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PFE - Q1 2016 Pfizer Inc Earnings Call

EVENT DATE/TIME: MAY 03, 2016 / 2:00PM GMT

OVERVIEW:

Co. reported 1Q16 reported revenues of approx. $13b and reported diluted EPS of $0.49. Expects 2016 reported revenues to be $51-53b and adjusted diluted EPS to be $2.38-2.48.

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's first-quarter 2016 earnings conference call. Today's call is being recorded. At this time I would like to turn the call over to Mr. Chuck Triano, Vice President of Investor Relations. Please go ahead.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thank you. Good morning and thanks for joining us today to review Pfizer's first-quarter 2016 performance and 2016 financial guidance. I'm joined today by our Chairman and CEO, Ian Read; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide R&D; Albert Bourla, President of Pfizer Innovative Pharma; John Young, President of Established Pharma; and Doug Lankler, General Counsel.

The slides that will be presented on the call can be viewed at our homepage, Pfizer.com, by clicking on the link for Pfizer Quarterly Corporate Performance First-Quarter 2016, which is located in the For investors section in the lower right hand corner of this page. Before we start, I would like to remind you that our discussion during the call will include forward-looking statements that are subject to the risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements.

Additional information regarding these factors is discussed under the disclosure notice section in the earnings release we issued this morning, as well as in our 2015 Annual Report on form 10-K, including in part 1 item 1A risk factors, that is filed with the Securities and Exchange Commission and available at their website, SEC.gov, and our website, Pfizer.com. Forward-looking statements during this conference call speak only as of the original date of this call, and we undertake no obligation to update or revise any of these statements.

Discussions during the call will also include certain financial measures that were not prepared in accordance with US Generally Accepted Accounting Principles. Reconciliation of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's current report on form 8-K dated today May 3, 2016.

You may obtain a copy of the form 8-K on our website, Pfizer.com/investors. Also, any non-GAAP measures presented are not and should not be viewed as substitutes for financial measures required by US GAAP, have no standardized meaning prescribed by US GAAP, and may not be comparable to the calculations of similar measures at other companies.

We will now make prepared remarks, and then we will move to a Q&A session. With that, I will now turn the call over to Ian Read. Ian?

Ian Read - *Pfizer Inc. - Chairman & CEO*

Thank you, Chuck, and good morning, everyone. To my remarks this morning I will briefly recap the highlights from the quarter and comment on our strategies, including expected pipeline development this year, our approach to business development in light of our decision not to move forward with Allergan, and the steps we expect to take to assess a potential split of the Company.

2016 is off to a good start, with solid performance across both the Innovative and Established businesses, notably Prevnar 13, Ibrance, Eliquis, and Chantix are performing better than we initially projected. As we referenced in our earnings release, a portion of the growth in the quarter was attributable to additional selling days compared to the year-ago quarter which will be offset in the fourth quarter from a growth perspective.

We nonetheless had a strong quarter financially even without that impact, exceeding our internal projections, and it incorporated the strong operational performance as well as the recent weakening of the dollar into our updated financial guidance for the year. And compared to the first quarter, we expect that our LOE impact from Lyrica, Rebif, Enbrel will be more pronounced in the remaining quarters of the year.

Additionally, new product launch expenses and R&D investment are also phased higher for the remainder of the year. Frank will provide more details in a few minutes.

Overall looking at the quarter, on a revenue basis Pfizer's standalone business, excluding Hospira, grew 15% operationally and 26% operationally with the inclusion of Hospira. Our Innovative business generated impressive operational revenue growth of 28%, driven by the performance of Eliquis globally, Ibrance, Prevnar 13, Lyrica, Xeljanz, Chantix, and Nexium 24-hour principally in the US.

Of particular note, Ibrance has already earned broad patient and physician acceptance. Since launching in the US last year, about 6,800 prescribers have treated approximately 28,000 women with HR-positive, HER2-negative metastatic breast cancer, and the feedback continues to be very encouraging, particularly around the efficacy and tolerability profile and impact on the overall quality of life.

Recently we announced that the confirmatory Phase 3 Paloma-2 trial for Ibrance in first-line metastatic breast cancer met its primary end points of improving progression-free survival. Detailed results will be presented at ASCO in early June.

We are also seeing continued strong operational growth from Eliquis, which is yielding increased market penetration and market share gains in the US and Japan. The contribution of Eliquis to our alliance revenue line more than doubled year over year.

For the Prevnar 13 adult indication, while there was a year-over-year growth as expected, we saw a sequential quarterly decline in revenues given the rapid penetration we achieved in the US market during 2015. The pediatric indication remains strong, and we anticipate that global revenues for the Prevnar 13 franchise in full-year 2016 will be comparable to 2015.

And we were pleased at the results from the EAGLES study, the largest global clinical trial of smoking cessation medicines, were published in the Lancet. The study was designed to compare the neuropsychiatric safety of Chantix and bupropion with placebo and nicotine patch in adult smokers with and without a history of psychiatric disorders.

The authors concluded that the study did not show a significant increase in serious neuropsychiatric events with Chantix or bupropion relative to placebo or nicotine patch. The study also found that smokers treated with Chantix had significantly higher quit rates than those treated with bupropion, nicotine patch, or placebo.

Turning now to our Established business, it grew 24% operationally, primarily to the additional revenues from legacy Hospira products. Without Hospira and the impact of foreign exchange, the business grew 1%. In particular we saw strong performance from the sterile injectables portfolio.

The addition of Hospira's leading generic injectables portfolio with Pfizer's legacy branded injectables, establishes Pfizer as the number one sterile injectables company globally. We now have one of the broadest and most diverse offerings of difficult to manufacture sterile injectable medicines, which are critically important for patients around the world.

This leading market position combined with our expanded biosimilars offering and the continued growth of Pfizer's legacy branded portfolio in emerging markets, will help us to move the Established pharmaceuticals business from a period of loss of exclusivity driven decline to potential growth. The Hospira acquisition was a clear growth driver, and the integration continues to proceed well.

We have addressed specific issues related to legacy Hospira's manufacturing, and have developed a plan to implement Pfizer quality standards at the sites. And we have dedicated resources to support the sites as they complete their transition to the Pfizer network.

Based on Hospira's excellent strategic fit with our Established business and our intense focus on integration of Hospira, we expect to exceed our original synergy targets of $800 million in annual cost savings by 2018, and now expect to achieve approximately $1 billion in cost savings.

As you are aware, in early April we decided not to move forward with that Allergan transaction due to actions of the US Treasury department. Given these actions in the current political climate, we do not see any potential for a transaction involving inversions in the near term. While the outcome was disappointing, we always view the potential Allegan transaction not as a new strategy but as a way to accelerate our existing strategy which remains unchanged.

Our strategy is anchored by several elements, namely improving the Company's revenue growth profile so that greater proportion of our earnings-per-share growth is driven by incremental revenue opportunities. Our latest product launches including Eliquis, Xalkori, Xeljanz, Ibrance, and Prevnar 13 adult have now become meaningful revenue contributors.

In addition, the FDA's decision to approve Celltrion's biosimilar infliximab across all eligible indications, marks a critical and positive step forward in helping to create a pathway for biosimilars in the US. We hold the exclusive commercialization rights to this product in the US.

