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EDITED TRANSCRIPT

PFE - Q3 2015 Pfizer Inc Earnings Call

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OVERVIEW:

PFE reported 3Q15 reported revenues of approx. $12.1b and reported diluted EPS of $0.34. Expects FY15 reported revenues to be $47.5-48.5b and reported diluted EPS to be $1.37-1.43.

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PRESENTATION

Operator

Good day everyone, and welcome to Pfizer's Third-Quarter 2015 earnings conference call. Today's call is being recorded. At this time I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

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

Thank you, operator. Good morning, and thank you for joining us today to review Pfizer's Third-Quarter 2015 performance. I'm joined today as usual by our Chairman and CEO, Ian Read; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Albert Bourla, President of Vaccines, Oncology and Consumer; Geno Germano, President of Global 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 home page, Pfizer.com, by clicking on the link for Pfizer Quarterly Corporate Performance Third Quarter 2015, which is located the Investor Presentation section in the lower right-hand corner of this page.

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Before we start I'd like to remind you that our discussion during this conference call will include forward-looking statements and that actual results could differ materially from those projected. The factors that could cause actual results to differ are discussed in Pfizer's 2014 annual report, as well as on Forms 10-K and in our reports on Forms 10-Q and 8-K.

Discussions during the call will also include certain financial measures that were not prepared in accordance with Generally Accepted Accounting Principles. Reconciliation of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in our current report on Form 8-K dated today, October 27, 2015.

We'll now make prepared remarks and then we will move to a question-and-answer session. With that, I'll turn the call over to Ian Read. Ian.

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

Thank you, Chuck. Thank you for joining our call this morning. During my remarks I will briefly recap highlights from the quarter, provide a brief update on the pipeline, and close with a few thoughts on the issue of drug pricing.

To begin, I would note that we've had another quarter of strong operational performance, and we have grown revenues operationally every quarter this year. This top-line growth resulted from several factors including the strong performance of inline brands such as Lyrica in the US, Enbrel and Chantix, the uptake from our new products that are early in their life cycle, including Prevnar 13 Adult, Ibrance and Eliquis, and growth in the emerging markets. We remain focused on continuing to generate this type of performance where a greater proportion of our EPS growth is generated from top-line revenue growth.

Just a brief word regarding Prevnar 13. We continue to see a very attractive worldwide opportunity for the adult indication. In the US we have done an excellent job finding and protecting 25% to 30% of the eligible population older than 65, and we did this more quickly than anticipated. As a reminder, on the last quarter's earnings call we said we expect to continue to focus on the remaining population over 65 in the US, although this will require sustained effort as this group is more difficult to reach. Also of note, during the quarter we closed the Hospira acquisition. And I'm pleased to report that the integration is progressing smoothly and we're beginning to see the expected value contribution to our GEP business.

In terms of revenue, we are now the leading global player in the fast-growing sterile injectable business. And we're the number two biosimilars company in the world. Through the acquisition we now have three marketed products and more than seven years of in-market experience with one of these products. Our biosimilars pipeline is now one of the largest pipelines globally, with seven additional molecules in our portfolio under development.

We recently received a complete response letter from the FDA for Retacrit, a biosimiliar epoetin. We are working closely with the FDA to address the concerns of the letter, and at this time we do not believe any further clinical trials are needed. We are confident that the additional evidence we provide will support approval, and remain committed to bringing this important medicine to patients in the US as quickly as possible.

Few comments about the pipeline. I see our pipeline momentum continuing to build, and remain particularly encouraged by our growing strength and presence in immuno-oncology. Regarding the anti-PD-L1 avelumab partnered with Merck KGaA, the FDA recently granted Orphan Drug and Fast Track Designation for the treatment of metastatic Merkel cell carcinoma, a rare and aggressive type of skin cancer. If successful, the first potential commercial launch of avelumab is anticipated in 2017. And our goal is to have at least one or more additional launches each year through 2022.

Beyond avelumab, we have a broad immuno-oncology portfolio across numerous mechanisms including 4-1BB, OX40, a vaccine-based immuno-oncology regimen, and CCR2. Four of these assets are already in the clinic, 4-1BB, OX40, CCR2 and avelumab. And we expect to have up to 10 different I-O drugs in the clinic by 2016.

We continue to see combination therapy as having the greatest potential within immuno-oncology, and our broad portfolio of I-O, small molecule and ADC oncology assets will afford us the opportunity to test a wide range of combination regimens on our own and with our partner, Merck KGaA. We continue to grow our footprint in I-O through other collaborations, such a CAR-T with Cellectis, and in IDO1 with iTEOS. And we entered

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into a collaboration with Kyowa Hakko Kirin to combine our 4-1BB with their anti-CCR4 antibody, and started a Phase 1 study in May. We believe this portfolio, along with our skilled scientists, should enable Pfizer to be a formidable player in this high opportunity area.

