providing a sort of outline on R&D restructuring which involved removing layers of management. And today you are talking about lowering R&D spending for 2013 versus 2012 and narrowing your focus? Just curious to know if you see this R&D restructuring process as more iterative in nature or should we expect more substantial change ahead involving pairing back on your specific therapeutic focuses meaningful change in the way you allocate capital and R&D? Just wondering if there is more big news to come with respect to what you are doing to improve ROIC in R&D? And then secondly again on PD-1, just wondering if you can update us on your views on combo studies, where you are with that, if you are seeking to combine your drug with a CTLA-4 and when we can expect to see news on that front? Thanks.

Ken Frazier

Thanks, Jami. So, first of all, with respect to R&D structure and lowering expense, as I indicated the goal is to focus

our very substantial resources on the programs that matter the most and give them our complete attention. There will be a series of changes that take place in order to improve the efficiency of the process. And as that goes forward of course, we will communicate that to you, but our expectation is not that they are going to be big, enormous changes that will be announced in the way that you described. With regard to PD-1, we are interested first of all of course in delivering on the monotherapy promise in melanoma and in lung cancer. And as you know when we presented these data at ASCO, there are very impressive response rates that we have seen in patients with melanoma who have refractory disease, who have failed all prior therapies. And naturally, we want to bring the benefits of that therapeutic intervention to those patients. At the same time, we also recognized, because there will be opportunities to combine immunoregulatory modulators, or anti-PD-1 therapy 3475 with other agents both our own internally as well as others of the mother companies, they won't surprise you to know that a lot of companies are interested in working with us on that. We have had discussions with many of them and we will be talking about those combinations as we would announce more results for the PD-1 program. Okay, thanks Jami. Andrea?

Operator

Your next question comes from the line of Tony Butler with Barclays Capital.

Tony Butler - Barclays Capital

Thanks very much, Ken and Peter while you have reiterated guidance for the full year, and I may have missed this, what's the change from Q1 on the GAAP for your guidance, which I think is down now about a dime? And then Roger on 8931, the safety readout, will that be at a clinical meetings CTAB, for example, in November or would you expect that at a press release whether it would be any data coming out on the base inhibitor in the second half? Thanks very much.

Ken Frazier

I will turn the first question over to Peter, but just from the operating standpoint, we are reiterating our EPS guidance.

Peter Kellogg

Yeah, hi. So, in the GAAP P&L, there are some items that we actually exclude from the non-GAAP and sometimes, because they can be lumpy and it goes back to many cases the restructuring or the merger accounting. Now, in this case, we actually do have some adjustments to our R&D intangibles that we actually booked in the second quarter and that simply looking at either products as well as commercial intangibles, which is also a highlight. And so that's all part of the merger accounting. When you go through major merger, you look at the balance sheet and the items that are coming through and you actually allocate value both to the pipeline in the form of in-process R&D intangibles as well as the commercial products, which are intangible commercial assets. And then on a quarterly basis, we work very closely and monitoring that very accurately in terms of R&D expectations, those products all delivering exactly what we saw.

And from time-to-time, something happens to the pipeline perhaps and that causes us to write-down an in-process R&D intangible or conversely perhaps the commercial trends aren't quite as robust as we had originally bought. And so that would cause us to trigger a write-down or a reduction of the asset value in the intangible of our commercial asset. So, primarily, when you look at the change in the EPS at the GAAP level which what you're seeing are some of those evaluations that we go through on a quarterly basis where we actually change the value of intangibles and that's primarily the difference that you see in the gap EPS that's incremental of what you see in the non-GAAP and I certainly apologize for getting into that much accounting but that's really what you're seeing.

Adam Schechter

And Tony with respect to 8931 the structure of the program is that we have an initial phase in which we analyze, we enroll and analyze a set of patients over a three month period each patient exposed for three months in order to look at dose ranging and to look at safety intolerability and based on those results we then proceed into our large Phase-III study. We believe that we will complete that safety run-in period including the three months drug exposure by the end of this year. Our hope and belief of course is let's say intolerability will be expected and we will move on into the large efficacy portion of the trial. If there were any problem of course we would let you know and proceed into that we will let you know about that as well and ultimately those data will be presented in the scientific meeting. So you can expect to hear about it at the beginning of 2014.

Operator

Your next question comes from the line of Mark Schoenebaum with ISI Group.

Mark Schoenebaum - ISI Group

First of all congratulations to Adam and his team on the U.S. especially on the U.S. (inaudible) you probably know there is a lot of consternation around that number on the street, you guys delivered. So my questions are mainly around that, so number one you said there was a $30 million inventory that in the quarter, can you just remind us I believe there is a $70 million drawn down last quarter so it has been a fair bit of movement here. Has that stabilized? Should we expect further movements going forward? Yes or no and then I heard a couple of numbers thrown around I got a little bit confused just a clarification, what exactly was the price benefit in the U.S. year-over-year and in the ex-U.S. can you update us on what's going on with AMNOG and Iqwig in Germany there has been some I know movement over there and I guess you guys came out little bit ahead of your competitors but can you walk us through the potential scenarios there? I know no one knows looking at them what are some of the potential outcomes? Thanks so much.

Ken Frazier

Absolutely Mark it's I would try to give you as much as specific as we can because it's such a big growth driver for us and if you look at the interview (ph) what I said was that off the 9% U.S. growth about 1% was from volume, 4% was from inventory, the rest of it was from price so that makes about 4% price. You've to be careful extrapolating that over every quarter because mix can have a significant impact on how much price comes to it at any point in time also the timing of your price increase makes that a little difficult for you to try to predict and look for it to be the same quarter-over-quarter. With regard to the inventory, we did see about $30 million of inventory movement this month which I mentioned. On the base of business that we have it's very, very small $30 million so it's very difficult to predict the channel movements from one quarter to another, we are not seeing large channel movements in terms of how big the product is in the United States. It's relatively small but small channel movements can have $30 million to $50 million impact. So that's why for the guidance that I gave for the rest of the year I said mid-single digits for the U.S. but I excluded the movement of channel in there because you can't predict $30 million to $50 million of channel movement, it's within a half a day sales or something like that, so that's how I think about the inventory moving forward. With regard to Iqwig so on July 1st they announced the outcome of their assessment of Januvia and some other PP Force. We were pleased that they have recommended that there is add benefit for Januvia when added to metformin. We're very pleased with that.

That's the beginning of the process, the next step is a decision on the added medical value by the GBA and that's expected in the fourth quarter of this year. Once that happens you actually go into the reimbursement discussions so we're happy with where we are today, we're very pleased with the initial assessment but there is still a lot more work for us to do and it will be another six months before we probably know the final outcome of that. Just to put that in perspective for you Mark, if you look at Germany it represents less than 5% of our Januvia family sales to just give you a sense of the magnitude of that so we're excited with what's happened thus far which is still a long way to go.

Operator

Your next question comes from the line of David Risinger with Morgan Stanley.

David Risinger - Morgan Stanley

Yes, thanks so much. I have two questions. And they both relate to some cross currents and so Ken, I am hoping that you can clarify for me and I guess for investors on the call. With respect to the animal health and consumer businesses, I think you described them as complementary today, but there has been a lot of hoping and dreaming about Merck divesting these businesses or exiting these businesses on Wall Street? So, can you just sort of set the stage right in terms of how investors should think about them as being core to Merck that you will be building them or you will consider exiting them?

And then second, with respect to R&D cross currents, I think Ken you described how important it was to invest in R&D, but many on the Street have been hoping for significant R&D cuts. So, if you could maybe settle that debate and frame whether you expect R&D to remain flattish over time or whether there are meaningful cuts ahead? Thank you.

Ken Frazier

Okay. So, let me start with the animal health and consumer conversation that we had today. So, first of all, I have been saying for years that I think that, that is complementary to our business, but I also have been saying that we

periodically assess our overall business strategy based on business opportunity. We believe that business diversity can be complementary and contribute to our top and bottom line growth, but if we were to view these assets as being more productive outside the company, we would consider other alternatives. So, I am saying that we constantly reassess and reevaluate our entire portfolio. That's an ongoing thing for us. When I said that I consider them complementary again, that's not a new comment, I have made that ever since I have been CEO, but I am also saying that we have to look at the overall performance of the portfolio and decide basically how we can maximize long-term cash flow for shareholders.

With respect to R&D, the first point I would make is that we continue to think innovation is going to be the long-term driver of the company's success. We are going to continue to invest in programs like PD-1 to ensure that we bring those products to market as quickly as possible and reach their full potential. We are always looking to improve productivity across the company. So, I will let Roger comment on what he sees going forward, but I would say that in every aspect of our business, we are looking for an opportunity as you heard Roger saying he is evaluating programs, processes, and people. I think it's appropriate though to give him some time to assess that entire equation and decide how he is going to drive better ROI going forward. We also by the way did say that we are lowering our R&D guidance of 2013 versus 2012. So, all those things coming together, I think directionally say something about R&D spending inside the company, but I do again think Roger has the right opportunity to look at the overall picture and decide how he wants to improve ROI going forward. I will just close by saying at the end of the day all of these companies at the end of the day have to innovate and they have to bring forward clinically meaningfully differentiated products the way that Roger has said and that remains to me the major focus of Merck and Merck's strategy.

Joe Romanelli

Great, okay. Thanks David. Thanks for the questions. Andrea next caller please?

Operator

Yes sir. Your next question comes from the line of Andrew Baum with Citi.

Andrew Baum - Citi

Yes, good afternoon. Couple of questions. First on the DPP-IV class within Europe, the Transparency Commission in France just yesterday announced they are going to be focusing on the class and equate well Merck may benefit from the ongoing discussions there, so some of your competitors are going to have the pricing drag down, as far as that (indiscernible) the drug? And healthcare systems (indiscernible) are struggling in DPP-IV makes itself target and obviously you referenced Japan, and am I being too negative there, and I think about the pressures on the franchise outside the U.S.?