While launch timing of Inflectra will ultimately depend upon a number of factors, such as marketplace dynamics and intellectual property considerations, we are continuing with the preparation of our launch plans for 2016. Our current biosimilars portfolio includes three commercialized products available in select markets outside the US; Inflectra, Nivestim, and Retacrit.

We believe that biosimilars represent an attractive revenue growth opportunity for expanding patient access to important treatments. We also see continued opportunities for our Established pharm business in emerging markets with a robust portfolio position to compete in these markets.

GAAP revenues in emerging markets increased 10% operationally this quarter, and Company-wide revenues in emerging markets increased 14% operationally. Emerging markets revenues represented nearly 20% of our total Company's revenue base.

We are also continuing to make significant progress in securing potential future growth drivers across the advancement of our pipeline. Specific examples include a planned submission for ulcerative colitis for Xeljanz, which is on track to occur in the first half of 2017; the acceptance for review of the Xeljanz EU filing with rheumatoid arthritis.

We have completed enrollment in the Bococizumab SPIRE-2 outcomes trial. While it can be hard to predict duration of trial -- of a time to events trial, we currently anticipate a potential completion of this outcome study in the second half of 2017; presentation of the Ertugliflozin Phase 3 data at the American Diabetes Association meeting in June and a potential regulatory filing in the US; the Tanezumab Phase 3 program, where we are now conducting trials for osteoarthritis, chronic lower back pain, and cancer pain indications; a potential regulatory decision in EU for Ibrance in combination with endocrine therapy for the treatment of HR-positive, HER2-negative advanced metastatic breast cancer, and for Inotuzumab for adult patients who have relapsed or refractory CD22 positive acute lymphoblastic leukemia.

We are in discussions with the FDA on next steps to bring this important medicine to patients. Behind these assets is a strong and early mid-stage pipeline, most notably a broad portfolio of IO compounds which continued to advance.

Our Avelumab PD-L1 program with Merck KGaA has ramped up rapidly and now has 30 programs ongoing, both as monotherapy and in combination with other portfolio assets, eight of which are potentially registration enabling. We continue to expect the key advances in IO will come from novel combinations, both double and triple combination regimes and technologies that may have the potential to treat more patients with immunotherapy and ultimately transform the cancer treatment paradigm.

We have several combination studies that are already in the clinic, with our key combination assets being 4-1BB and OX40. We also have a range of immuno-oncology assets moving into the clinic, including our allogeneic CAR-T program in collaboration with Cellectis and Servier and a small molecule immunotherapy asset, IDO1, in collaboration with iTEOS and our biospecific antibody p-cadherin.

Recently we presented Phase 2 data at the AACR annual meeting showing that Ibrance was effective in slowing the multiplication of cancer cells in patients diagnosed with early-stage breast cancer who received no prior therapy. And we also expect a proof of concept readout with our next generation ALK inhibitor, lorlatinib, in ALK positive non-small cell lung cancer patients towards the end of the year.

Lorlatinib is our investigational follow-on drug to Xalkori. In neuroscience we began a Phase 2 proof of concept study this quarter for our novel dopamine modulation asset for Parkinson's disease.

If successful, this may have the potential to replace the standard of care in Parkinson's. In addition, through a collaboration with MedGenesis Therapeutix, we have a second compound being investigated in Parkinson's and expect to have a proof of concept study readout in the second half of the year.

The compound is a GDNF protein and may have the potential to provide the first disease modifying treatment that slows the progressive decline in Parkinson's patients. In vaccines we expect to have a C. difficile proof of concept readout towards the end of the year.

C. difficile is growing hard to treat infection in the hospital and long-term care setting. Currently there are no vaccines available to prevent the disease, and the infection control practices are challenging to implement. Overall, we are anticipating a steady stream of pipeline updates throughout 2016.

Our strategy will also capitalize on the opportunities and specific expertise resulting from our distinct competitive and growing businesses, namely our Innovative and Established business. Each is led by strong leaders with the experience and know-how to effectively direct and grow these organizations.

In addition to capitalizing on the strength of our pipeline, our strategy includes allocating our capital to shareholder-friendly initiatives with an eye towards sustainable value creation. This includes continuing to look for ways, other than inversions, to improve our tax rate.

It also includes pursuing business development opportunities that use our capital efficiently in ways that create meaningful shareholder value that have the potential for near-term solid value creation, that strengthen our individual businesses with capabilities in key assets, and enhance our leadership position in the most attractive core areas. As you know, we're also considering a potential separation of our Innovative and Established businesses. No decision has been made at this point and as we recently announced we plan to make an assessment of the merits of a separation by the end of 2016. By this time we will be completing our third and final year of building the required segment financials to support any split and will also be in a position to complete the necessary financial analysis needed to determine if the time is right to move forward with a split. If we determine the timing is right... then we expect to be in a position to execute a split by the end of 2017, and if we determine through our process that a split isn't appropriate, we will continue to have the flexibility to assess the option and proceed if and when we deem the time is right. Our decision framework has not changed.

It continues to be based on these four questions: Are the businesses performing well within Pfizer? Could the businesses perform well as standalone entities? Is there trap value in the combined entity? And can the trap value be unlocked efficiently?

Throughout the year we will be assessing our performance to answer each of these factors. In summary, the business is performing well, driven by a sound strategy.

The outlook for the year is strong, based on the demonstrated ability of the Innovative and Established businesses to execute against this goal. We have a healthy pipeline with strong candidates at every stage of the pipeline, and we have the financial flexibility and several options for creating short-term and long-term value for shareholders. I'll now turn it over to Frank. And thank you.

Frank D'Amelio - *Pfizer Inc. - CFO*

Thanks, Ian. Good day, everyone. As always, the charts I am reviewing today are included in our webcast. As a reminder, because we completed the acquisition of Hospira on September 3, 2015, Pfizer's first-quarter 2016 financial results include three months of legacy Hospira global operations compared with first-quarter 2015 results, which do not include any legacy Hospira operations.

Now moving on to the financials. We had a good quarter. First-quarter 2016 reported revenues were approximately $13 billion and reflect year-over-year operational growth of $2.9 billion, or 26%, of which $1.2 billion, or 11%, is attributable to the inclusion of legacy Hospira operations; and approximately $900 million, or 8%, is attributable to five additional selling days in the US and four additional selling days in international markets in the first quarter of 2016 versus the year ago quarter.

Excluding legacy Hospira operations in these additional selling days, reported revenues grew $800 million, or 7% operationally, which reflects continued strong performance of Ibrance, Prevnar 13, Eliquis, Xeljanz, Lyrica, and Chantix and the 14% operational growth in emerging markets, which were partially offset by the absorption of an approximately $300 million negative operational impact due to product losses of exclusivity. With respect to selling days, I want to point out that because of our accounting calendar there was greater variability of selling days during the quarters in 2015 than there will be in 2016.

But this will not impact total number of selling days or our revenue for 2016. To illustrate, there were five more US and four more international selling days in the first quarter of 2016 compared with the year-ago quarter, and there are four fewer US and three fewer international selling days in the fourth quarter of 2016 versus the fourth quarter of 2015.

So the imbalance in selling days we saw in the first quarter will be offset in fourth quarter 2016, and they will be essentially the same number of selling days in full year 2016 as in full year 2015. Consequently, the only impact will be to the quarterly year-over-year comparisons, notably for the first and fourth quarters.