Turning to vaccines. In early July we announced the first patient was enrolled in a Phase 2 clinical trial of our investigational Staphylococcus aureus vaccine. We anticipate this study will complete in late 2017, with an interim analysis planned for late in 2016. Also in agreement with FDA we restarted the Phase 2 trial for our Clostridium difficile vaccine, which has previously received Fast Track Designation in August 2014. Enrollment in this program is now complete, and we expect to review data from it by end of the year.

In chronic pain there remains a significant unmet need, with nearly one in five adults affected. To address that opportunity, Pfizer and Lilly have resumed the Phase 3 chronic pain program for tanezumab. This program consists of six studies in approximately 7,000 patients across osteoarthritis, chronic low back pain and cancer pain. The study results are projected to begin reporting out in 2017 and 2018. Of note, in the prior clinical studies of more than 11,000 patients, tanezumab demonstrated clinically meaningful efficacy versus placebo and other commonly used pain medicines.

In inflammation and immunology, we are focusing our future investment and development programs on indications for Xeljanz in rheumatoid arthritis, psoriatic arthritis and ulcerative colitis while deprioritizing further development in Crohn's disease and ankylosing spondylitis.

Additionally, we received a complete response letter from the FDA on psoriasis. While we have yet to meet with the Agency to discuss their concerns, we recognize overcoming the issues raised may be difficult, especially in light of the evolving marketplace. We will reconsider our investment in the psoriasis indication for Xeljanz following this discussion with the FDA.

I would note that a new generation of potential therapies including oral-selected JAK inhibitors and IRAK4 are planned to enter Phase 2 studies in 2016 for inflammatory bowel disease, atopic dermatitis and rheumatic diseases. We have a once-daily filing for Xeljanz under review at the FDA. We have a PDUFA date in February for the treatment of moderate to severe RA in patients who have had inadequate response or intolerance to methotrexate. If approved, we believe once daily dosing will add to its competitive profile. In addition, we intend to resubmit a Marketing Authorization Application to the European Medicines Agency by the first quarter of 2016 for the treatment of moderate to severe RA.

In assessing the current profile of our pipeline, I believe we have a competitive mix of compounds and modalities across the therapeutic areas I just spoke about, in addition to cardiovascular diseases, rare diseases and neuroscience where our expertise matches the potential we see. I am pleased with our rate of progress.

Before turning to the call over the Frank, I'd like to offer a few thoughts regarding drug pricing. There's been a lot of attention on the issue of drug pricing, and given the upcoming US elections it will continue to be discussed and debated. Ultimately, I believe good public policy will prevail, ensuring the best outcome for patients while preserving a market-based system that enables the industry to continue developing new treatments and cures. However, that policy discussion must take into account the role of medicines and the value they deliver to the overall healthcare system.

Medicines are among the most effective and efficient use of private and public healthcare dollars. They represent around 10% of total healthcare costs, and are expected to remain the same percentage over the next several years. This is because the price of medicines drops significantly once the patent expires.

Today, about 9 out of 10 prescriptions in the US are for generic drugs, which leads to significantly reduced costs in the healthcare system. For example, 12 million people take atorvastatin, and the cost has declined around 90% since 2005. Given the high use of generics, many patients have access to medicines with low copays.

What's difficult is when individuals cannot afford the increases in their copays when their treatment is on a specialty tier. No individual should have to bear the full cost of their treatment when they become sick. The increase in copays stems from healthcare policies that have a short-term focus with limited incentives to pay for treatments or cures.

Having an efficient and affordable healthcare system requires incentives where insurance plans can be successful when they invest in long-term outcomes, and providers are successful by ensuring wellness and prevention rather than treating sickness. And to sustain the most vibrant, innovative

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biopharmaceutical industry in the world, we must preserve the market-based system in the US that enables us to continue to develop breakthrough treatments and cures for the benefit of patients.

In summary, we had another quarter of solid execution on all fronts. Product launches, cost and expense management, and the continued successful integration of Hospira into our business. We are on track to have a solid finish to the year. We remain focused on creating value for our shareholders, and continue to research and develop new treatments that help patients live longer, healthier lives. Now I will turn it over to Frank who will take you through you the numbers for the quarter.

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

Thanks, Ian. Good day, everyone. As always, the charts I'm reviewing today are included in our webcast. As you know, on September 3, 2015 we completed the acquisition of Hospira. Consequently and in accordance with our US and international reporting periods, our results for Third-Quarter 2015 and nine months ended September 27, 2015 include approximately one month of legacy Hospira US operations, but do not include any financial results from legacy Hospira international operations.