And then second question is for Roger, perhaps you could outline what the split in current investment is between research and development within Merck and then following along from that, what scope do you see for downsizing Merck's current research as opposed to development and research infrastructure. Thank you.

Ken Frazier

So why don't I talk a little bit about DDP-4 class, and I will focus outside the U.S. because that's where you focus and I spoke a lot about the U.S. already. I just want to reiterate that we had good volume growth in all regions and we had good growth if you just look at the five core European markets we've very strong growth, not only in volume, but also in dollars. I believe the environment in Europe is tough and I think it will continue to be tough but I also believe that the value that physicians and patient see in a product like Januvia is very strong and also when you talk to the government. I do believe that they see the value that a product like to Januvia can bring into the marketplace. And the marketplace tends to show you the value of the product based upon the utilization and when you look at the utilization of Januvia. I think it's because position, not only the great efficacy that you can see on HbA1C but they also feel comfortable with the safety profile that they have been accustomed to.

And if you look at the cost of the implications of diabetes they are very significant, in Europe typically the DDP-4s are utilized after metformin so it's not threatening the largest generic in Europe, it's actually being utilized after the generics are used in Europe. So I think that it shows that there is a way to try to use a low-cost metformin but since many patients can't get the goal on a low cost metformin sulfonylurea has safety or side effect issues that the physicians are looking for a way to control diabetes such as with Januvia and then the government sees the implications of notching diabetes in terms of the macrovascular disease and microvascular disease in terms of hospital admissions and so forth. So I still think that there is a strong potential for Januvia in Europe. In addition to that we still

have markets that we're waiting for reimbursement outside of Europe such as in China, where we think there is also opportunities for the future.

Roger Perlmutter

With respect to the split in current investment that we could spend quite a long time talking about the way in which funds are allocated at Merck but let me just point out that has been described in detail by academic analyses of expenditures and pharmaceutical companies, investments and discover research as a fraction of the total investment in R&D have been declining monotonically since 1980 and discovery research is actually a very small component of all large pharmaceutical companies. It represents the simply the fully allocated costs of the people doing the work and the expense associated with clinical trials has been rising progressively, Merck is no different from all other big companies we spent far more on development that we do on research. Having said that you should keep in mind that there is a lot of stuff that is classified as a research that really relates to development, questions are raised by regulatory agencies with respect to products that have long been on the market that require preclinical studies. Its research effort but it actually is contributing to the development role. So there is a lot of complexity in there and with respect to opportunities that exists for reducing expenditure in research I think the real question to be asked is what you do to improve the productivity of the R&D organization to actually create breakthrough products that make a real difference to patients.

Ultimately you innovate or you die and that's what needs to be done, and you need to do it as effectively, efficiently and productively as possible and that's what we intend to do.

Joe Romanelli

Great. Thank you Andrew. Next question please?

Operator

Your next question comes from the line of Alex Arfaei with CMO Capital.

Alex Arfaei - CMO Capital

A couple for Roger if I may, are you doing an core formation work to combine the SGLT2 you got from Pfizer with Januvia as affixed those combination similar to what your competitors are doing and also, could you please provide us an update on your once weekly DDP-4 and is there any possibilities for a core formulation there? Thank you.

Roger Perlmutter

With respect to the SGLT2 program of course we're just moving forward with that program. We expect to advance that program into Phase III this year but we also are interested as I said last quarter that you know that one of the things that's extremely attractive about this program is it's very well behaved pharmaceutical and hence we expect it to play nicely with others. We have always had an interest in the idea that this could be used in combination with our existing programs and so we're looking at those things very closely that will be something of course, that we would include in our registration programs and we're making – we continue to make progress on our once-weekly program. Our Phase 3 program is ongoing, and we are enthusiastic about it and we think it's a very, very good opportunity.

Joe Romanelli

Okay, thank you Alex. Next question please?

Operator

Your next question comes from the line of Jeff Holford with Jefferies.

Jeff Holford - Jefferies

Hi, thanks for taking my questions. Just got two for you. On a margin basis, where do you think the greatest scope for cost saving going forwards on this company over two, three year view would be, would it be in COGS, SG&A and R&D maybe you can rank those for us? And then just secondly coming back to I think consumer health specifically, probably under 4% of group EBITDA in terms it would actually produce it, how do you think of that really as being as an asset to give diversification to the company. It was such a small contribution and how would you assess the margins of that company versus some of its peers of larger scale? Thank you.

Ken Frazier

Okay. Let me take the consumer question. We have looked at the profitability of our consumer business and we believe its back up well against its competitors. I agree that the asset is smaller compared to our pharmaceutical business. I said before that it's not global scale, but it's a very good business that produces really strong cash flow. And we also continue to see that the OTC opportunities, which I control is the most recent example for us do give us the complementary tag to our pharmaceutical business.

Peter Kellogg

So, Jeff, it's Peter Kellogg. Let me answer your first question regarding margins and opportunities in our P&L. So, we are a large complicated business, so I can appreciate the targets that we are through, but let me go back to kind of the couple of pieces. First of all, we announced the merger almost four years ago. We did highlight that we had a fairly extensive manufacturing network. Quite frankly, we combined three companies, Merck, Schering-Plough, and Organon, and really had an extensive manufacturing network of over 90 plants. And I think you recall that's what we highlighted on day one was that required rationalization over time. We have made great progress on that. At this point, the number of plants we have in the network is numbered kind of in the low 70s. And I think that it's very clear that we are keen to do that as we indicated at the time of the merger. That's not something we can get done in three or four years. It's really an ongoing process, so continuing to drive more and more efficiencies. I think there is more to come there.

Obviously, how it shows up on the P&L through the cost of goods eventually, there is always if you measure things in terms of PGM percent, then you get the blend between your efficiencies and productivity coming to the cost of goods sold versus the pricing that you can realize and that really comes down to again the innovation and the exciting new products that we bring forward. So, but I do think that clearly on the cost of goods sold that's an ongoing opportunity we talked about. In the – just going down the P&L in the R&D side, I think what I know Roger and I talked a lot about it, it's really a question of the ROI that we think about there.

We have the right opportunities such as the PD-1. We are going to spend the money on that. And we are intending to have an exciting pipeline. So, it's not a goal of ours to have unexciting – not have exciting opportunities and not spend money. Conversely, we do really want to pay close attention to how we are spending and making sure it's focused on as Roger said the really big things that can make a big difference in the marketplace and then obviously drive the top line. So, R&D, I think is very much of a focus for us from a productivity standpoint with very much from an ROI perspective that we have the great opportunities we are going to go after them. And we will make sure that we are doing efficiently.

And then obviously the last thing is on SG&A, we continue to evaluate that globally at which our footprint look like and how do we operate in the most efficient manner. We made tremendous progress since the merger is I think we highlighted at the end of last year. We actually hit and exceeded all our merger synergy goals that we had which were pretty expensive. I think we highlighted that we achieved a net benefit of $3.5 billion, which actually means that our gross savings were over $6 billion. So, that's a very, very substantial merger synergy program that we have executed. But I think what's very important is as Ken said in his talk today, cost management is very important for us to resource that creates on the one hand a more efficient P&L, but quite frankly, it also allows us to spend on the growth drivers, which is so important to our future. So, I don't want you to conclude that we are simply thinking about our cost structure as how do we take cost out, but it's also how do we reinvest to drive shareholder value and really create a lot of value in this company, most of the pipeline as well as the commercial assets around the world. So, I think SG&A continues to be a focus for us. But on the other hand, I think we are also going to balance all those savings with where we have opportunities to invest.

So, I am not going very specific answer I realize that but I do want to make a point that while we have opportunities and we are going to continue to pursue them, we certainly executed well in the merger synergies that we have laid out and we're going to continue on that to through the manufacturing network elsewhere in the organization we're thinking about we turn on investment and creating value, but we never will be passive about you, as Ken likes to say we're going to be ambitious in driving performance in the short term but we are never going to back away from investing for long term potential long-term value creation.

Joe Romanelli

Okay, great. Thanks and Andrea I think we have time for two more callers, so we can start with the next questions.

Operator

Yes sir. Your next question comes from the line of Steve Scala with Cowen.

Steve Scala - Cowen and Company

First will the tax rate be so much higher in the second half of the year versus the first half and what does it tell us about the tax rate in 2014, secondly you mentioned 2013 R&D spend will be lower but you haven't quantified it. I guess we should assume it will only be modestly lower, would you like to recalibrate that expectation? And then thirdly why was it up sequentially down in the second quarter it had been sequentially up in the second quarter 2012. Thank you.

Peter Kellogg

Let me take the first question on tax, so I think you had a couple of question there so let me just take them one at a time if I can. You asked why would the tax rate be higher in the second half of the year than the first half of the year. SO as we went into the first half of the year and I'm just going to take it quarter by quarter and the first quarter we saw some significant tax benefits that came through. I think we highlighted that time and they are very kind of one time in nature, there were R&D tax credit being reimplemented and so forth. We also had a couple of resolution of some tax audit situations allowed us to release some reserves. And so that caused our R&D our tax line to be lower in the first quarter.

In the second quarter we also had a reduction in some tax reserves because we had the exploration of some statute of limitations and so that allowed us to free up some tax reserves and basically some of these benefits were things that we thought about over the course of a full year. We didn't really actually when we first put the plan together just by getting all these things in the first and second quarter quarters. So as you think about how the year comes together, when you think about the full-year tax guidance of 22% to 23% the way you get to that on a full year basis is it ends up weighted average of all the quarter. So the first two quarters were lower that by definition it means the third quarter and fourth quarters will be higher and they will only be higher because we just won't have those one-time benefit pulling the rate down. We can kind of return to a more natural run-rate that we would expect.