Reported revenues continued to be unfavorably impacted by foreign exchange of $729 million, or 7%, including losses related to the Venezuelan bolivar. First quarter adjusted diluted EPS was $0.67 versus $0.51 in the year ago quarter.

The increase was primarily due to increased revenues, the inclusion of Hospira operations, a lower effective tax rate, and fewer diluted weighted average shares outstanding, which declined by 78 million shares versus the year ago quarter due to our share repurchase program, which includes the impact of our $5 billion accelerated share repurchase agreement executed in February 2015 and completed in July 2015. And by another 136 million shares associated with a partial quarter benefit from the accelerated share repurchase agreement executed in March of 2016, which will be partially offset by an aggregate operational increase on adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses of $1.1 billion or 16%, $0.07 negative impact due to foreign exchange, and continuing product losses of exclusivity.

Reported diluted EPS was $0.49 compared with $0.38 from the year-ago quarter due to the previously mentioned factors and the favorable impact of lower charges for business and legal entity alignment activities incurred during the first quarter, which were partially offset by higher acquisition related costs, legal charges, purchase accounting adjustments, and higher asset impairment charges. Foreign exchange negatively impacted first quarter reported revenues by approximately $729 million, or 7%, and positively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D in the aggregate by $197 million, or 3%.

As a result, foreign-exchange negatively impacted first quarter adjusted diluted EPS by approximately $0.07 compared with the year-ago quarter. The results for the GIP, VOC, and GEP businesses are available and can be found at the end of the presentation that is posted on our website.

Moving on to our 2016 financial guidance. We are updating our 2016 reported revenues and adjusted diluted EPS ranges due to our strong performance to date and improved business outlook for 2016, as well as a favorable impact from foreign exchange rates since mid-January 2016.

Consequently, we raised the midpoint of our 2016 revenue guidance by $2 billion and the midpoint of our 2016 adjusted diluted EPS guidance range by $0.18. We now expect 2016 reported revenues to be in the range of $51 billion to $53 billion versus our previous expectation of $49 billion to $51 billion, and we expect adjusted diluted EPS to be in the range of $2.38 to $2.48 versus our previous expectation of $2.20 to $2.30.

I want to punctuate what Ian said previously. Operational factors such as our strong performance to date in 2016 in addition to our improved business outlook for 2016, favorably impacted the midpoint of the reported revenue guidance range by approximately $1 billion and the adjusted diluted EPS guidance range by $0.12.

Favorable changes in foreign exchange rates since mid-January 2016 also favorably impacted the midpoint of the reported revenue guidance range by approximately $1 billion, and the adjusted diluted EPS guidance range by $0.06. Finally, given our first-quarter results and the benefit of continued support of recently launched products as well as foreign exchange, we are raising the midpoint of our adjusted SI&A guidance range by $500 million.

Consequently we now expect adjusted SI&A expenses to be in the range of $13.7 billion to $14.7 billion. Moving on to key takeaways, this quarter marks our sixth consecutive quarter of Pfizer standalone operational revenue growth, which was primarily driven by new products that are early in their life cycles such as Ibrance, Prevnar 13, Eliquis, Xeljanz, and Lyrica and additional selling days during the first quarter.

As I just mentioned, we raised the midpoints of our 2016 reported revenues and adjusted diluted EPS guidance ranges to reflect strong operational performance to date, favorable changes in foreign exchange rates, and improved business outlook for 2016. We accomplished several key R&D milestones during the first quarter.

We continued to deliver significant value to shareholders in the form of $1.9 billion in first quarter 2016 dividends, and a $5 billion accelerated share repurchase agreement executed in March 2016. And finally we remain committed to delivering attractive shareholder returns in 2016 and beyond. With that, I will turn it back to Chuck.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thank you, Ian and Frank, for the prepared comments. Operator, can we please move to the question-and-answer session?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Your first question comes from Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

A clarification and then a two-part question. First the clarification, Frank, just want to confirm that the guidance increase for the full year has nothing to do with selling days.

And then my two-part question for John, when is the earliest biosimilar Remicade could be launched when you consider the legal and regulatory framework that exists today? And then for Ian, I'm curious to hear your thoughts on how the recent Treasury moves and your subsequent actions affect the decision to split or not to split.

If you don't see obvious trap value today based on your current structure and domicile, does your separation assessment consider the domicile and tax structure of other companies that could potentially maximize value for Pfizer's shareholders? Thanks.

Frank D'Amelio - *Pfizer Inc. - CFO*

On the guidance, the guidance increase has nothing to do with the selling days. Think about it this way, selling days in 2016 have not changed since we issued our initial 2016 guidance on the last earnings call. So the short answer is absolutely nothing to do with our improved guidance, it's really about the operational performance, the strong operational performance and to a lesser extent foreign exchange.

John Young - *Pfizer Inc. - President of Established Pharma*

Thanks for the question, Gregg. In regard to Inflectra, launch timing will ultimately depend on a number of factors including marketplace conditions, payer dynamics, expected timing for entry of other products, and intellectual property-related considerations among others.

Pursuant to the stipulation entered in recent core conference related to ongoing litigation between Hospira, Celltrion, and Janssen, Hospira agreed not to sell Inflectra in the US prior to June 29, 2016, expiration of the Crohn's patent. We are moving ahead with the preparation of our launch plans for 2016 as you heard in Ian's comments, and we can't comment further beyond those points.

Ian Read - *Pfizer Inc. - Chairman & CEO*

So Gregg, the delay caused by -- the potential split caused by Allergan was just the structural work needed to be done to incorporate them in. That going away, it put us back on our original timeline as we've continued to work on that as a standalone company.

There are many factors we'll take into account in whether we want to split or not, and one of them is of course the tax structure of the two companies if they are split. And I think the Treasury action and the government's willingness to act in this area will make us think deeply about what are the alternatives to let part of this Company if possible have a different tax jurisdiction.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thank you. Can we move to the next question, please?

Operator

Your next question comes from Marc Goodman from UBS.

Marc Goodman - *UBS - Analyst*

Good morning. Just to continue on that thought process, do you feel like you need to strengthen the Innovative business before you would break this Company up? Or are you pretty satisfied with the way it is right now?

And if you do split up, can you give us your best estimate of what the dissynergies would be? And then secondly you mentioned on Prevnar there were government purchases. Can you quantify how much that helped in the quarter? Thanks.

Ian Read - *Pfizer Inc. - Chairman & CEO*

So, Marc, the dissynergies, can we do that first?

Frank D'Amelio - *Pfizer Inc. - CFO*

I can do dissynergies. So Marc, on dissynergies once again assuming we were to exercise our option, and no decision has been made to date, it would be immaterial relative to overall earnings.

Couple -- current estimates are a couple of cents a share on an annualized basis. Obviously we'll fine tune that as we go forward, but current estimates are a couple of cents a share.

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

On the Prevnar, there was some US ordering partner this quarter. It's to the range of $40 million approximately.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Okay. And on the -- the businesses I think are strong enough to be standalone businesses without any further BD, but either as separate companies or as one company we will always continue to look at doing BD when it is appropriate and when it can add value. And that would be an ongoing

process either pre-split or post-split, I would imagine from both company's perspectives. But always with a focus of -- strong focus on value on our part.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thank you. Can we moved to the next question please, operator?

Operator

Steve Scala, Cowen.