Third-Quarter 2015 reported revenues were approximately $12.1 billion and reflect year-over-year operational growth of $795 million, or 6%, mainly driven by the strong performance in developed markets of Prevnar 13 Adult, Ibrance and Eliquis, all of which are early in their lifecycles; Lyrica, primarily in the US; one month of legacy Hospira operations in the US; and 5% operational growth in emerging markets, mainly from innovative products. Reported revenues continued to be unfavorably impacted by foreign exchange of $1.1 billion, or 9%, and the loss of exclusivity of Celebrex and Zyvox in the US and Lyrica in certain developed European markets.

Adjusted diluted EPS was $0.60 versus $0.57 in the year-ago quarter. The increase was primarily due to revenue growth of certain new inline and acquired products, a lower effective tax rate and fewer diluted weighted average shares outstanding, which declined by 160 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 of 2015 and completed in July.

Adjusted diluted EPS was unfavorably impacted by $0.06 due to foreign exchange and the continued product losses of exclusivity in certain geographies. Reported diluted EPS was $0.34 compared with $0.42 in the year-ago quarter due to the previously mentioned factors and the non-recurrence of a one-time charge associated with the healthcare reform fee versus the year-ago quarter, as well as the unfavorable impact of increased purchase accounting adjustments, restructuring charges, and acquisition-related costs associated with the acquisition of Hospira and higher asset impairment charges.

Foreign exchange negatively impacted Third-Quarter reported revenues by approximately $1.1 billion, or 9% and positively impacted adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses in the aggregate by $601 million, or 8%. As a result, foreign exchange negatively impacted third-quarter adjusted diluted EPS by approximately $0.06 compared with the year-ago quarter.

Now moving onto the financial highlights of our business segments. In the third quarter Global Innovative Pharmaceutical revenues increased 10% operationally year over year due to the strong performance of recently launched products including Eliquis globally and Xeljanz in the US, and the strong performance of Viagra and Lyrica in the US and Enbrel in most international markets, which were partially offset by continued generic competition for Rapamune in the US.

Income before taxes increased 14% operationally due to the operational increase in revenues and the 7% operational decrease in cost of sales, partially offset by a 6% operational increase in SI&A expenses primarily due to additional investment and recently launched products and certain inline products, and the 7% operational increase in R&D reflecting increased investments in our late-stage pipeline primarily for bococizumab, tanezumab partially offset by lower post-marketing trial expenses.

Third-Quarter VOC revenues increased 37% operationally due to the 50% operational revenue growth from our Global Vaccines business as a result of Prevnar 13, which grew 77% in the US and 10% internationally; a 54% operational increase in Oncology revenues driven by Ibrance in the US

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and to a lesser extent by Sutent, Xalkori, and Inlyta in most markets; and the 7% operational increases in Consumer Healthcare revenues due to Nexium 24 Hour in the US.

Income before taxes increased 52% operationally mainly due to increased revenues with an associated improvement in gross margin, which were partially offset by a 26% operational increase in SI&A expenses due to higher promotional expenses for Prevnar 13 Adult and Ibrance, and an 18% operational increase in R&D expenses due to increased costs associated with our Oncology programs, primarily our alliance with Merck KGaA, partially offset by lower clinical trial expenses for certain vaccine programs.

In the Third Quarter Global Established Pharmaceutical revenues decreased 8% operationally mainly due to the loss of exclusivity and immediate multi-sourced generic competition for Celebrex in the US in December of 2014 and generic competition for Zyvox in the US beginning in the first half of 2015 and Lyrica in certain developed markets in Europe beginning in the first quarter 2015, which were partially offset by the $330 million contribution from one month of legacy Hospira operations in the US and 1% operational growth in emerging markets.

Income before taxes declined 11% operationally due to the decrease in revenues and a 3.2 percentage point operational increase in cost of sales as a percentage of revenues due to unfavorable change in product mix, an 8% operational increase in R&D expenses reflecting increased spending in biosimilars and legacy Hospira development programs largely offset by lower post-marketing clinical trial expenses, all of which were partially offset by an 11% operational decrease in SI&A expenses driven by lower expenses for products that have recently lost exclusivity and cost reduction productivity initiatives.

I want to remind everyone that on September 30 we updated our 2015 financial guidance ranges for reported revenues and reported and adjusted diluted EPS, solely to reflect the anticipated impact of legacy Hospira operations on Pfizer's financial results from September 3, 2015 through fiscal year end FY15. Today we are updating the ranges for certain components of our 2015 financial guidance to reflect the following factors: standalone Pfizer's strong performance to date coupled with an improved operational business outlook for the remainder of the year; the anticipated impact of legacy Hospira operations from September 3, 2015 through fiscal year end FY15 on components other than reported revenues and adjusted diluted EPS; and the minimal favorable impact from foreign exchange rates since mid-July.