And I think that you will recall that we have talked about in the past is the ongoing tax rates the company will be a little higher than what you're seeing right now and so generally we've talked about the long-term tax rate, recognizing that uncertain things can move around, but excluding any unusual items or any items that pull it down or move it up that are kind of unique in nature we expect it to be running that in the higher rate in the range of something like 25% to 26% on an ongoing basis.

But I think we want to be careful that all these years we go into the year we will update you in terms of what we see on the horizon relative to how it's axes are evolving. I think on the second question you were asking about R&D and why would it be lower in the second half and in the first half in fact, you know, how should we think about what we're looking at.

So obviously in my comments I highlighted that entire year we actually did have a payment for ENDOSITE (ph) in the second quarter of last year so we're laughing in that sense. But we also basically see as we move forward kind of there is a flow of activity, Roger's making decisions and so forth and I think that basically we're using kind of the most recent updated view of R&D as we think about it. So and quite frankly it's ties to productivity, to focus and we're not talking about the sea change we're just simply, we previously we thought it will be a little bit higher and now we're kind of (inaudible) our expectation is based on what we see will be a little bit lower.

The third question was….

Adam Schechter

I will take the third one, see this is Adam and with regard to (inaudible) there is definitely a seasonal nature to the business and we have predicting that all along. In 2012 it was up first year with full U.S. supply. When we have full supply the offices were buying the vaccine and they were stocking and getting ready for vaccinations and in addition to that we had just started our direct to consumer proportion in the second quarter of 2012 because we wanted to ensure that we would have adequate supply before we would actually drive demand through the DTC promotions. So I want to use 2012 as a direct year-over-year comparison to 2013.

We expect that the second half of this year will be stronger and the strongest quarter will be dependent upon when flu vaccinations occur, because that's when we believe we will see many people getting vaccinated for (indiscernible) as well.

Joe Romanelli

Great. Thank you for the questions Steve. And I think Andrea, is it time for one last question?

Operator

Yes sir. Your last question comes from the line of Gregg Gilbert with Bank of America/Merrill Lynch.

Gregg Gilbert - Bank of America/Merrill Lynch

Thank you. For Roger, I would love to get your personal view on the opportunity and the risks associated with odanacatib at this point? Secondly, could you be in a position to file LAMBRO in melanoma early next year given the unmet need in that population and your breakthrough status? And maybe lastly, Adam, can you talk about what prompted the GARDASIL decision in Japan and whether that has implications anywhere else? Thanks.

Roger Perlmutter

Well, but at the same time asks that we continue the study in order to obtain additional efficacy and safety data. We are continuing to study in that way. We do anticipate that we will have the opportunity to look at those data and adapt to distant future, and based on what we see there, we hope to be able to move forward with the odanacatib filing, but we have to see the data of course. With respect to PD-1, again, the information that we have is that as you can see from looking at ClinicalTrials.gov, we have ongoing pivotal studies in melanoma refractory to therapy. We have a Phase 3 study in melanoma versus ipilimumab. Those studies will deliver results either in the latter case at the end of next year or in 2015. If in fact it were the case that there were overwhelming efficacy earlier on there might be opportunities for a more accelerated filing strategy, but that's something that we really will have to wait to see data on. And of course, we are working very, very closely with the FDA on that. And with regard to Japan, the government suspended the proactive. So, it's important to say that proactive recommendation of HPV vaccines, the vaccines still remain on the market in Japan. And the MLHW is just looking into some post marketing use that they have seen specific to Japan. We have not seen any significant impact at this time in other markets around that world and MRL continues to monitor the AEs as appropriate and we are confident in that safety profile of GARDASIL.

Gregg Gilbert - Bank of America/Merrill Lynch

Yes, absolutely.

Ken Frazier

Okay, so thanks Gregg. Let me just close by saying I think this was a good quarter, a solid quarter. Going forward, our strong focus will remain on growth for the company as well as driving greater profitability. It was good to see a bounce back in certain sales, particularly JANUVIA. We had good back scenes in immunology sales. It's great to see that the emerging markets are still moving ahead in a very strong way. As we go further, we will continue to invest thoughtfully in these commercial opportunities as well as our pipeline opportunities. We are very excited about, for example, PD-1s. And as we think about this business going forward, we continue to think that innovation has got to be the key, but we've got to be very careful to deliver the right kind of reductions at our cost base that will allow us to do that in a sustainable way. So, thank you very much for your attention, and I look forward to talking to you in future quarters and in future venues. Thank you. Bye-bye.

Operator

Thank you. Ladies and gentlemen, this concludes today's conference call. You may now disconnect.

Executives

Joe Romanelli - Investor Relations

Ken Frazier - Chairman and Chief Executive Officer

Roger Perlmutter - President, Merck Research Laboratories

Adam Schechter - President of Global Human Health

Peter Kellogg - Chief Financial Officer

Analysts

Marc Goodman - UBS

Tim Anderson - Sanford Bernstein

Jami Rubin - Goldman Sachs

Mark Schoenebaum - ISI Group

David Risinger - Morgan Stanley

Andrew Baum - Citi

Alex Arfaei - CMO Capital

Jeff Holford - Jefferies

Steve Scala - Cowen and Company

Gregg Gilbert - Bank of America/Merrill Lynch

Merck & Co., Inc. (MRK) Q2 2013 Earnings Conference Call July 30, 2013 8:00 AM ET

Operator

Good morning. My name is Andrea, and I will be your conference operator today. At this time, I would like to welcome everyone to the Merck's Second Quarter 2013 Earnings Call. All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question-and-answer session. (Operator Instructions)

I would like to now turn the call over to your host, Joe Romanelli. You may begin your conference.

Joe Romanelli

Thank you, Andrea, and good morning everyone. We would also like to say good afternoon and good evening to everyone listening outside the United States. Welcome to Merck's second quarter 2013 conference call. Before I turn the call over to Ken, I want to point out just a couple of items.

First, there are number of items in the GAAP results, such as acquisition-related charges, restructuring costs and certain other items. You should note that we have excluded those items in our non-GAAP reconciliation tables and you can see this in our press release in table two. This will give you a better sense of the underlying performance of the business. There are three tables in the press release. The first table is the GAAP results. Table number two reconciles our GAAP P&L to the non-GAAP results for the second quarter and table three provide the sales performance for the company's business units and our products, both on a recorded basis and excluding exchange.

During the call, we will refer to table two when we discuss the P&L and table three when we talk about revenue performance. Finally, I would like to remind you that some of the statements we make during today's call may be considered forward-looking statements within the meaning of the Safe Harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Such statements are based upon Merck's current beliefs of management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. The company's SEC filings, including Item 1A in the 2012 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 statements. Our SEC filings can be found on the website at merck.com. You can also find our earnings release and all the tables there as well.

So, with that this morning, I am joined by Ken Frazier, our Chairman and Chief Executive Officer; Adam Schechter, our President of Global Human Health, he will update you on our product and geographic performance; Peter Kellogg, our Chief Financial Officer, who will review our P&L and provide an update on our outlook for 2013; and lastly, Roger Perlmutter, our President of Merck Research Labs will provide you with an update on some of our key programs.

With that, I would like to introduce Ken Frazier. Ken?

Ken Frazier

Thank you, Joe. Good morning, everyone. It's a pleasure to be here again today to provide an update on our performance and to highlight some of the key events from the quarter. We continue to focus on our core strategy. In so doing, we will build shareholder value by prioritizing investments in our best commercial growth opportunities with key in-line products and in innovative R&D. Second, making disciplined decisions regarding the allocation of resources and managing our cost effectively, this approach is especially critical in a period when we are navigating significant patent expirations and adapting to the global healthcare environment.

This quarter, our business momentum accelerated while we continued to manage our costs. We believe these results more accurately reflect the strength of our underlying portfolio when compared to the first quarter of this year. We are still working hard to improve the competitive position and growth potential of key brands like JANUVIA, which will allow us to drive our top line growth in the future. In addition, we continue to managing our expenses and are maintaining our EPS guidance for the year. Peter Kellogg will provide more detail on our revenue and cost assumption. For the quarter, we delivered an EPS of $0.84. This reflected underlying sales growth of 3% excluding the impact of foreign exchange and patent expiries. The growth was driven primarily by our Global Human Health business, including strong performance from our diabetes, immunology, and vaccine franchises. In total, 7 of our top 10 products grew in the second quarter. As always, Adam will provide more detail on specific product performance. The fundamentals of our complementary businesses, animal health and consumer care remained strong. We continue to view these businesses as important components of our diverse portfolio.

In terms of geographic performance, we grew 10% in emerging markets in the second quarter, excluding exchange. In the past several months, I have had the opportunity to visit Brazil and Korea to see firsthand both the tremendous potential of these markets and the extraordinary enthusiasm of the MSD colleagues there. In Korea, for example, our diabetes and vaccine businesses are performing particularly well. The emerging markets now account for approximately 22% of our pharmaceutical sales with China continuing as a key growth driver.

Moving to the longer-term view, we remain committed to pursuing innovative science that translates into medically important products. To sustain our ability to do so however we are mindful that we must continue to find ways to improve our cash flow and build shareholder value over both the short and long term a commitment we also take very seriously. One way we demonstrate our commitment to building value in the short term is by returning cash to shareholders. Year-to-date we have returned nearly $9 billion to shareholders who both our dividend and stock buybacks. We have repurchased over a 120 million shares including our accelerated share repurchase in May.

Longer term shareholder value is of course driven by innovative R&D and improving the return on R&D investments. Roger will share his views in a moment but I would like to comment on why we believe innovation is the path to sustainable value and needs to remain the cornerstone of Merck's efforts despite challenges like the recent (inaudible) exit and Sugammadex delays. There is an increasing need for innovative treatments that offer meaningful differentiation of patients and demonstrate value to payers. This is true for chronic diseases like diabetes but also in areas of tremendous scientific opportunity such as cancer immunotherapies and neuroscience.