Steve Scala - *Cowen and Company - Analyst*

Good morning. I have two questions. First Ian, I have a follow up on an earlier question, and I apologize for being picky, but the fourth criteria for a split appears to have changed a bit.

So previously it was can the split be done in a tax efficient way, and today I believe you said can the split be done in an efficient way. So the word tax may have been deleted. Is this an accurate observation? The interpretation --

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Ian Read - *Pfizer Inc. - Chairman & CEO*

We're probably just simplifying semantics. Efficient means efficient, both operationally and from a tax perspective.

Steve Scala - *Cowen and Company - Analyst*

Okay. Second question for Dr. Dolsten, it would appear that Pfizer is in the first wave of IO combos. Now considering that Pfizer once studied tremelimumab, how big a disadvantage is it to Pfizer that you do not have access to a CTLA-4? Do you view CTLA-4 as here to stay, or will Pfizer's other targets make CTLA-4 obsolete in your opinion? Thank you.

Mikael Dolsten - *Pfizer Inc. - President of Worldwide R&D*

Thank you for the comment. I think CTLA-4 was the first of the immuno-oncology products, but as you know its utility has been somewhat limited for both melanoma and combos because of its systemic immune activation, which can be quite demanding for oncologists to manage. Although I am sure that there will be growing knowledge how to use the product.

We are much more excited about the new checkpoint augmenting compounds like 4-1BB and OX40 that seems to offer an ability to augment different parts of the immune system on top of likely PD-1 and PD-L1, but with retaining really promising tolerability. So we think that is the path to go, compounds that augment PD-1, PD-L1 but retain the stable tolerability, and that's really our focus and really no regrets.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thanks, Mikael. Next question, please.

Operator

Jami Rubin, Goldman Sachs.

Jay Olson - *Goldman Sachs - Analyst*

It's Jay Olson on for Jami Rubin. Thanks for taking the question. With regard to the GEP business and the four criteria that you gave to determine whether or not to separate the GEP business in particular, can you give us an idea of what metrics you plan to use to measure the performance of GEP within Pfizer and the potential performance outside of Pfizer? And then similarly what metrics will you use to determine how much trapped value there is within GEP and how efficiently that could be untrapped? Thank you.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Thank you. The metrics inside Pfizer will be of course are their growth and their operations against our budget. Outside of Pfizer we'll try and establish similar like companies.

It would be easier for the Innovative business, it's not as easy for the Established because really the Established business is a unique business including strong sterile injectables, strong biosimilar capabilities in big emerging markets, and it's not really a generic business. So it's very hard to find a comparison there. I'm sure we'll be able to find some composite.

On whether we can unleash where there's trapped value, we'll obviously use outside advisors. But one of the classic methods would simply be to look at the sum of the parts as much as we can establish by disaggregating our business the same ways we give you information to do.

So we can take those businesses and compare them to standalone businesses and see what a potential evaluation would be with the parts, and compare it to the sum. That is one way of looking at their trapped value.

Another is to look historically at what has happened to companies where they have spun but they have been spun in an unforced manner, i.e. because of management's decision and not because of activist pressure, and see what has happened to the shares of those companies subsequently. And of course we'll also have to look at what are the tax implications, which really circles back to standalone abilities if companies are disadvantaged in a more specific way because of their tax situation compared to their competitors.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thanks, Ian. Next question, please.

Operator

Tim Anderson, Bernstein.

Tim Anderson - *Bernstein - Analyst*

Thank you. A couple of questions, please. My understanding is that right before the Allergan deal was terminated, maybe a week before or something like that, Pfizer went through a round of layoffs of various folks at that mid-management level in anticipation of the merger. And obviously earlier in the year Geno Germano left.

So now with the deal off I'm wondering what the plan is from here in terms of filling these types of positions? Are you for example calling up folks that were going to leave and asking them to stay on for now, or what?

I'm trying to understand what sort of disruption this might have caused unexpectedly. And second question on splitting up, how much of a drive internally is there to do this?

My understanding is that because of different reasons there is an internal desire by a lot of Pfizer folks at that mid-manager level to separate the organization. I am not sure if you have town hall meetings or that sort of thing, but what is the feedback internally at the rank and file level on the Company splitting up?

Ian Read - *Pfizer Inc. - Chairman & CEO*

Tim, I really am not aware of any layoffs or major changes prior to the Allergan deal. I think there were certain specific positions that may have been reorganized. But to answer your question succinctly, there is no disorganization or disruption.

I think the results of the first quarter show that, so I am not at all worried about that. And as to the internal conversations, I would say they are very robust. We have a great enterprise-wide view in the Company that stems from John's leadership in Established and his team.

And the internal decisions or internal motivations are totally directed to what we believe will be best for shareholder values, and it's a very transparent process. So I don't think there is in any way factions within the Company trying to push one way or the other. We will focus the management team on what the best decision for Pfizer's shareholders would be. Thank you.

Chuck Triano - *Pfizer Inc. - VP of IR*

Next question, please.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Thanks for the question. Just had two on business development. The first one is could you elaborate on your priorities and appetite at this point?

As part of that, do you have a bias when it comes to bolstering Innovative versus Established, and is there a focus on in market or near to market products versus pipeline? The section question was about the competitive environment for business development.

I know you've been very financially disciplined in the past, but it appears that we've got a pretty competitive environment out there, and some of your peers may be less focused on ROI than you are. How do you balance that opportunity to acquire attractive assets with maximizing long-term shareholder value in this environment? Thanks very much.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Our BD approach has always been one of BD is not a strategy, it complements your ongoing strategy. So I think our BD post-Allergan remains on that same course.

We will look for assets that we think can add value to shareholders that are appropriately priced and meet our returns. We have always been very disciplined on that, although not concerned about pulling the trigger when we see those opportunities.

So I think there is after all the work we've done on the Established side there will be a tendency towards a bias for the Innovative side, and we will be biased more towards products that are near market or in market that we believe we could generate incremental growth and value by owning them, rather than looking at very early products because we think we have a very full and complete pipeline in that area. On the competitive stance, I would ask Frank to make a few comments on that.

Frank D'Amelio - *Pfizer Inc. - CFO*

I think the way to think about this, at least the way we think about this, is clearly there's been some changes in valuation and in sectors within the industry. So biotech, for example clearly had a change in valuation, a decrease in valuations.

Without speaking for those management teams or those boards, I think at a macro level if you were to ask do they believe that the current valuations represent the valuations of the company I would say I'm not sure. I think that they are probably in transition, that they really haven't decided that the latest valuations are indeed the valuations that are the real valuations.

What I always believe is what really will determine this is when those individual companies have to go out and have a capital market event. A capital market event will be very informing in terms of what the valuation of those companies are. And I think so over time we will see some of that thinking take place.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thanks. Next question, please.

Operator

John Boris, SunTrust.

John Boris - *SunTrust Robinson Humphrey - Analyst*

Thanks for taking the questions, and congrats on the results. First question just on Chantix, on the EAGLES results that you got.

Is that going to help to relax the need to mention neuropsychiatric side effects on direct-to-consumer advertising ads? We're already seeing a nice uptick, but if you're able to relax that one would think that you might be able to see a faster uptick.

Second question on GEP, you've indicated that you're going to be to divesting the pumps business. Where are you in the process on identifying a financial or strategic buyer for the pumps business?