Consequently, we now expect reported revenues to be in the range of $47.5 billion to $48.5 billion, mainly driven by the performance of Prevnar 13 Adult and Ibrance in the US, as well as Eliquis globally. I want to point out that this range continues to absorb an anticipated $3.3 billion negative impact from product losses of exclusivity and losses of alliance revenue this year and a $3.1 billion negative impact from foreign exchange versus 2014.

We also anticipate adjusted cost of sales as a percentage of revenue to be in the range of 18.7% to 19.2%, adjusted SI&A to be in the range of $13.6 billion to $14.1 billion, and adjusted R&D expenses to be in the range of $7.5 billion to $7.8 billion. Finally, we expect reported diluted EPS to be in the range of $1.37 to $1.43 and adjusted diluted EPS to be in the range of $2.16 to $2.20.

Now I'd like to walk you through the 2015 guidance ranges for reported revenues, reported diluted EPS and adjusted diluted EPS. Specifically what I'm pointing out on this chart is the impact of standalone Pfizer's operations on these three guidance ranges. With respect to reported revenues, we're raising the midpoint of the previous guidance range provided on September 30 by $1 billion and we're increasing the midpoint of our adjusted diluted EPS guidance range by $0.11. With respect to reported diluted EPS, as a result of Pfizer's standalone operations we've increased the midpoint of the range by $0.09. This increase includes a $0.02 negative impact from restructuring charges associated with the Hospira acquisition that are incremental to our previous guidance provided on September 30.

Moving onto key takeaways. We achieved another quarter of strong financial performance, despite product LOEs. I want to point out this is the fourth consecutive quarter that standalone Pfizer achieved operational revenue growth which was driven by products that are early in their lifecycles, including Prevnar 13 Adult, Ibrance and Eliquis. We raised the midpoints of our 2015 reported revenue and adjusted diluted EPS guidance ranges by $1 billion and $0.11 respectively to reflect both our year-to-date strong operational performance, as well as our improved operational outlook for the remainder of the year.

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We closed the Hospira acquisition on September 3, which was immediately accretive to adjusted diluted EPS upon closing and expect it to be accretive by $0.10 to $0.12 in first full year after the close with additional accretion anticipated thereafter. And we continue to expect the transaction to deliver $800 million in cost savings by 2018.

We continue to create shareholder value through prudent capital allocation. To date in 2015 we've returned $11.4 billion to shareholders through dividends and share repurchases, and we continue to expect to return approximately $13 billion to shareholders in 2015 through a combination of dividends and share repurchases. Finally, we remain committed to delivering attractive shareholder returns in 2015 and beyond. Now I'll turn it back to Chuck.

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

Thank you, Frank and Ian, for the commentary. Operator, can we please poll for questions?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Your first question comes from David Risinger of Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

I have two questions. The first is on Ibrance. Ian, could you just talk about the first-mover advantage for Ibrance and how you see that playing out in the marketplace? And also if you could comment on expectations for breast cancer survival data, and then any comments on the timing of readouts in other cancers?

And then separately, with respect to your pursuit of M&A in Innovative Pharma, maybe both you, Ian and Frank, can comment on your current focus and how you want to set expectations for investors. And also, Frank, if you could just talk through the difference between the benefits of a 60/40 inversion versus an 80/20 inversion, and just characterize how the economics would differ in those two different scenarios? Thank you very much.

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

Thank you. Albert, could you answer the Ibrance questions, please?

Albert Bourla - *Pfizer Inc. - President Vaccines, Oncology and Consumer*

Yes, certainly. Let me start with the competitive environment and the first-mover advantage. I believe that speaking about our program, we have the most advanced and much broader program than any other competitor so far. And I say the most advanced because we are the first one, and the only one that we have registration right now in US, a product has been prescribed with over 4,000 physicians, and has been received by more than 15,000 patients so far. And we have also filed in Europe, and our file has been validated by the European authorities.

Also I say that we have a much broader program, because we do have right now already two studies in first line. We have two studies in recurrent metastatic breast cancer. And we have three studies clinical running in earlier phases of breast cancer. In addition beyond breast cancer, we have

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already 30 studies that are -- excuse me, 22 studies are running in other indications of solid tumors. So we have a clear, not only first-mover advantage, but we have a much broad program, as we see palbociclib as a major franchise going forward.

In terms of timing on readouts, and that depends on the studies. The two studies we have already read out, the PALOMA 2 study which is the confirmatory study, will read out next year. We have the early breast cancer studies, the pilot will read around 2017, or will come in completion in 2017. And the other two, PENELOPE B and PALLAS will come around 2020.

And as regards survival data, we don't have any news on survival data, which is expected, because the median survival in this type of population is approximately four years. So it will take some time until all these events will be accumulated.