I'm excited about the program like our anti-PD-1 for oncology and our ACE inhibitor for Alzheimer's disease to have

the potential to alter the course of medicine. With the opportunities we see before us I want to be clear that we intend to aggressively manage our costs in the short term and our fundamental cost space over the long term. We need to do this in order to preserve our ability to invest in our future and have the flexibility to respond to the opportunities and challenges presented by the global healthcare environment. In the second quarter we continue to take out cost and prioritize our investments. We're doing this while supporting future growth in core brands and in the pipeline.

Let me share two examples, first with Januvia, we continue making the necessary investments behind this franchise to ensure that we maintain our leadership position in the increasingly competitive diabetes market and maximize opportunities for future growth. Second with PD1 we have created a strong expert team which streamline decision making. We committed to making critical investments to ensure that we fully realize the potential of this important product and bring it to patients as quickly as possible.

In summary we're committed to driving top-line performance with key growth product and key geographies. Advancing and augmenting our pipelines and aggressively managing our cost base. By doing these things well we will preserve the ability to invest in our future, continue to generate strong cash flow and drive shareholder value and return over both the short and long term. I would like to now turn the call over to my colleague Adam Schechter. Adam?

Adam Schechter

Thank you Ken. Good morning everyone. This morning I will focus my remarks and the performance of our core products and our core markets. Let me begin with the overall performance. Human health sales declined 12% in the second quarter, our top-line results continue to reflect the loss of exclusivity a SINGULAIR, PROPECIA, CLARINEX and MAXALT and weakness in the yen, excluding sales in these products are underlying business grew 4% on a constant currency basis. Two contributors were Januvia and Janumet, Simponi and our vaccine business, only provide some more details. I'll start with the Januvia and Janumet franchise. The franchise has sales of $1.5 billion and 10% growth excluding exchange. The franchise grew 9% in the United States and 11% in International markets. In the United States, demand price, and inventory contributed to growth. With regard to demand we were able to maintain a 75% TRx share of the very competitive DPP-4 market.

Volume grew slightly by about 1% this quarter, regarding price we did see a benefit this quarter from price. We have increased price over the last year but we have also seen increase rebate and pricing pressures as competitors seek to improve their former position by increasing discounts.

Finally, on inventory, our customers increased their inventory levels by about $30 million in the second quarter. If we exclude this inventory benefit, we believe our sales would have grown by about 5% in the United States in line with our expectations. In the international markets, JANUVIA and JANUMET had good volume growth in every region around the world and retained market leadership with a 70% global market share.

Now, let me touch on our outlook for the rest of the year. We continue to expect mid-single-digit sales growth in the United States, which excludes channel movements that are difficult to predict. We also continue to expect low double-digit growth, excluding exchange internationally. In the United States, we continue to invest and change the current TRx trend. We have focused our resources on JANUVIA to drive demand and to defend our strong leadership position in a highly competitive market. Globally, there continued to be good growth opportunities in the diabetes market and we are positioned well with the market leading DPP-IV inhibitor.

So, moving now to ISENTRESS, ISENTRESS sales of $410 million, which represents about 5% growth? In the United States, we are maintaining our patients here despite new competition. Outside of the U.S., ISENTRESS continues to have good volume growth offset partially by pricing pressure in Europe and timing of emerging market purchases this quarter. In our cholesterol franchise, ZETIA and VYTORIN global sales were up by about 1% over the prior year. ZETIA growth was partially offset by decline in VYTORIN sales. We are currently launching LIPTRUZET, the combination of ZETIA plus atorvastatin in the U.S. This product reinforces the benefit that this family of products can provide to many patients who continue to have high LDL cholesterol despite the wide use of statins.

Moving to immunology, the combined immunology business consisting of REMICADE and SIMPONI grew 11% in the quarter, excluding exchange. The growth was driven mostly by SIMPONI. Sales of SIMPONI grew 60% to $120 million this quarter. We are continuing to see a positive impact in the launch in France and the reintroduction of the autoinjector in Germany. Last week, we received a positive CHMP decision for an additional indication in ulcerative colitis, and we look forward to potential approval later this year.

Moving to VICTRELIS, the global sales of $116 million this quarter. Growth in emerging markets was offset by continued contraction of the Hepatitis C market in many countries, including the United States.

Lastly, moving to our vaccine business, which had another strong quarter. GARDASIL maintained its strong performance with 20% growth year-over-year. Second quarter sales benefited from continued uptake of the male indication in the United States and timing of government purchases in Latin America. Those were partially offset by lower sales in Japan. In Japan, the government recently suspended the proactive recommendation of HPV vaccines. We anticipate this decision will have a significant negative impact on the rest of sales of GARDASIL in Japan. For reference, sales of GARDASIL were $140 million in Japan last year. We are working with and we are providing information to the government on the vast amount of safety and efficacy data available for GARDASIL. On the other hand, we are pleased that the Ministry of Health in Brazil recently announced the National Immunization Program with GARDASIL to begin in 2014.

Moving on to ZOSTAVAX, ZOSTAVAX sales were $140 million this quarter. As we had expected, sales in United States declined sequentially due to seasonality. We expect the second half of the year to be stronger than the first half and the strongest quarter will likely depend on the start of the flu vaccination season. We continue to see ZOSTAVAX as a key growth driver. In the United States, we estimate that a little over 20% of the population ages 16 or older have received vaccine to-date. So, there remains opportunity for growth. Internationally, we are just beginning launches in the few Asian markets, including Korea. And we continue to anticipate our first European launch in the UK this fall with additional markets in 2014.

Now, I would like to touch on our performance on a regional level. In the United States, Europe, and Canada, sales continued to be affected by the loss of exclusivity of SINGULAIR, MAXALT, PROPECIA and CLARINEX excluding these products U.S. sales increased by 7% and sales in Europe and Canada were flat in the second quarter. Japan's sales declined 4% ex-exchange that was due to an increase in the utilization of generic versus branded products and lower sales of Gardasil which I mentioned earlier. Emerging markets has another good quarter with 10% ex-exchange sales growth that includes 10% growth in China. Growth in the emerging market was broad-based that came from our base business, our new products and our joint ventures. And key emerging markets, our growth is outpacing the overall market and we expect to continue to deliver strong growth in 2013.

In closing the human health business demonstrated growth of our underlying portfolio of key brands. In August we will annualize the SINGULAIR expires in the United States but we also anticipate generic entry in the United States for Temodar, despite the significant number of patent expires we're facing this year. I'm confident that we can drive growth of our strong and our diverse portfolio. Now I would like to turn the call over to my colleague, Peter Kellogg.

Peter Kellogg

Thank you Adam and good morning. As you heard from Ken and Adam our core brands performed well this quarter. Furthermore we continue to manage cost effectively while investing for future growth; additionally we executed a significant capital initiative in the quarter. Our confidence and our future cash flows and the historically low cost of debt allowed us to return cash to shareholders in the form of $5 billion accelerated share repurchase. This accelerated repurchase is a key component of our goal to buyback $7.5 billion of shares within the first 12 months of our $15 billion repurchase program announced in May.

These results and actions demonstrate that Merck is committed to improving our performance in the short term, investing for the long term and continuing to allocate capital in a shareholder friendly manner. This morning, I will briefly talk about our performance in the second quarter and now I will discuss our outlook for the remainder of 2013.

My remarks will focus on our non-GAAP financials, starting on the bottom-line we're a $0.84 per share this quarter compared to a $1.05 in the prior year. On the top-line, total company sales declined 8% in the second quarter excluding an unfavorable exchange impact of 3%. As Adam said sales increased 4% in our pharmaceutical business if you exclude generic erosion and foreign exchange.

Animal health sales increased 1% year-over-year excluding exchange driven by companion animal and poultry businesses. In consumer health we had a onetime unfavorable adjustment to sales this quarter excluding these adjustment consumer health sales would have been up 4% on a constant currency basis. Moving to other revenues we saw an increase in supply sales to AstraZeneca in the second quarter. Despite this we continue to expect the supply sales will decrease as we approach the May 2014 U.S. patent expiration for Nexium.

At the PGM line as previously discussed generic erosion of high gross margin products also created 2.5% headwind on the gross margin this quarter. As a result our non-GAAP gross margin declined on a year-over-year basis to 75.7%. As we indicated previously we expect the full year gross margin ratio to be about 1% lower than 2012 due to this mix shift in our sales. Turning to marketing and administrative expenses, our second quarter SG&A expenses were about $60 million lower year-over-year excluding foreign exchange benefits and some onetime corporate charges, we reduced our

SG&A spending by about a $100 million this quarter. Similar to last quarter we continued to proactively reduce spending.

As a result of our cost reductions we continue to expect SG&A spending in 2013 will be lower than 2012. Moving on to R&D, research and development expenses in the second quarter were a $144 million lower than prior year. However we recall that last year we had a significant upfront payment of a $120 million for our agreement within the site excluding this R&D expense would have been relatively flat.

Other income and expense was about a $100 million higher year-over-year primarily as a result of foreign exchange losses and interest expenses. In the month of May we concluded a $6.5 billion debt offering at a blended average interest rate of less than 2%. This debt offering funded our accelerated share repurchase and we now have new interest expense and lower shares outstanding

Moving to tax, our non-GAAP tax rate was 21.9% in the second quarter. We are maintaining our estimated full year tax rate to be in the range of 22% to 23%. The tax rate for the second half of the year will be considerably higher compared to the rate in the first two quarters.

Now, turning to the 2013 outlook, on the bottom line, we are reconfirming our 2013 non-GAAP EPS guidance range of $3.45 to $3.55. On a GAAP basis, we expect to earn between $1.84 and $2.05. Now, for additional color on the outlook for the rest of the year, let's start with revenue. During the second quarter, the U.S. dollar continued to strengthen against many global currencies. If today's foreign exchange rates persist, we would expect full year 2013 sales to be negatively affected by about 3 percentage points, which is greater than we had previously anticipated.