And one of your competitors announced this morning that they are going to be spinning their hemophilia business. Any thoughts within the innovation core to possibly considering spinning and/or divesting businesses that are not receiving enough R&D attention that could be better as standalone businesses out of innovation core? Thanks.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Okay. Albert, if you could talk about EAGLES or Chantix, please?

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

Obviously we're pleased with the positive results of the EAGLES. In this monumental study the authors concluded, as Ian said, that the trial did not see a significant increase of serious neuropsychiatric adverse events with Chantix or bupropion compared to placebo and nicotine patch.

We're submitting this data to various regulatory bodies proposing revisions to the product labeling, including a request for the removal of the boxed warning. We believe that the available scientific evidence doesn't support the box warning, and we look forward to discussing this data with the FDA, EMA, and other global regulatory bodies.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Thank you. I would just add that also having it published in the Lancet is clearly a good medical communication and education, and will allow an appropriate dialogue. John?

John Young - *Pfizer Inc. - President of Established Pharma*

Okay, so thanks for the question, John. Just to correct any misunderstanding that may be out there, because we have made no announcement regarding to any intention to do anything in regard to our pump or infusion systems business.

We are obviously aware of market speculation, which we do not comment on. Across all of our businesses we regulate and review our business portfolio from the perspective of maximizing value creation.

If there are any developments with our business we would certainly communicate that publicly, but as we've said previously we believe that in the Hospira acquisition we acquired what is a scarce asset that is performing well. The Management team have taken the right steps to turn the business around, and we are extremely positive about the opportunity to continue to help the infusion systems business to perform well and to return to growth.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Thank you. Frank, if you could talk about the hemophilia. I think it was hemophilia, yes.

Frank D'Amelio - *Pfizer Inc. - CFO*

Obviously, John, we are aware of the announcement this morning on the hemophilia business of one of our competitors. The way I think about this is we have done similar things in the past.

If you think about our sale of Capsugel, the sale of Nutri, the creation of Zoetis, and I think our compass on all of those transactions has been creating shareholder value. Our compass going forward will continue to be creating shareholder value.

If we think there is an opportunity to do that through any action, including something like a spin we would clearly consider that. Hopefully our actions in the past have demonstrated that we have more than a willingness to do that.

Chuck Triano - *Pfizer Inc. - VP of IR*

Next question, please.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - *Leerink Partners - Analyst*

Thanks very much for the question. I just had a couple here. First off, can you talk a little bit about the expectations for biosimilar product launches outside the US and how you see them evolving relative to Inflectra's launch, which seems to have been ahead of expectations?

The second question is relative to international Enbrel. Is Inflectra uptake and Remicade pricing a good comparison for Enbrel's performance as biosimilars hit the market in the next call it 8 to 12 months?

And then the last question is on Consumer. On the recent GlaxoSmithKline conference call when asked about interest in additional consumer assets and the possibility of interest in Pfizer's Consumer business, the current CEO suggested that they continue to evaluate all options and would welcome opportunities to participate in these larger assets.

I guess my question is how creative are you willing to get with the Consumer business in order -- and would a ViiV-like deal be ever a consideration for the Consumer business at Pfizer? Thanks

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Ian Read - *Pfizer Inc. - Chairman & CEO*

Thank you, Seamus. I will deal with the Consumer one first. The consumer asset in Pfizer's portfolio is a very valuable asset. It's growing well, we're continuing to add to that business, we have a great management team.

That being said, all of Pfizer is aware internally that we continually look at all of our different assets and we're always focused on creating shareholder value. To this date, to this moment I think the best way of creating shareholder value is the plan we had with Consumer growing inside Pfizer.

But as facts change we are always willing to look at those facts. If you could deal with the biosimilars, John, please.

John Young - *Pfizer Inc. - President of Established Pharma*

Thanks for the question, Seamus. Clearly biosimilars are a very important part of the GEP growth strategy. The portfolio consists of both Pfizer, legacy Pfizer, and legacy Hospira assets, as well as some assets from external partnerships.

We remain very bullish about the opportunity. There is something in the order of $100 billion of currently patented branded biologics expected to lose patent protection in the next 5 to 10 years, and the global market for biosimilars is expected to grow from around $1 billion annually in 2013 to somewhere in the order of $17 billion to $20 billion in 2020.

In regard to our plans for our portfolio, we have overall around nine distinct biosimilar molecules in different stages of development and approval. We are going to look to optimize the launch of that portfolio on a global basis over the coming years.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Albert, could you discuss the impact on Enbrel?

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

First of all on the pricing, let me say that I don't think we can draw conclusions from one biosimilar to the other. Every one has its own dynamic.

From the limited pricing for Enbrel biosimilar so far the discount levels are in line with our expectations, and we expect Enbrel's pricing to be competitive. In the general comment on the performance of biosimilars, so far Enbrel had a strong quarter of 8% up.

So basically knowing today from biosimilars, but of course it's very early. We do expect a modest uptake of biosimilars, but due to their limited long-term safety and efficacy data, at launch, we anticipate their use will be primarily in new patients.

Chuck Triano - *Pfizer Inc. - VP of IR*

Our next question, please.

Operator

Mark Schoenebaum, Evercore ISI.

Mark Schoenebaum - *Evercore ISI - Analyst*

Hi, thanks for taking the question. Ian, I appreciate your comments regarding you'll make a decision on a potential split up by the end of 2016. Can you confirm or not confirm that that decision would be a yes or no that you would split by the end of 2017, or should we be extending our timeline for the actual timing of a split?

And then number two, I know you've given this before, Frank, but can you comment roughly speaking on what you see the go forward growth rates for both the growth business and the Established products business being? I think you've given us a ballpark figure for that, I know there is no official guidance out there, but just a ballpark figure. It would be nice to get those ballparks refreshed.

And then finally you had made some commentary, Frank, around -- I think you'd made some commentary around the leverage ratio that the Allergan/Pfizer NewCo, you'd be willing to take the Allergan/Pfizer NewCo too. I was just wondering now that obviously Allergan isn't going to be part of the future, what leverage ratio you would go to maximum, and whether or not you would be willing to take out debt in order to do a large share repurchase? Thanks a lot.

Ian Read - *Pfizer Inc. - Chairman & CEO*

On the timing of the split, if we made a decision to split in the fourth quarter, we believe that the transaction could be completed by the end of 2017. Obviously those timelines are subject to change if we encounter things that we don't expect in the process, but right now the planning assumption would be with a fourth-quarter decision we would be able to complete the transaction by the end of 2017. Frank, do you want to handle the other questions?

Frank D'Amelio - *Pfizer Inc. - CFO*

Sure. On the going forward growth rates, I have not provided going forward growth rates other than our 2016 guidance for revenue, which we just increased by $2 billion, $1 billion of which was operational. On the leverage ratio, what I have said previously, Mark, on that is I would be willing to take it to 2.5 to 3 times.

We mentioned that as part of -- when we were going through some of the Allergan meetings. If I was willing to do it for that I'd be willing to do it for the right transaction on a going forward basis.

In terms of leveraging the balance sheet for buybacks, the way I think about this is if you go back to 2010 and if you include the $5 billion accelerated share repurchase that we added this past March, $50.7 billion of share buybacks. $50.7 billion, 1.9 billion shares excluding the 405 million shares as a result of the Zoetis exchange.

So we have done actually a massive buyback without having to borrow leveraged balance sheet which allows us to keep our powder dry if we wanted to do a different kind of a transaction. So hopefully that answers your question.