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

Thank you, Albert. On Innovative Pharma and BD, I think I'll sort of limit my comments to something similar to the previous quarter where we look as BD as a way of accelerating value to shareholders. We feel that if all things are equal on returns, strengthening the Innovative part of the Company will give a more balanced business between both Established and Innovative, especially in a potential split scenario, if we were to split the Company. And we continue to be actively looking at BD and looking at sources of value which are both pipeline, which are operational synergies and potential financial synergies. And certainly all our strength to expand upon and talk about the 60/40 or 80/20 space, and about how potentially wide the targets are for this type of innovation.

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

So Dave, the way to think about this is less than 60% full inversion, less than 80% but call it greater than 60%, kind of an in between, a tweener inversion. The way we think about this is, there's four buckets of cash in a hypothetical transaction like this. There's our existing overseas cash, and then there's our going-forward operating cash flow. And then there's the target's existing overseas cash, and then their going-forward operating cash flow. The target's existing overseas cash and going-forward operating cash flow would be unencumbered. Our existing overseas cash and going-forward operating cash flow would be encumbered.

And then the question becomes in a tweener situation, how much of our encumbered existing overseas cash and how much of our encumbered going-forward operating cash can become unencumbered? That's based on tax planning and those kinds of actions. And that is really, I'll call it on a case-by-case, situation-by-situation, company-by-company basis. But we think of it in those four buckets.

David Risinger - *Morgan Stanley - Analyst*

Thank you, Frank. So when you look at doing BD, you have to trade off what's the price, what's the value, what's the pipeline, and what's the risks you see in a case-by-case basis of sitting in the 80/20 space and 60/40 space. So thank you.

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

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

Operator

Your next question is from Jami Rubin of Goldman Sachs.

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Jami Rubin - *Goldman Sachs - Analyst*

Can you hear me all right?

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

Yes, loud and clear, Jami.

Jami Rubin - *Goldman Sachs - Analyst*

Okay. All right, great. Ian, just a follow-up on that question on M&A. The last time we met, you had highlighted the attractiveness of a tax inversion deal. In fact, you sort of signaled a preference for a tax inversion deal over an outright, say, US-based acquisition. And now with Congress looking less and less likely to act on tax reform and your stock holding up exceedingly well in this volatile healthcare space, particularly given how much specialty pharma has pulled back, where are you in your quest to deploy capital? Can you give us a sense of time lines? It just seems to me like a phenomenal time to use your stock. Thanks.

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

Thank you, Jami. I'd have to check the transcripts. I'm not quite sure that I expressed a preference either way. I think I expressed a preference for an Innovative deal. And I think I expressed a preference for any deal that creates the greatest shareholder value, which would have to be a combination of, as I said, pipeline, operational synergies, and financial synergies. I do think there has been an adjustment in the price of some of the specialty companies.

There's been adjustment in their price. I'm not so sure there's been an adjustment in their expectations of what they want to sell the company. But I do agree with you that BD is -- we do have the ability to do BD. It can be an important way of adding value. This management team is not afraid of taking bold steps. And we're looking at opportunities and when we make our decision as to what is the best way of enhancing value, we will move.

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

Thanks, Ian. Can we move onto the next question, please, operator?

Operator

Your next question is from Gregg Gilbert of Deutsche Bank.

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

Good morning, Gregg.

Gregg Gilbert - *Deutsche Bank - Analyst*

Good morning. I've heard the two CEOs use the word bold in the last couple months. So we'll see how telling that is. Quick three-parter. First, is the Prevnar franchise, how big could that become and how durable do you think that could be? Secondly, Merck seems pretty excited about the SGLT2 program they licensed from you, especially in light of Lilly's outcomes benefit. So can you remind us what the economics are there, and anything you've said about the profile of that product? And lastly, on Retacrit, on that CRL, Ian, are there any signs that the FDA's grappling with policy or legal or precedent issues there, or is it simply just about the application and some data they want, nonclinical data? Thanks.

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

I'd ask Albert to talk about Prevnar. And then Frank will give you an idea of the contractual relationship on SGLT2, which I think is an under-appreciated asset and a huge opportunity for us and Merck in that marketplace. And then perhaps John could talk about what we're experiencing with the FDA on the biosimilars approval.

Albert Bourla - *Pfizer Inc. - President Vaccines, Oncology and Consumer*

Thank you, Ian. Gregg, thanks for the question. We are obviously very pleased with the results so far, and we continue to be excited with the opportunity. In the US, let me start. Two things stand out. The first is that we were able to make pneumonia vaccination an age-based rather than a seasonal event that used to be until now. The second, of course, that we were very successful catching up adults previously vaccinated with the old technology product.