Given our performance in the first half of 2013, the continued strength of the U.S. dollar and select product trends, we have adjusted our full year revenue expectations. We now anticipate that total company revenue will be 5% to 6% below 2012, including the negative impact of foreign exchange. While we have adjusted our sales guidance, we are maintaining our EPS guidance through cost management and SG&A and R&D. Accordingly, we now expect R&D expenses in 2013 to be lower than 2012.

Moving to the quarters, as we think about the back half of the year, we see improvement in EPS performance compared to the first half of the year. Additionally, we anticipate that the fourth quarter will be higher than the third quarter from an EPS perspective. So, in conclusion, this was a solid quarter, where we successfully executed a major capital initiative to return cash to shareholders. We also drove growth in our key brands while managing costs and we continue to step up our efforts on our key R&D programs. Thank you.

Now, I will turn the call over to Roger who will provide an update on MRL. Roger?

Roger Perlmutter

Thanks Peter. During the second quarter, we made steady progress in clarifying the registration process for Merck's next wave of products and advanced our clinical trials in important areas. For SUVOREXANT, our first-in-class orexin antagonist for the treatment of insomnia, the FDA has provided a clear path to registration through their complete response letter, which we received at the end of the quarter. We are making good progress in preparing 10 milligram and 5 milligram SUVOREXANT dosage forms to enable initiation of therapy at lower starting doses, which was the principal change requested in the FDA's review.

We hope to be able to begin stability testing of these materials in the very near future with a goal of submitting definitive data in response to FDA's requests in the first half of 2014. As was demonstrated at the FDA Advisory Committee Review in May, SUVOREXANT has distinctive therapeutic properties, which we believe will enable it to become an important treatment for patients suffering from insomnia.

Turning to other regulatory actions, two weeks ago, we announced that the FDA had postponed its Advisory Committee Review of SUGAMMADEX, our parenteral agent for the rapid reversal of certain types of neuromuscular blockage during surgery. This still enable the FDA to complete audits of certain U.S. and European study sites that were involved in generating data contained in our submission. We are working closely with the FDA to facilitate these audits and will have more to say about the registration timeline for SUGAMMADEX once the FDA has completed this review. As you know, SUGAMMADEX is already registered in more than 40 markets around the world.

Also during the second quarter, we had the opportunity to present encouraging data on MK-3475, our monoclonal antibody directed against PD-1 for the treatment of malignant melanoma at the American Society of Clinical Oncology meeting in Chicago. This immunomodulatory approach for the treatment of malignant disease is also under study in

patients with non-small-cell lung cancer. We hope to present preliminary results observed in such patients in October at the International Association for the Study of Lung Cancer meeting in Sydney. Our data thus far have encouraged us to begin a Phase 2/3 study in non-small-cell lung cancer for which enrollment is just beginning.

We are also continuing to study responses in patients with other malignancies before we believe treatment with MK-3475 may be beneficial by itself or in combination. New studies have recently begun in patients with hormone receptor negative breast cancer, neuroepithelial tumors, head and neck cancer, and in certain patients suffering from colorectal cancer. In the plenary's presentations at the ASCO meetings in Chicago, it was noted that immunomodulatory agents offered great promise for the treatment of desperately ill patients suffering from malignant disease. Our portfolio includes not only MK-3475 but other immunomodulatory agents which have emerged following a systematic evaluation of cell surface proteins involved in immune regulation. With respect to MK-3475 OU will recall that we have received breakthrough designation from the FDA for this therapy and we're in very close communication with the agency regarding requirements for an viable data set in the setting of advanced melanoma.

Meanwhile our MK-8931 program, a small molecule inhibitor beta secretase for the treatment of Alzheimer's disease continues to enroll patients and advance of a safety review which we believe we will complete at the very end of this year.

Satisfactory completion of this review will permit expansion of the study for formal efficacy testing, in this pivotal study patients with mild to moderate Alzheimer's disease will be evaluated for the effect of MK-8931 on a cognitive performance and activities of daily living: following 78 weeks of treatment as compared to placebo.

Finally, during my first few months in this role at Merck I found much to be proud of in terms of the quality of our programs and our people. However, I see the clear need for changes that will strengthen the return on investment in R&D. My review is focused on each critical area of performance, programs, processes and people and I have begun to make adjustments along each dimension.

From the programmatic point of view we're moving to narrow our focus to make certain that products with unambiguous clinically meaningful advances receive our complete attention. With respect to process the governing structure has been flatten considerably removing some layers of decision-making. Much has already been achieved here, but more will be required to improve our efficiency in providing resources to leading project. Finally, with respect to people we're moving quickly to build our leadership in R&D and specifically brought our licensing, business development function into my senior leadership area. As for all large bio pharmaceutical companies, licensing plays a key role in the development of breakthrough therapies. I expect Merck to participate fully in this area.

Additional details of our revised R&D strategy will be the subject of future reviews. I'm very much looking forward to sharing this information with you. Ken?

Ken Frazier

Okay so thank you Roger and thank you and I have thank you letter and thank you, Andrea (ph). So before we move into Q&A, I just remind you that we're going to try to get to as many questions as possible. If you could keep your questions to one or two and if you have additional questions if you can rejoin the queue this way we can get to as many calls as possible. So Andrea you can go ahead and open up the first line for questions.

Question-and-Answer Session

Operator

(Operator Instructions). Yes sir, your first question comes from the line of Marc Goodman with UBS

Marc Goodman - UBS

Couple of things, first can you comment a little bit more about animal health and consumer both very seem to be a little weak even consumer excluding that one time change you made. You talked about add products for immunotherapy can you talk about how quickly you can get those in demand? And then R&D, can you talk about some of the changes that allowed you to take spending down for the quarter. Thanks.

Ken Frazier

Let's start with the animal health and consumer question. So, I would say that overall reflecting on this quarter it was an okay quarter for those businesses but if you step back, you'll see that they grew low single-digits and we look back

beyond the third quarter we think both are performing well. So I would not let one quarter be the answer for those two businesses, as I've said we continue to think of them as being complementary businesses that will help us over the longer term contributing to our top and bottom line growth.

Adam Schechter

I would add I think in the animal health business they are in the middle of rolling out the Activel (ph) product line which we're very excited about as well as SUPRIVA rather and I think I reminded you that last year in the second quarter we actually had some very strong performance as we picked up some business where there were other stocks some of our competitors, so we're probably are in the animal health business slapping a pretty strong prior year. For the other questions maybe I will pass it over to Roger.

Roger Perlmutter

Yes just Marc just a couple of things with respect to the immunomodulatory agents there is a whole set of different cell surface molecules that involvement as checkpoint regulators if you will that control the response of limfositosis too stimulus and we have had the opportunity to inventory, we use to develop antibodies directed against the whole set of them and to look at them in pre-clinical setting. We hope to be advancing those into the clinic relatively soon you'll see them come up on clinicaltrials.gov and I have more to say on them in subsequent quarters. With respect to expense there is no single category of expense control that we can point to, but there are whole variety of things that I have been able to do in terms of reassigning resources and in that process have pulled back on some of the spending levers, which enabled us to reduce our expense now and will going forward as well.

Joe Romanelli

Okay, great. So, next call?

Operator

Your next question comes from the line of Chris Schott with JPMorgan.

Chris Schott - JPMorgan

Thanks very much. Just had two questions. The first is on JANUVIA, obviously you saw a rebound in reported 2Q growth, but it looks like prescription volume growth left in the U.S. is still fairly low. I guess my question is do you believe you are seeing a benefit from the additional resources you put on the franchise earlier this year? And maybe more broadly you talk about the overall DPP-IV market at this point? I guess, as we start to annualize the TVD benefit, do you believe you can reaccelerate growth for this category? My second question which was going back to some of the comments that Roger had made about the licensing of assets. I guess, I am thinking kind of little bit more, should we think of this as a greater focus on M&A from Merck that we have seen in the past and is that focused more on early stage assets or those that have achieved proof-of-concept? Thanks very much.

Ken Frazier

Okay, let me start with the second one first. I just would say, Chris that for us, when we think about capital allocation strategy, one of the most important ventures Roger said is to augment the pipeline. And that means looking for the best technology that we can find, the best opportunities we can find that are value-creating opportunities and that will remain a major priority, and I know for Roger, it's even a greater priority. So, why don't I turn it over to Roger?

Roger Perlmutter

Chris, just let me emphasize as I think I did at the first quarter earnings call, that I am really interested and really focused on products. And so it is to me less important that we consider at this stage and more important that we consider what is the potential value of this new therapeutic entry? Does it have unambiguous meaningful clinical impact that can change the practice of medicine and bring important benefit to patients suffering from grievous illness, that's the critical point? And I am prepared to go after those wherever those exist, and I know Ken and Adam and Peter are completely onboard with that.

Ken Frazier

And with respect to your JANUVIA question, I will turn it over to Adam, but again we are pleased that we saw the product perform better this quarter versus the first quarter, we think it's rebounding and we are continuing to provide

tremendous support behind it. So, with that, I will turn it over to Adam.

Adam Schechter

Yes, hi Chris. Let me give you some additional context in the U.S. and also give you a little bit of more color outside the U.S. Now, we are thinking about outside the U.S. So, as I discussed in the U.S., we had 9% growth and I tried to give you some context of that by breaking it down, where we had 1% that was volume, 4% was inventory, and the rest was price. The real key is changing this TRx trend, and that's what we are frankly focused on. The real issue Chris is that we have a 75% market share in the U.S. despite a very significant number of competitors. So, it's not about time to gain more market share, it's really about getting sulfonylurea use over into DPP-IVs of which we have the lion's share.