Chuck Triano - *Pfizer Inc. - VP of IR*

And we move on to the next question.

Operator

David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. With respect to considerations for Established products, could you comment on how you are considering potentially shifting Viagra and Lyrica from the Innovative segment to Established products? Second, could you discuss your plans to launch a biosimilar Remicade in the US this fall and your level of conviction there?

And then third, could you help us understand how we should think about Prevnar comps going into next winter? Obviously Prevnar has been extremely strong, but that may present tough comps a year from now. So any color on your thinking there would be helpful. Thank you.

Ian Read - *Pfizer Inc. - Chairman & CEO*

So we would expect that we would continue with our policy to move products like Viagra and Lyrica as they get close to be peri-LOEs from one business to the other. The exact timing we would decide, but in general you clearly want to have an Innovative company that is focused on growth and not focused on managing the end cycles of products like Lyrica and Viagra.

On the biosimilar Remicade, I really think John has made comments on that and we really can't add any more than that. I would say that we are preparing for a 2016 launch and it's dependent upon the factors that John has already mentioned. And with Albert on the Prevnar comps.

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

Let's start with the adult. In the US we have a fifth operational growth of 28%. So apparently we continue to do an excellent job with a catch up opportunity.

To put it into context, as of the end of the quarter from the 49 million adults eligible for vaccination we have already covered 37% of them. In fact the vast majority previously vaccinated with Pneumovax.

As we have said before, while many adults remain this cohort is much more difficult to capture, and going forward we expect the US adult revenues to decline compared to last year. This will be partially offset by Europe and the rest of the world, with 63% operational growth this quarter and will continue growing strongly.

And also as both Ian and Frank said in the beginning the pediatric will have a strong performance. So as a whole the Prevnar franchise will have very comparable revenues this year compared to last year.

Chuck Triano - *Pfizer Inc. - VP of IR*

Next question, please.

Operator

Vamil Divan, Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

Good morning. Thanks so much for taking my question. Two on the immuno-oncology side.

One on Avelumab, I believe merkel cell you mentioned is the lead registrational indication there. I'm wondering if you have that data in-house now, and are you still confident in getting -- being able to file that in an accelerated manner?

And if you could just clarify between yourselves and Merck KGaA how the registration process works? Who is in charge of that or is it done jointly?

And then second on the combination side, you mentioned 4-1BB and OX40 being two of the key agents as you think about combinations. Can you talk a little bit about how you prioritize those two, given it seems like several companies have OX40s in early development while 4-1BB it appears it's just you and maybe one or two other competitors?

I'm trying to get a sense of how important having something that is unique or differentiated to offer physicians and payers for combinations could be going forward when you think about how to prioritize resources behind the two different agents. Thank you.

Ian Read - *Pfizer Inc. - Chairman & CEO*

I will ask Albert to talk about the merkel cell and the registration, the split of responsibilities. And then Mikael can deal with the choices we make between our unique 4-1BB and our OX40.

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

With regards to merkel cell, first of all we're going to have some data presented at ASCO this year. It will be an oral presentation.

We have already received breakthrough designation, and we plan to file this year. With the work between us and Merck KGaA, we split in a very collaborative way.

They are doing parts of the work and we are doing other parts, and we have a very good collaboration. So we're very confident of executing on that.

Mikael Dolsten - *Pfizer Inc. - President of Worldwide R&D*

Both our 4-1BB and OX40 have unique design versus major competitors. As you know, our 4-1BB has performed very well when it comes to tolerability.

And we already reported at last ASCO of augmenting effect when combined with Rituximab. And we will start reporting early signs when combined with PD-1 and PD-L1 this year.

So we do think that 4-1BB will be a key molecule as performance we start to see. We are the only company that can put the 4-1BB, OX40, PR1 in place, and we're moving swiftly to have that as an option and expect late this year or early next year to have that triple combo.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thanks. And can we moved to the next question, please.

Operator

Colin Bristow, Bank of America.

Colin Bristow - *BofA Merrill Lynch - Analyst*

Good morning and thanks for taking the questions. On potential competition to Ibrance, there is increasing optimism on the Street around Lilly's CDK 46, and I guess we will see data on their 8-K. Could you discuss how you view Lilly and Novartis' CDK 46 in terms of their level of threat to Ibrance going forward?

Second, on the Xeljanz finding in the EU, what is your level of confidence that this will get through, and what do you feel you've satisfied in this submission that's previously been lacking? And then lastly in your earlier stage pipeline, any assets you would highlight that you're particularly excited about that we should be paying closer attention to?

Ian Read - *Pfizer Inc. - Chairman & CEO*

Okay why don't we ask Mikael to deal with the early assets that we're excited about, and perhaps also comment on the Xeljanz submission. And then Albert may want to add something. And then Albert will deal with the Ibrance competitor situation.

Mikael Dolsten - *Pfizer Inc. - President of Worldwide R&D*

Thank you. We have a very comprehensive pipeline, as you heard. Ian alluded to that in his prepared remarks.

We have 85 projects spread across Phase 1 to Phase 3 registration. And let me just mention a couple that we think will be really unique and differentiating.

We already touched base on 4-1BB and OX40 and the triple IO combo. Lorlatinib in the ALK and ROS space is generating very interesting data that we will start to share. We have a normal ADC called PTK7 that we also see some really interesting response rates.

In the immuno-inflammation field, in addition to Xeljanz we now have four different immunokines going to Phase 2 with several highly specific JAKs going to inflammatory bowel disease, dermatological inflammation, and lupus. So we will share more data around those, but I think that we really move the entire JAK field over time into new areas and with the new profiles.

Vaccines, it's our C. diff and staph aureus that we're really excited about. And Ian mentioned in his introduction that we have built some interesting assets in Parkinson with a completely novel dopamine modulator, and also have an interesting GDNF study together with MedGenesis.

And finally in rare disease I'll exemplify that we have a growing sickle-cell franchise with Rivipansel and a plan to start PD-9 as a way to prevent occurrence of difficult to treat rare disease episodes. So you can see our opportunities span multiple therapeutic areas.

Xeljanz in Europe I think is based on a very comprehensive find. We have six complete clinical trials with two open label extensions, and the ORAP program contains more than 19,000 patients here, more than 6,000 patients in long-term extension up to 8 years.

I want to remind everyone that Xeljanz has been used by more than 6,500 physicians and more than 50,000 patients in the US with a very favorable profile. And so you can see it's a completely different profile.

We have it now with the European regulatory agencies and we'll also have some specific sub-studies that they were interested on that we have executed on. So we view the dialogue with them as very constructive at this moment.

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

Nothing to add in Xeljanz, except maybe that it's already approved in more than 45 countries. And let me move to the Ibrance and competition.

I cannot speak much about competition, that includes Lilly and Novartis, because there is limited clinical data in the public domain on their efficacy and safety. What I can do is I can speak about our product, and I can tell you we have the most advanced and broad program in the industry.

First, we are the only company with a registered product in the US and eight other countries, and an accepted filing in Europe where we may obtain registration this year. In just over a year on the market Ibrance has been prescribed by almost 7,000 physicians reaching more than 28,000 patients.

This rapid uptake is a testament to its efficacy and outstanding safety profile, with a very low rate of global 3 and 4 GI effects such as fatigue and diarrhea. Ibrance has delivered positive results across three randomized pivotal trials.