For 2016, we continue to believe that the catch-up opportunity will still be robust, although may not grow versus 2015. We give you some greater context. There were 45 million eligible adults when the recommendation was issued. We estimate that we have penetrated approximately 25% to 30% of this population so far, and that were mostly previously vaccinated with the other product, with Pneumovax. While there are still many adults remaining, this cohort, as Ian said, is much harder to capture and will take more work to reach. But we do have programs to reach them and also have program to reach the population below 65 that is immuno-comprised and they can benefit from Prevnar 13.

Now in Europe we received approval for pneumonia and we continue to work with technical committees, country by country to obtain recommendations and reimbursement. These will be phased over phased over the next two years period, depending on the country. But in general I expect Europe to demonstrate strong growth.

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

Thank you. So in summary, we think it's a durable franchise and we're very, very enthusiastic about continuing to invest in and develop that marketplace. Frank, would you like to talk about the economics of the SGL2 contract with Merck?

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

Yes. So I think just a summary is, think about it as a 60/40 split on profit. We get the 40% of the profit.

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

Okay. And then on the biosimilars Retacrit.

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

So thanks for your question, Gregg. Just as you heard in Ian's opening comments, we received a complete response letter for the epoetin Hospira BLA from the FDA on October 16 this year. I think importantly our initial assessment indicates no additional clinical studies are required at this point. So obviously we can't, to your wider question, comment on what the FDA or the position they're taking with other companies' biosimilars. We don't have any insight into that. All we can say is that we are currently reviewing our CRL, preparing our responses. We expect submission of a response sometime during the first half of 2016 with an expected six-month review under the BSUFA, Biosimilars User Fee Act.

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

Thank you, John.

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

Thanks, John. Can we move on to the next question, please?

Operator

Your next question is from Mark Schoenebaum of Evercore ISI.

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

Good morning, Mark.

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

Operator, we seem to be getting a lag on the questions coming in.

Mark Schoenebaum - *Evercore ISI - Analyst*

Is that better. This is Mark.

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

Yes, I can hear you now, Mark.

Mark Schoenebaum - *Evercore ISI - Analyst*

Okay. I'm sorry about that. First of all, congratulations on all the great share performance and the fantastic shareholder communication over the last year or so. A lot of my questions have been answered. But I thought I'd ask for a couple clarifications. Number one, Ian, I think, and again please correct me if I'm wrong, I think you've said before that if you were to do -- if you were to find a value-enhancing deal that wasn't an inversion, that you would like that deal to close before the end of 2016 because after the end of 2016 risks of policy -- legal statutory changes increase. I'd just like to know if you still feel that way.

And then on the R&D side, I heard a remarkable number, and I wanted to make sure I understood the number. The number was 16. What was that number? I heard it as you will have 16 immuno-oncology drugs in the clinic next year, or was it something else? And if that's really true --

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

10. We'll have 10 novel drugs in the clinic next year, Mark, that are different. And we can ask Mikael to run through those in a moment. There's just too many to remember now.

And on the comment on taxes, given the proposed rule by the Treasury, which has not yet been implemented but has a retroactive date, clearly anything around this area you need to be -- one needs to be very careful on legislative changes. So if there was a deal to be done, I prefer it to be

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done under the present Congress, and then you're out of risk for the new Congress coming in and making changes in the rules. And of course you don't know what the confirmation of the new Congress will be. So you'd rather do it in a Congress what you do know who are setting the rules and what the rules are. If we could go to the 10 products, Mikael?

Mikael Dolsten - *Pfizer Inc. - President Worldwide Research and Development*

Yes, yes. So Mark, we have said that we'll have up to 10 by next year, and they include already in the clinic, avelumab, 4-1BB, OX40, CCR2. We're just now starting to enroll for our first triplet based on the vaccine, VIVR. We are moving swiftly with an additional PD1. We have starting to file an IND that we'll be dosing next year for our first bifunctional against [p-keterine], another small molecule immunomodulator ID-01. We have an NCSF antibody, which brings it to nine. And then we have a couple of programs that are running towards likely end of 2016, early 2017 which includes platforms such as additional bifunctional CAR-T, additional vaccines, and further checkpoint inhibitors. I think you got the sense it's very robust. It touches multiple modalities and gives us unprecedented opportunity for combinations.

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

Thank you, Mikael.

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

Next question, please, operator?

Operator

The next question is from Marc Goodman of UBS.

Marc Goodman - *UBS - Analyst*

On Ibrance, I think I heard the metric that there's 50,000 patients on the drug. Can you just confirm that and tell us how that's changed over the past quarter? Second, maybe Frank, you can talk about the gross margin and just some of the underlying dynamics and movement in the gross margin so we can understand how to think about it, going forward, what's sustainable and what's one-time? And then third, maybe some of the pipeline Phase 2 assets that you haven't talked about before, but something that we should be keeping an eye on as we move into 2016? Thanks.