Typically, with multiple new entrants in the market, you see a lot of class growth. We don't see a lot of class growth despite all the new competitors that have come into the marketplace. So, the way for us to change the trend is really to focus on the switch from sulfonylureas. And sulfonylureas still represent about 35% of the patient days of therapy. So, there is still a big opportunity there for us to go after. So, what we have done is we have increased our focus. We now have dedicated sales force and thereafter they are promoting they are engaged. In addition to that, we have increased our promotion spending and our print direct-to-consumer advertising. All of our focus now is on the sulfonylurea utilization up until the first quarter this year most of our focus is on the TVD opportunity, that's no longer there. So, it really is about sulfonylureas.

The good news is that we have maintained our strong managed care access in the U.S. So, we have access to our products in over 80% of the patients we have preferred access. And now it really is about executing on the sulfonylureas strategy in the United States. Outside the United States, we still have a very significant opportunity in every region outside the U.S. had strong volume growth. The one thing I think is important that although we had 11% growth X effects. The big difference between X effects and FX was the yen. We have a very significant amount of our sales in Japan for JANUVIA. In Japan, you may recall the DPP-IV class is the number one class of oral diabetics in Japan. In Japan, it's ahead of metformin, it's ahead of sulfonylureas, and we have by far the leading market share. At the same time on every other quarter we get supply sales from our co-marketing partner which happened this quarter, so when you look at our success in Japan, plus the supply sales coming in lumpy you can see how the yen would have a very significant impact on our sales when you don't adjust for exchange that's the difference primarily for the underlying business performance being very strong but what you see including foreign exchange.

Outside the US, we continue to anticipate low double-digit growth, and we see that we're getting that volume and I think the opportunity remains very strong there for us.

Joe Romanelli

Okay thanks Chris. And Andrea can we have the next question?

Operator

Your next question comes from the line of Tim Anderson with Sanford Bernstein.

Tim Anderson - Sanford Bernstein

On the new guidance changes this is the second time this year that you're kind of changing guidance albeit here you're not changing earnings guidance and the revenue guidance that speaker is not just foreign exchange, which is something that's out of your control, Ken you first took over at Merck you withdrew long term guidance that was standing at the time, so my question is that kind of a higher level here what's happening within the company such that numbers are assuming to move around as much as they are and then going back to outlook for mergers and acquisitions historically Merck did not do big mergers until it did Schering-Plough back in 2009 what's the outlook for M&A from here in terms of deal sizes, are you going to revert back really only looking at bolt-ons or are you considering mid-sized targets as well or what exactly?

Ken Frazier

Let me just start by saying we of course maintained our EPS guidance and so I want to make that very clear. In terms of what's happening with the sales you heard, Adam talk about the foreign exchange but there also have been during the course of this year we took on some I think at the beginning some pretty ambitious revenue targets given the fact that we were facing major patent expires that's how we try to deal with the situation last year that was undertaking this year. We have seen some things that have impacted product trends this year and including Januvia happened and

what have you heard out without warning, saying it would also have been arguing the court this year we took on them. I think in the beginning. This is readily talking. Given the fact that we were facing major, naturally, but I would try to deal with the situation last year. That was not undertaken this year we have been found things that have impacted product this year, including Januvia we have seen the, we're housing an is unique. We are helping HCV (ph) just to pick up couple of major growth drivers that we have seen an impact on this year. So I just want to just underscore that we take our guidance very seriously during the course of the year as you know we have seen negative impact on four year sales of about 3% for foreign exchange but we have also seen some other impacts that it us like this quarter there was a onetime charge for MCC and I would also point out that if you look at our overall you can see that we're managing cost in order for us to continue to deliver our bottom-line EPS guidance which again I take very seriously.

Peter Kellogg

On the M&A front, so Tim I guess you kind of went through this chronology of Merck for long time I hadn't done any really big M&A deals I guess and then (inaudible). I think as we go forward really in many ways we're thinking a lot about the product portfolio in the business we have I think we reiterate a lot of what Roger commented on relative to making sure we have great two products and really exciting products and if that ends up leading as to business development deals or joint ventures or M&A I think we're comfortable with any of those. I think as Ken commented earlier we really do talk about our capital structure as having the number one goal of supporting strategic needs of the business and so we're certainly, all we maintain a position to be able to do that that said we also don't want to build up inefficient balances on the balance sheet so that's why we had a more proactive capital structure program recently. But no ways that could say we wouldn't be doing the right things to build the pipeline and we're always on the prowl looking for the right things the great assets that are out there.

Ken Frazier

I will just underscore what Peter just said I think from our standpoint looking for M&A deals that would be sensible value creating bolt-on deals is something that we will be very interested in doing but we have tried to become and remain a very discipline company when it comes paying for assets so that we can actually create shareholder value with them over the longer term. So deals is the number one priority that we can create value, we have enhanced our share repurchase, we obviously remain committed to our dividend but in the long term it's product that drive this business and that's why we're going to continue to look for sensible opportunities to augment our pipeline whether it's licensing or bolt-on M&A deals.

Joe Romanelli

Great, thanks and thanks for the questions. Andrea, next caller?

Operator

Your next question comes from the line of Jami Rubin with Goldman Sachs.

Jami Rubin - Goldman Sachs

So, Roger, a question for you, we – Merck issued a press release about a month ago providing a sort of outline on R&D restructuring which involved removing layers of management. And today you are talking about lowering R&D spending for 2013 versus 2012 and narrowing your focus? Just curious to know if you see this R&D restructuring process as more iterative in nature or should we expect more substantial change ahead involving pairing back on your specific therapeutic focuses meaningful change in the way you allocate capital and R&D? Just wondering if there is more big news to come with respect to what you are doing to improve ROIC in R&D? And then secondly again on PD-1, just wondering if you can update us on your views on combo studies, where you are with that, if you are seeking to combine your drug with a CTLA-4 and when we can expect to see news on that front? Thanks.

Ken Frazier

Thanks, Jami. So, first of all, with respect to R&D structure and lowering expense, as I indicated the goal is to focus our very substantial resources on the programs that matter the most and give them our complete attention. There will be a series of changes that take place in order to improve the efficiency of the process. And as that goes forward of course, we will communicate that to you, but our expectation is not that they are going to be big, enormous changes that will be announced in the way that you described. With regard to PD-1, we are interested first of all of course in delivering on the monotherapy promise in melanoma and in lung cancer. And as you know when we presented these data at ASCO, there are very impressive response rates that we have seen in patients with melanoma who have

refractory disease, who have failed all prior therapies. And naturally, we want to bring the benefits of that therapeutic intervention to those patients. At the same time, we also recognized, because there will be opportunities to combine immunoregulatory modulators, or anti-PD-1 therapy 3475 with other agents both our own internally as well as others of the mother companies, they won't surprise you to know that a lot of companies are interested in working with us on that. We have had discussions with many of them and we will be talking about those combinations as we would announce more results for the PD-1 program. Okay, thanks Jami. Andrea?

Operator

Your next question comes from the line of Tony Butler with Barclays Capital.

Tony Butler - Barclays Capital

Thanks very much, Ken and Peter while you have reiterated guidance for the full year, and I may have missed this, what's the change from Q1 on the GAAP for your guidance, which I think is down now about a dime? And then Roger on 8931, the safety readout, will that be at a clinical meetings CTAB, for example, in November or would you expect that at a press release whether it would be any data coming out on the base inhibitor in the second half? Thanks very much.

Ken Frazier

I will turn the first question over to Peter, but just from the operating standpoint, we are reiterating our EPS guidance.

Peter Kellogg

Yeah, hi. So, in the GAAP P&L, there are some items that we actually exclude from the non-GAAP and sometimes, because they can be lumpy and it goes back to many cases the restructuring or the merger accounting. Now, in this case, we actually do have some adjustments to our R&D intangibles that we actually booked in the second quarter and that simply looking at either products as well as commercial intangibles, which is also a highlight. And so that's all part of the merger accounting. When you go through major merger, you look at the balance sheet and the items that are coming through and you actually allocate value both to the pipeline in the form of in-process R&D intangibles as well as the commercial products, which are intangible commercial assets. And then on a quarterly basis, we work very closely and monitoring that very accurately in terms of R&D expectations, those products all delivering exactly what we saw.

And from time-to-time, something happens to the pipeline perhaps and that causes us to write-down an in-process R&D intangible or conversely perhaps the commercial trends aren't quite as robust as we had originally bought. And so that would cause us to trigger a write-down or a reduction of the asset value in the intangible of our commercial asset. So, primarily, when you look at the change in the EPS at the GAAP level which what you're seeing are some of those evaluations that we go through on a quarterly basis where we actually change the value of intangibles and that's primarily the difference that you see in the gap EPS that's incremental of what you see in the non-GAAP and I certainly apologize for getting into that much accounting but that's really what you're seeing.

Adam Schechter

And Tony with respect to 8931 the structure of the program is that we have an initial phase in which we analyze, we enroll and analyze a set of patients over a three month period each patient exposed for three months in order to look at dose ranging and to look at safety intolerability and based on those results we then proceed into our large Phase-III study. We believe that we will complete that safety run-in period including the three months drug exposure by the end of this year. Our hope and belief of course is let's say intolerability will be expected and we will move on into the large efficacy portion of the trial. If there were any problem of course we would let you know and proceed into that we will let you know about that as well and ultimately those data will be presented in the scientific meeting. So you can expect to hear about it at the beginning of 2014.

Operator

Your next question comes from the line of Mark Schoenebaum with ISI Group.