It's being studied in additional five pivotal studies in early, advanced, and recurrent breast cancer as well as 62 ongoing investigator initiated research, 38 of which are in breast cancer and 28 are in non-breast cancer. So this is what I call a clear lead.

Operator

Andrew Baum, Citi.

Andrew Baum - *Citigroup - Analyst*

Three questions, please. First, Ian, you touched upon triple combinations, or it may have been Mikael. There's obviously a significant cost burden attached with that.

Could you talk to the idea of where you feel specialist care pricing is going in the US and how quickly it has passed similar cost effectiveness arguments in the gridlocked House sufficient to maintain status quo? Or how do anticipate and how quickly do you anticipate change?

Second, on PBMs, again to Ian, some of your peers have identified PBMs as bad actors in the whole health care value chain given their disproportionate rebate capture. Do you believe that PBMs or other pricing transparency is a good or bad thing from an industry perspective?

And then finally for Mikael, I saw some data recently on Selzentry, your CCR5 antagonist in an immuno-oncology setting. Do you have any plans to develop that drug within that setting, or is the IP an issue?

Ian Read - *Pfizer Inc. - Chairman & CEO*

So on the pricing oncology assets, clearly products are sold on their value and their value to patients, their value to society. There is also an element of total affordability.

So I think the ability of companies to have the complete regime, like in Pfizer's case the PDL-1, the OX40, the 4-1BB or a small molecule, will enable offerings to payers that I think society will find acceptable from a cost/benefit return, as distinct from looking at the complications of acquiring all of those elements separately in the marketplace. On pricing itself, I agree with you, there is a large amount of rhetoric given the election year, and there is concerns from individuals about accessing pharmaceuticals.

This is extremely complex. It is in great part due to the pressure on plans that have been transformed away from having the ability to really be an insurance company and become somewhat more of benefit administrators than insurers.

It has to do with the quality of insurance and also to do with the value of these specialty products. So I expect a robust discussion, but I expect that in the end the United States will continue to support innovation and find ways to make sure the innovation is supported and products get to patients.

And that will obviously be a robust policy discussion, but I do think in the end that is where the United States will end up in that discussion. On PBMs, in a market-based system PBMs provide value by aggregating volumes and negotiating discounts.

To the extent those discounts are passed on to the end user or the end payer, or an appropriate amount is passed on, then they're serving a valid market function. As the market changes they may have a larger or smaller role, but I think what I would emphasize is I like to see the marketplace work.

I like to see incentives in the marketplace, make sure it works, and I like to see the appropriate amount of transparency. So that's really all I can comment on that. Thank you.

Chuck Triano - *Pfizer Inc. - VP of IR*

Mikael. Mikael's question.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Mikael, yes.

Mikael Dolsten - *Pfizer Inc. - President of Worldwide R&D*

I think you were likely referring to our CCR2 small molecule antagonist. And we have together with the academic collaborator really observed some interesting effects on suppressive immune cells in pancreatic cancer and some early encouraging clinical signals. So we do continue with a second study in pancreatic cancer with a CCR2. And in total we currently have eight different new medical entities in the immuno-oncology field in the clinic and expect by the end of this year to have 10 different immuno-oncology compounds in the clinic.

Chuck Triano - *Pfizer Inc. - VP of IR*

Next question, please.

Operator

Geoff Meacham, Barclays.

Geoff Meacham - *Barclays Capital - Analyst*

Good morning, thanks for taking the question. Just a couple, Ian, just to continue the strategy discussion, I want to get a sense as to what at this point you characterize as the top one or two priorities post Allergan when you look at things like tax rate, cash flow, expected multiple growth rates.

And then just on the pipeline front, a few for Ibrance. The adjuvant trials really aren't until much later, say 2020, but how do you see the role of CDK46 in this?

And does your long-term thinking assume success here? And then for Boco and PCSK9, clearly outcomes data are going to dictate the share, but how much of a role do you think that imaging plays throughout this and product differentiation? Thanks.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Thank you. The priorities post Allergan continue to be our four strategies, which is to continue to show excellence in our innovative core and bring forward innovative products. I think you've seen us do that.

Continue to drive the growth rates of our inline and newly launched products, which you can see are happening. Eliquis is performing extremely well with an LOE in the United States out I think in 2019. Sorry, Lyrica that is. Sorry, Lyrica.

Eliquis doing very well, Xeljanz is doing well. So I think the priorities are continue to ensure that our science comes to market; grow our inline products, which I think we're doing well; execute on capital discipline, which we continue to do; and in our Established products business it's to roll out successfully the biosimilar strategy to continue to utilize and maximize the value of our sterile injectables around the world.

So frankly, I think there's lots to do in that area. We'll continue to look at our tax situation. We have a very good tax group, Frank and his team are very good at looking at how to improve that.

It continues to be an area of focus. Vis a vis Ibrance, I agree with you that the trials are on the timeline you talk about, but that's the nature of the trials in oncology.

And the reality is we have already started those trials and are well ahead of any of our competition. So it's a matter of a lead established in the marketplace. So I'm very optimistic about the long-term growth rates of Ibrance, both in the indications it has now and the indications to come as we go earlier in the advance -- the breast cancer.

And also outside of breast cancer I think we have a lot of work going on. And then you asked -- the last question was?

Chuck Triano - *Pfizer Inc. - VP of IR*

Boco. PCSK9 and Boco.

Ian Read - *Pfizer Inc. - Chairman & CEO*

I have always thought, and we discussed this, that Boco should -- these products should only have been launched when you have outcomes data. I've always felt, and I think if you go back in our transcripts we've always said that on LDL alone it will be difficult to convince society to pay what's necessary, and you really need to include along with LDL the outcome.

Clearly outcomes is important. Imaging has been used previously with lipid agents, it doesn't really move the needle. What moves the needle is the large prospective trials which show that outcomes are changed.

And an image just doesn't do the same as that data. So I look forward to that class expanding when we have the outcomes data and we have the right value equation for society.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thank you, Ian. Next question, please.

Operator

Manoj Garg, Healthco.

Manoj Garg - *ABR-Healthco - Analyst*

Thanks for taking the questions. One for Albert on Ibrance and then one for Frank on financials. When would you expect submitting the PALOMA-2 data to FDA?

And then maybe you can talk about what that would do to the intent to treat population? And then just a follow up there.

What is the general timing in Europe on approval? And then for Frank, on the $500 million in increase in SI&A, was that driven largely by FX, or is there some additional investment there?

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

Thank you. As you know we announced positive top line results from PALOMA-2. We will present details at ASCO with an oral presentation. It will be a late breaker.

Now this trial provides additional confirmatory evidence on the benefits of Ibrance for breast cancer patients. These will add to the momentum of this. Also it will be used for regulatory filings.

It is a requirement from FDA so that we can convert the accelerated approval to a permanent approval, and we plan to file -- we are in discussions now with the FDA. In EU we have already filed, and have an accepted filing based on PALOMA-1 and 3.

But also we have submitted already PALOMA-2 over there as additional supporting data. And as we said before, we expect to receive Ibrance approval in the US as early as this year if eventually -- excuse me, in Europe as early as this year if we have a positive opinion from European authorities.