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

Okay. I'll ask Albert to clarify the number of patients on Ibrance.

Albert Bourla - *Pfizer Inc. - President Vaccines, Oncology and Consumer*

Yes. The number that I mentioned was 15,000 one-five, not the 50,000. And compared to the previous number in Q2, we had 9,000. So it's 15,000 up from 9,000 in Q2. Also to give you another statistic, it is 4,000 healthcare practitioners, up from 3,000 at the end of Q2.

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

Thank you, Albert. Frank?

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

On the gross margin, the way I'll answer it is I'll do cost of goods sold, just a reciprocal. Last year Q3, 18.3%. This year Q3, 17.4%. So down 90 bips. What really drove that was operational improvement. There's a lot going on there, Mark. Think about foreign exchange in terms of cost of goods sold as a percentage as a good guy, lowers the cost of goods sold.

Our LOEs, particularly Celebrex, is a bad guy. So hurts our cost of goods sold in terms of we'll be increasing it. Those kind of mitigate each other. And then for the quarter, operational improvements really drove the number. Our guidance for the year, 18.7% to 19.2%. So what's really going on there, if you compare that to the year-to-date number, the 17.3% year-to-date cost of goods sold is foreign exchange. If you adjust for foreign exchange, that 17.3% becomes almost 18.5%, which is close to the guidance range. And then when you add in Hospira, some of our projected sales remainder of the year get a little bit of a lift in the number, which gets you to the 18.7% to 19.2%.

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

Okay. So I'd ask Mikael if he'd run through some of our near-term opportunities, and then take that and extend it a bit to the third one about Phase 2 opportunities.

Mikael Dolsten - *Pfizer Inc. - President Worldwide Research and Development*

Thank you very much. So near term, maybe a way to look upon it is we have really a few real exciting oncology platforms. You're well aware, and we discussed, Ibrance in breast, but also moving into head and neck and pancreatic and adenocarcinoma. The second platform oncology, obviously avelumab with I-O combination, 4-1BB, OX40, and we'll actually soon share data on 4-1BB in various combinations and also Inlyta that's used in I-O combination, in this case we have with Merk's Keytruda. We have two breakthrough drug designations that are moving toward registration planning, inotuzumab for ALL and Xalkori for ROS1-positive lung cancer, an indication where you have long duration of treatment. Now, these were four oncology platforms.

In non-oncology and near term are ertugliflozin that we briefly touched upon today. Tanezumab in pain, bococizumab (PCSK9) in cardiovascular, Xeljanx in UC, psoriatic arthritis. Coming towards the earlier pipeline we have less touch-up on -- we have a real exciting rare disease pipeline starting to emerge. Recently Phase 3 for Rivipansel, sickle cell disease. We have another PD9 inhibitor for prevention of sickle cell disease. And we have studies ongoing in Duchenne's and Huntington's with drugs that are touching these orphan diseases. And if data's very strong, there are potential to consider paths for accelerated approval. We heard from Ian mentioning that our C difficile Phase 2 study is now completely enrolled. We are really looking forward to see that data come next year.

Coming back to oncology, we have a new ADC PTK7 that show interesting data in Phase 1 going towards Phase 1B2. We have the follow-on drug to Xalkori, 3922, that have shown real robust signals in this part of the pipeline. And we starting next year multiple Phase 2 for our emerging immunokinase platform with IRAK4 where we think we may be industry-leading, highly selective JAK 3, dual acting JAK 1 [tick] 2, and also JAK 1 inhibitor that it will touch carefully selected indication where we think each profile has a unique purpose and fit-to-fill for the needs of patients. I hope that gave you a little bit of a flavor of an exciting, both near and midterm pipeline.

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

Thank you for that.

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

Thanks, Mikael. Next question, please, operator?

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Operator

Your next question is from Tim Anderson of Bernstein.

Tim Anderson - *Bernstein - Analyst*

Thank you. A pipeline question, a non-market question and then a strategy question. Earlier in the year when we talked to you, you mentioned you have an oral PCSK9 in development. And if I remember right, you said we might see data in 2016, human data. I'm wondering if that's still the plan.

Second question goes back to Prevnar in adults. When we've, I think, looked in the past the benchmarks, healthy penetration into the adult population might be something like 60%. I'm wondering if you can say what you think realistic penetration of Prevnar in adults is likely to be in US and Europe?

And then last question is on potentially splitting up. Investors are obviously assuming that you'll do this at some point in 2017, or maybe later. But looking at it from the other end, what would be the counter arguments to splitting up? In other words, why might it make sense that Pfizer would not want to go down the route of splitting up? What are some of the biggest hurdles to overcome?