Mark Schoenebaum - ISI Group

First of all congratulations to Adam and his team on the U.S. especially on the U.S. (inaudible) you probably know there is a lot of consternation around that number on the street, you guys delivered. So my questions are mainly

around that, so number one you said there was a $30 million inventory that in the quarter, can you just remind us I believe there is a $70 million drawn down last quarter so it has been a fair bit of movement here. Has that stabilized? Should we expect further movements going forward? Yes or no and then I heard a couple of numbers thrown around I got a little bit confused just a clarification, what exactly was the price benefit in the U.S. year-over-year and in the ex-U.S. can you update us on what's going on with AMNOG and Iqwig in Germany there has been some I know movement over there and I guess you guys came out little bit ahead of your competitors but can you walk us through the potential scenarios there? I know no one knows looking at them what are some of the potential outcomes? Thanks so much.

Ken Frazier

Absolutely Mark it's I would try to give you as much as specific as we can because it's such a big growth driver for us and if you look at the interview (ph) what I said was that off the 9% U.S. growth about 1% was from volume, 4% was from inventory, the rest of it was from price so that makes about 4% price. You've to be careful extrapolating that over every quarter because mix can have a significant impact on how much price comes to it at any point in time also the timing of your price increase makes that a little difficult for you to try to predict and look for it to be the same quarter-over-quarter. With regard to the inventory, we did see about $30 million of inventory movement this month which I mentioned. On the base of business that we have it's very, very small $30 million so it's very difficult to predict the channel movements from one quarter to another, we are not seeing large channel movements in terms of how big the product is in the United States. It's relatively small but small channel movements can have $30 million to $50 million impact. So that's why for the guidance that I gave for the rest of the year I said mid-single digits for the U.S. but I excluded the movement of channel in there because you can't predict $30 million to $50 million of channel movement, it's within a half a day sales or something like that, so that's how I think about the inventory moving forward. With regard to Iqwig so on July 1st they announced the outcome of their assessment of Januvia and some other PP Force. We were pleased that they have recommended that there is add benefit for Januvia when added to metformin. We're very pleased with that.

That's the beginning of the process, the next step is a decision on the added medical value by the GBA and that's expected in the fourth quarter of this year. Once that happens you actually go into the reimbursement discussions so we're happy with where we are today, we're very pleased with the initial assessment but there is still a lot more work for us to do and it will be another six months before we probably know the final outcome of that. Just to put that in perspective for you Mark, if you look at Germany it represents less than 5% of our Januvia family sales to just give you a sense of the magnitude of that so we're excited with what's happened thus far which is still a long way to go.

Operator

Your next question comes from the line of David Risinger with Morgan Stanley.

David Risinger - Morgan Stanley

Yes, thanks so much. I have two questions. And they both relate to some cross currents and so Ken, I am hoping that you can clarify for me and I guess for investors on the call. With respect to the animal health and consumer businesses, I think you described them as complementary today, but there has been a lot of hoping and dreaming about Merck divesting these businesses or exiting these businesses on Wall Street? So, can you just sort of set the stage right in terms of how investors should think about them as being core to Merck that you will be building them or you will consider exiting them?

And then second, with respect to R&D cross currents, I think Ken you described how important it was to invest in R&D, but many on the Street have been hoping for significant R&D cuts. So, if you could maybe settle that debate and frame whether you expect R&D to remain flattish over time or whether there are meaningful cuts ahead? Thank you.

Ken Frazier

Okay. So, let me start with the animal health and consumer conversation that we had today. So, first of all, I have been saying for years that I think that, that is complementary to our business, but I also have been saying that we periodically assess our overall business strategy based on business opportunity. We believe that business diversity can be complementary and contribute to our top and bottom line growth, but if we were to view these assets as being more productive outside the company, we would consider other alternatives. So, I am saying that we constantly reassess and reevaluate our entire portfolio. That's an ongoing thing for us. When I said that I consider them complementary again, that's not a new comment, I have made that ever since I have been CEO, but I am also saying that we have to look at the overall performance of the portfolio and decide basically how we can maximize long-term cash flow for

shareholders.

With respect to R&D, the first point I would make is that we continue to think innovation is going to be the long-term driver of the company's success. We are going to continue to invest in programs like PD-1 to ensure that we bring those products to market as quickly as possible and reach their full potential. We are always looking to improve productivity across the company. So, I will let Roger comment on what he sees going forward, but I would say that in every aspect of our business, we are looking for an opportunity as you heard Roger saying he is evaluating programs, processes, and people. I think it's appropriate though to give him some time to assess that entire equation and decide how he is going to drive better ROI going forward. We also by the way did say that we are lowering our R&D guidance of 2013 versus 2012. So, all those things coming together, I think directionally say something about R&D spending inside the company, but I do again think Roger has the right opportunity to look at the overall picture and decide how he wants to improve ROI going forward. I will just close by saying at the end of the day all of these companies at the end of the day have to innovate and they have to bring forward clinically meaningfully differentiated products the way that Roger has said and that remains to me the major focus of Merck and Merck's strategy.

Joe Romanelli

Great, okay. Thanks David. Thanks for the questions. Andrea next caller please?

Operator

Yes sir. Your next question comes from the line of Andrew Baum with Citi.

Andrew Baum - Citi

Yes, good afternoon. Couple of questions. First on the DPP-IV class within Europe, the Transparency Commission in France just yesterday announced they are going to be focusing on the class and equate well Merck may benefit from the ongoing discussions there, so some of your competitors are going to have the pricing drag down, as far as that (indiscernible) the drug? And healthcare systems (indiscernible) are struggling in DPP-IV makes itself target and obviously you referenced Japan, and am I being too negative there, and I think about the pressures on the franchise outside the U.S.?

And then second question is for Roger, perhaps you could outline what the split in current investment is between research and development within Merck and then following along from that, what scope do you see for downsizing Merck's current research as opposed to development and research infrastructure. Thank you.

Ken Frazier

So why don't I talk a little bit about DDP-4 class, and I will focus outside the U.S. because that's where you focus and I spoke a lot about the U.S. already. I just want to reiterate that we had good volume growth in all regions and we had good growth if you just look at the five core European markets we've very strong growth, not only in volume, but also in dollars. I believe the environment in Europe is tough and I think it will continue to be tough but I also believe that the value that physicians and patient see in a product like Januvia is very strong and also when you talk to the government. I do believe that they see the value that a product like to Januvia can bring into the marketplace. And the marketplace tends to show you the value of the product based upon the utilization and when you look at the utilization of Januvia. I think it's because position, not only the great efficacy that you can see on HbA1C but they also feel comfortable with the safety profile that they have been accustomed to.

And if you look at the cost of the implications of diabetes they are very significant, in Europe typically the DDP-4s are utilized after metformin so it's not threatening the largest generic in Europe, it's actually being utilized after the generics are used in Europe. So I think that it shows that there is a way to try to use a low-cost metformin but since many patients can't get the goal on a low cost metformin sulfonylurea has safety or side effect issues that the physicians are looking for a way to control diabetes such as with Januvia and then the government sees the implications of notching diabetes in terms of the macrovascular disease and microvascular disease in terms of hospital admissions and so forth. So I still think that there is a strong potential for Januvia in Europe. In addition to that we still have markets that we're waiting for reimbursement outside of Europe such as in China, where we think there is also opportunities for the future.

Roger Perlmutter

With respect to the split in current investment that we could spend quite a long time talking about the way in which funds are allocated at Merck but let me just point out that has been described in detail by academic analyses of

expenditures and pharmaceutical companies, investments and discover research as a fraction of the total investment in R&D have been declining monotonically since 1980 and discovery research is actually a very small component of all large pharmaceutical companies. It represents the simply the fully allocated costs of the people doing the work and the expense associated with clinical trials has been rising progressively, Merck is no different from all other big companies we spent far more on development that we do on research. Having said that you should keep in mind that there is a lot of stuff that is classified as a research that really relates to development, questions are raised by regulatory agencies with respect to products that have long been on the market that require preclinical studies. Its research effort but it actually is contributing to the development role. So there is a lot of complexity in there and with respect to opportunities that exists for reducing expenditure in research I think the real question to be asked is what you do to improve the productivity of the R&D organization to actually create breakthrough products that make a real difference to patients.

Ultimately you innovate or you die and that's what needs to be done, and you need to do it as effectively, efficiently and productively as possible and that's what we intend to do.

Joe Romanelli

Great. Thank you Andrew. Next question please?

Operator

Your next question comes from the line of Alex Arfaei with CMO Capital.

Alex Arfaei - CMO Capital

A couple for Roger if I may, are you doing an core formation work to combine the SGLT2 you got from Pfizer with Januvia as affixed those combination similar to what your competitors are doing and also, could you please provide us an update on your once weekly DDP-4 and is there any possibilities for a core formulation there? Thank you.

Roger Perlmutter

With respect to the SGLT2 program of course we're just moving forward with that program. We expect to advance that program into Phase III this year but we also are interested as I said last quarter that you know that one of the things that's extremely attractive about this program is it's very well behaved pharmaceutical and hence we expect it to play nicely with others. We have always had an interest in the idea that this could be used in combination with our existing programs and so we're looking at those things very closely that will be something of course, that we would include in our registration programs and we're making – we continue to make progress on our once-weekly program. Our Phase 3 program is ongoing, and we are enthusiastic about it and we think it's a very, very good opportunity.

Joe Romanelli

Okay, thank you Alex. Next question please?

Operator

Your next question comes from the line of Jeff Holford with Jefferies.

Jeff Holford - Jefferies

Hi, thanks for taking my questions. Just got two for you. On a margin basis, where do you think the greatest scope for cost saving going forwards on this company over two, three year view would be, would it be in COGS, SG&A and R&D maybe you can rank those for us? And then just secondly coming back to I think consumer health specifically, probably under 4% of group EBITDA in terms it would actually produce it, how do you think of that really as being as an asset to give diversification to the company. It was such a small contribution and how would you assess the margins of that company versus some of its peers of larger scale? Thank you.