Frank D'Amelio - *Pfizer Inc. - CFO*

And on the SI&A and the impact of FX, so we took it up $500 million. Midpoint went up $500 million. Approximately half of that is due to foreign exchange, approximately half of it is due to operations including increased investment in new and certain inline products.

Chuck Triano - *Pfizer Inc. - VP of IR*

Next question, please.

Operator

Richard Purkiss, Piper Jaffray.

Richard Purkiss - *Piper Jaffray & Co. - Analyst*

Thanks, I've got three questions. Firstly for Albert, can you update us with your thoughts on how Prevnar penetration into the adult indication is like to play out over the next 12 months in Europe?

Secondly also for Albert, can you give us an update on how well the adjuvant breast cancer studies are enrolling? And then thirdly perhaps for Mikael, also on Ibrance, whether you see it largely restricted to the ER post inverted negative breast cancer setting, or whether its mechanism ultimately gets used for other metastatic tumors too? Thanks.

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

Let me start with Europe. As I said, in Europe we have 63% operational growth. And this will continue. We will have strong growing in Europe.

The demographics are very favorable there. We have a larger eligible population. The price per dose is less than in the US, and that's another factor.

We need to obtain a recommendation, and this is a process that in Europe can take -- not recommendation I mean reimbursement, can be faced over two years because it's happening country by country. In some cases within the same country it's happening district by district.

So we are working very intensively on that because we see the opportunity as a major one. Moving to how we're doing with our expansion into other breast cancer segments, and particularly into the adjuvant setting, actually we have two studies in the adjuvant setting.

That's PENELOPE B; this is for high risk early breast cancer, and we have PALLAS for intermediate risk early breast cancer. And they are recruiting very nicely right now. I need to also emphasize that we have another one which in -- PALLET is a collaborative study, but it is in the neo-adjuvant setting in cooperation with Washington University.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Mikael.

Mikael Dolsten - *Pfizer Inc. - President of Worldwide R&D*

We are increasingly excited as we have learned more about Ibrance, how significant we can see opportunity to expand utility or potential of that drawing. So we have studies ongoing, and we will likely see some data this year or next year in head and neck cancer in combination with Erbitux,

Pfizer sponsored, and collaborative studies, in mantle cell lymphoma with Ibrutinib, and in pancreatic cancer in combination with Abraxane in 2017.

And more recently we are also studying uniform mutant lung cancer combining Ibrance with our own 7775 ED4 inhibitor. Also within breast cancer we see opportunities and have initiated triple therapy based on Ibrance, as well as we are looking at the novel segment of breast cancer that may go from ER into double positive segments. So substantial opportunities, and of course our enthusiasm growing as we see how well Ibrance is performing, the patient experience is so good, and our studies -- confirmatory studies deliver real encouraging data.

Chuck Triano - *Pfizer Inc. - VP of IR*

Next question please.

Operator

Alex Arfaei, BMO Capital Markets.

Alex Arfaei - *BMO Capital Markets - Analyst*

Good morning, folks, thanks for taking the questions and congratulations on the quarter. Three questions if I may. Ian, on business development all things being equal, would you prefer ex-US assets so that you can deploy your capital more efficiently?

Second, apologies if I missed this, but can you tell us what Prevnar adult sales were in the quarter ex-US if possible? And then finally on the Hospira business, it was a little bit lower than we expected despite the higher selling days.

Could you comment on that? And is it because your own sterile injectable business is doing better? Thank you.

Ian Read - *Pfizer Inc. - Chairman & CEO*

On the question of US or non-US, as I say, we are value investors. So it comes down to what is the return on assets and what is the MPV?

And of course in that would be included the different costs of doing our onshore or offshore deal. So we'd make that decision based on that. Next I think it's Mikael, sorry, Albert.

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

The Prevnar adult. The global sales were $439 million, so that was 31% up. But most of that was in US. $390 million in the US and $47 million were internationally. International, as I said, grew 63%.

Ian Read - *Pfizer Inc. - Chairman & CEO*

And the last question?

John Young - *Pfizer Inc. - President of Established Pharma*

Overall we were very positive about the performance of the Hospira business. We saw positive performance across all of our segments this quarter, both sterile injectables, biosimilars, and the infusion systems business continues to return to growth. So overall in addition with the ongoing efforts

to integrate the two companies that are ongoing but proceeding very well and in line with our plans, we remain very positive about the performance that we're seeing from the legacy Hospira business.

Frank D'Amelio - *Pfizer Inc. - CFO*

And we increased our synergy target from $800 million to $1 billion.

Chuck Triano - *Pfizer Inc. - VP of IR*

Operator, can we take our last question, please?

Operator

Your final question comes from Jeff Holford from Jefferies.

Jeff Holford - *Jefferies LLC - Analyst*

Can you help us think about the potential investor positioning for GEP to help us think about valuations? You say there aren't good comps out there, but I would tend to think of this as perhaps a slower-growing part of business, but perhaps one that could sustain a greater dividend than the rest of the business over time.

So just help us think is that the investor positioning of that business? Secondly on Ibrance, I wonder if you could update us for the US?

What is the duration of therapy that you are seeing, and what is the market share in your label population? And then last question, have you prioritized any specific tumor types or indications yet for either 4-1BB or OX40 in terms of pivotal planning? Thank you.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Okay. On GEP, I have always used the analogy although it's a pharmaceutical business that really given it's in sterile injectables which we sell on quality and barriers to entry, and given it's biosimilars which also will be eventually sold on the quality of the manufacturer and the data we have, and then the emerging markets which is sold on brands and quality, that it sort of looks like a consumer business with just a touch more risk than a normal consumer business.

So perhaps some nice comparables for PEs really ought to be the consumer-like business. Now you may or may not agree with that, but it is slower growing, growing with GDP just like consumer businesses do, being sold on brands, and then a little more affected because it does have pricing risks and some development risks. That's how I would look at it.

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

The first line market share is now 38%. That's number one. We have achieved leadership and to have surpassed AI monotherapy.

The second and third line market share are 26% and 14% respectively. When it comes to duration of treatment, it's too early to assess because as you know the product has been launched a year approximately ago, and PFS duration from the data is around 20 months since PALOMA-2. So we need some time to assess what will be the actual duration period.

Ian Read - *Pfizer Inc. - Chairman & CEO*

Thank you.

Mikael Dolsten - *Pfizer Inc. - President of Worldwide R&D*

On one hand with 4-1BB, we presented last year at ASCO, and we will provide update during this year. 4-1BB with Rituximab and lymphoma, that had very promising response rate in refectory -- Rituximab patients, about 35%. We have expanded that study, it looks certainly very promising so that could be one opportunity for moving 4-1BB fast forward. 4-1BB and OX40 are expressed in many tumors in the immune infiltrating cells. So we will have a broad ambitious program where we see opportunity for these across many different solid tumors and some blood related cancers.

Albert Bourla - *Pfizer Inc. - President of Pfizer Innovative Pharma*

Let me make a correction. I think I said 20 months in PALOMA-2. It is 20 months in PALOMA-1. We haven't disclosed the duration treatment of PALOMA-2. We'll do that at ASCO.

Chuck Triano - *Pfizer Inc. - VP of IR*

Thank you everybody for your attention today.

Frank D'Amelio - *Pfizer Inc. - CFO*

So long everybody.

Operator

Ladies and gentlemen, this does conclude Pfizer's first-quarter 2016 earnings conference call. Thank you for participating. You may now disconnect.