Ken Frazier

Okay. Let me take the consumer question. We have looked at the profitability of our consumer business and we believe its back up well against its competitors. I agree that the asset is smaller compared to our pharmaceutical business. I said before that it's not global scale, but it's a very good business that produces really strong cash flow. And we also continue to see that the OTC opportunities, which I control is the most recent example for us do give us

the complementary tag to our pharmaceutical business.

Peter Kellogg

So, Jeff, it's Peter Kellogg. Let me answer your first question regarding margins and opportunities in our P&L. So, we are a large complicated business, so I can appreciate the targets that we are through, but let me go back to kind of the couple of pieces. First of all, we announced the merger almost four years ago. We did highlight that we had a fairly extensive manufacturing network. Quite frankly, we combined three companies, Merck, Schering-Plough, and Organon, and really had an extensive manufacturing network of over 90 plants. And I think you recall that's what we highlighted on day one was that required rationalization over time. We have made great progress on that. At this point, the number of plants we have in the network is numbered kind of in the low 70s. And I think that it's very clear that we are keen to do that as we indicated at the time of the merger. That's not something we can get done in three or four years. It's really an ongoing process, so continuing to drive more and more efficiencies. I think there is more to come there.

Obviously, how it shows up on the P&L through the cost of goods eventually, there is always if you measure things in terms of PGM percent, then you get the blend between your efficiencies and productivity coming to the cost of goods sold versus the pricing that you can realize and that really comes down to again the innovation and the exciting new products that we bring forward. So, but I do think that clearly on the cost of goods sold that's an ongoing opportunity we talked about. In the – just going down the P&L in the R&D side, I think what I know Roger and I talked a lot about it, it's really a question of the ROI that we think about there.

We have the right opportunities such as the PD-1. We are going to spend the money on that. And we are intending to have an exciting pipeline. So, it's not a goal of ours to have unexciting – not have exciting opportunities and not spend money. Conversely, we do really want to pay close attention to how we are spending and making sure it's focused on as Roger said the really big things that can make a big difference in the marketplace and then obviously drive the top line. So, R&D, I think is very much of a focus for us from a productivity standpoint with very much from an ROI perspective that we have the great opportunities we are going to go after them. And we will make sure that we are doing efficiently.

And then obviously the last thing is on SG&A, we continue to evaluate that globally at which our footprint look like and how do we operate in the most efficient manner. We made tremendous progress since the merger is I think we highlighted at the end of last year. We actually hit and exceeded all our merger synergy goals that we had which were pretty expensive. I think we highlighted that we achieved a net benefit of $3.5 billion, which actually means that our gross savings were over $6 billion. So, that's a very, very substantial merger synergy program that we have executed. But I think what's very important is as Ken said in his talk today, cost management is very important for us to resource that creates on the one hand a more efficient P&L, but quite frankly, it also allows us to spend on the growth drivers, which is so important to our future. So, I don't want you to conclude that we are simply thinking about our cost structure as how do we take cost out, but it's also how do we reinvest to drive shareholder value and really create a lot of value in this company, most of the pipeline as well as the commercial assets around the world. So, I think SG&A continues to be a focus for us. But on the other hand, I think we are also going to balance all those savings with where we have opportunities to invest.

So, I am not going very specific answer I realize that but I do want to make a point that while we have opportunities and we are going to continue to pursue them, we certainly executed well in the merger synergies that we have laid out and we're going to continue on that to through the manufacturing network elsewhere in the organization we're thinking about we turn on investment and creating value, but we never will be passive about you, as Ken likes to say we're going to be ambitious in driving performance in the short term but we are never going to back away from investing for long term potential long-term value creation.

Joe Romanelli

Okay, great. Thanks and Andrea I think we have time for two more callers, so we can start with the next questions.

Operator

Yes sir. Your next question comes from the line of Steve Scala with Cowen.

Steve Scala - Cowen and Company

First will the tax rate be so much higher in the second half of the year versus the first half and what does it tell us about the tax rate in 2014, secondly you mentioned 2013 R&D spend will be lower but you haven't quantified it. I guess

we should assume it will only be modestly lower, would you like to recalibrate that expectation? And then thirdly why was it up sequentially down in the second quarter it had been sequentially up in the second quarter 2012. Thank you.

Peter Kellogg

Let me take the first question on tax, so I think you had a couple of question there so let me just take them one at a time if I can. You asked why would the tax rate be higher in the second half of the year than the first half of the year. SO as we went into the first half of the year and I'm just going to take it quarter by quarter and the first quarter we saw some significant tax benefits that came through. I think we highlighted that time and they are very kind of one time in nature, there were R&D tax credit being reimplemented and so forth. We also had a couple of resolution of some tax audit situations allowed us to release some reserves. And so that caused our R&D our tax line to be lower in the first quarter.

In the second quarter we also had a reduction in some tax reserves because we had the exploration of some statute of limitations and so that allowed us to free up some tax reserves and basically some of these benefits were things that we thought about over the course of a full year. We didn't really actually when we first put the plan together just by getting all these things in the first and second quarter quarters. So as you think about how the year comes together, when you think about the full-year tax guidance of 22% to 23% the way you get to that on a full year basis is it ends up weighted average of all the quarter. So the first two quarters were lower that by definition it means the third quarter and fourth quarters will be higher and they will only be higher because we just won't have those one-time benefit pulling the rate down. We can kind of return to a more natural run-rate that we would expect.

And I think that you will recall that we have talked about in the past is the ongoing tax rates the company will be a little higher than what you're seeing right now and so generally we've talked about the long-term tax rate, recognizing that uncertain things can move around, but excluding any unusual items or any items that pull it down or move it up that are kind of unique in nature we expect it to be running that in the higher rate in the range of something like 25% to 26% on an ongoing basis.

But I think we want to be careful that all these years we go into the year we will update you in terms of what we see on the horizon relative to how it's axes are evolving. I think on the second question you were asking about R&D and why would it be lower in the second half and in the first half in fact, you know, how should we think about what we're looking at.

So obviously in my comments I highlighted that entire year we actually did have a payment for ENDOSITE (ph) in the second quarter of last year so we're laughing in that sense. But we also basically see as we move forward kind of there is a flow of activity, Roger's making decisions and so forth and I think that basically we're using kind of the most recent updated view of R&D as we think about it. So and quite frankly it's ties to productivity, to focus and we're not talking about the sea change we're just simply, we previously we thought it will be a little bit higher and now we're kind of (inaudible) our expectation is based on what we see will be a little bit lower.

The third question was….

Adam Schechter

I will take the third one, see this is Adam and with regard to (inaudible) there is definitely a seasonal nature to the business and we have predicting that all along. In 2012 it was up first year with full U.S. supply. When we have full supply the offices were buying the vaccine and they were stocking and getting ready for vaccinations and in addition to that we had just started our direct to consumer proportion in the second quarter of 2012 because we wanted to ensure that we would have adequate supply before we would actually drive demand through the DTC promotions. So I want to use 2012 as a direct year-over-year comparison to 2013.

We expect that the second half of this year will be stronger and the strongest quarter will be dependent upon when flu vaccinations occur, because that's when we believe we will see many people getting vaccinated for (indiscernible) as well.

Joe Romanelli

Great. Thank you for the questions Steve. And I think Andrea, is it time for one last question?

Operator

Yes sir. Your last question comes from the line of Gregg Gilbert with Bank of America/Merrill Lynch.

Gregg Gilbert - Bank of America/Merrill Lynch

Thank you. For Roger, I would love to get your personal view on the opportunity and the risks associated with odanacatib at this point? Secondly, could you be in a position to file LAMBRO in melanoma early next year given the unmet need in that population and your breakthrough status? And maybe lastly, Adam, can you talk about what prompted the GARDASIL decision in Japan and whether that has implications anywhere else? Thanks.

Roger Perlmutter

Well, but at the same time asks that we continue the study in order to obtain additional efficacy and safety data. We are continuing to study in that way. We do anticipate that we will have the opportunity to look at those data and adapt to distant future, and based on what we see there, we hope to be able to move forward with the odanacatib filing, but we have to see the data of course. With respect to PD-1, again, the information that we have is that as you can see from looking at ClinicalTrials.gov, we have ongoing pivotal studies in melanoma refractory to therapy. We have a Phase 3 study in melanoma versus ipilimumab. Those studies will deliver results either in the latter case at the end of next year or in 2015. If in fact it were the case that there were overwhelming efficacy earlier on there might be opportunities for a more accelerated filing strategy, but that's something that we really will have to wait to see data on. And of course, we are working very, very closely with the FDA on that. And with regard to Japan, the government suspended the proactive. So, it's important to say that proactive recommendation of HPV vaccines, the vaccines still remain on the market in Japan. And the MLHW is just looking into some post marketing use that they have seen specific to Japan. We have not seen any significant impact at this time in other markets around that world and MRL continues to monitor the AEs as appropriate and we are confident in that safety profile of GARDASIL.

Gregg Gilbert - Bank of America/Merrill Lynch

Yes, absolutely.

Ken Frazier

Okay, so thanks Gregg. Let me just close by saying I think this was a good quarter, a solid quarter. Going forward, our strong focus will remain on growth for the company as well as driving greater profitability. It was good to see a bounce back in certain sales, particularly JANUVIA. We had good back scenes in immunology sales. It's great to see that the emerging markets are still moving ahead in a very strong way. As we go further, we will continue to invest thoughtfully in these commercial opportunities as well as our pipeline opportunities. We are very excited about, for example, PD-1s. And as we think about this business going forward, we continue to think that innovation has got to be the key, but we've got to be very careful to deliver the right kind of reductions at our cost base that will allow us to do that in a sustainable way. So, thank you very much for your attention, and I look forward to talking to you in future quarters and in future venues. Thank you. Bye-bye.

Operator

Thank you. Ladies and gentlemen, this concludes today's conference call. You may now disconnect.

Thank you!