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

On the split, as we said before, we haven't made a decision. We said we'll make the decision in -- the latest we'll make it is the fourth quarter of 2016. And the four criteria we've set up is, are the businesses doing well inside Pfizer? Are they likely to be successful outside of Pfizer? Is there trapped value, and do we believe we can realize that trapped value? From the other end of not doing a split, if we were to do a major acquisition in the intervening time period, then it would certainly change the time lines of a split. It wouldn't necessarily change the logic of it, to the extent that that logic proves out. It would certainly -- it may even strengthen the logic for it. But that would be a decision that would be taken post any type of acquisition and post understanding the time lines that involves.

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

And the answer to all four of the questions that Ian summarized needs to be yes in terms of we will go down a split path. The answer to all four questions needs to be yes.

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

So on the pipeline question, Mikael?

Mikael Dolsten - *Pfizer Inc. - President Worldwide Research and Development*

So thank you for remembering our exciting small molecule program against the PCSK9 target. Obviously we are increasingly excited about that space, as we have seen some of the struggle around the CETP drugs. And we are on track for dosing patients end of this year. And we have collected our IND document. So it's perfectly on track. And I should say, it's a novel mechanism that we have identified in our discovery work to intervene with the PCSK9 function, and we're very excited to get into humans and see its impact.

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

Thank you, Mikael. Albert, on the Prevnar 13 Adult penetration question?

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Albert Bourla - *Pfizer Inc. - President Vaccines, Oncology and Consumer*

Yes. It's a very interesting question, and let me say that it seems that previous benchmarks or analogs of adult penetration have become somehow irrelevant after the very successful introduction of Prevnar Adult. And this was -- I will give you just some data to support my statement. But right now we have achieved a market sort of 87%. That's extremely high, as you can understand.

In pharmacies right now we are having a market of 90%. Keep in mind that pharmacies also, their overall share of participating in vaccinating and catching up patients has increased dramatically. I would say that we have disrupt this (inaudible) with our introductions.

Also our consumer activation and information campaigns have become very successful. And our commercials have run very, very high. As a result, the awareness among healthcare practitioners, for example, in US has exceeded 90% according to market research that we have run, which of course it's an exceptional -- exceptionally high. So I cannot predict what eventually will be the overall penetration of adults in this country, but I would say that we are very optimistic with the success of this first year as to how much we can achieve for the benefit of the patients in US.

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

Next question, please, operator?

Operator

Your next question is from Seamus Fernandez of Leerink.

Seamus Fernandez - *Leerink Partners - Analyst*

Thanks very much for the question. Just a couple quick ones. Historically you guys have provided some numbers around your thoughts on the size of the biosimilars market. Where do you see that? Can you just update us on your thoughts on the size of the overall biosimilars market, and where and when you really see the acceleration in that market occurring?

And then the second question. Can you just give us a sense again of the level of penetration that we're at with 15,000 patients, what does the Ibrance label currently approach? And then ultimately with the adjuvant setting in breast cancer, can you remind us again how much of the market that would open up? Thanks.

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

Thank you. Size of the biosimilars opportunity. John, would you like to comment on that, please?

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

Yes, sure. Thanks for the question, Seamus. Obviously as you know, the biosimilars market is still in the process of forming in different regions of the world. We're very excited to be playing a leading role in the formation of that market with the portfolio that we now have, both of our own legacy Pfizer pipeline of biosimilars, but also the end market portfolio of products from Hospira. Overall, the market opportunity that we see is around about $100 billion worth of revenues from currently patented branded biologics that will lose patent protection over the next five years. The global market for biosimiliars, looking at many analysts, is expected to grow from around about $1 billion today to somewhere in the order of $17 billion to $20 billion by 2020.

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Clearly there are a number of factors that will drive and influence the evolution of that marketplace, such as substitutions, such as the labels, that extrapolation of labels that products that come to market will have. Overall I would just say that we believe that we're really well placed to draw on the heritage as a really strong biologics company in R&D and in manufacturing, which we believe will leave us to be very well placed in that market as it forms around the world.

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

Okay. So Albert, perhaps you could take us for a little bit vis-a-vis the layers of opportunities we see in a number of patients or potential patients, probably talking about the US and for Ibrance.

Albert Bourla - *Pfizer Inc. - President Vaccines, Oncology and Consumer*

Yes, and I will also speak a little bit more generally. Let me start by saying how excited we are, of course, with this opportunity. The breast cancer is the most common cancer among women worldwide. There is 1.7 million diagnosed every year with breast cancer. And approximately 60% of them, which means approximately 1 million, are ER-positive, HER2-negative, an area that Ibrance has demonstrated efficacy so far. Now, with Ibrance we are working to build a broad franchise, and this is how you see it around breast cancer and beyond.

Speaking about breast cancer, we're starting with the first line and then we move to recurrent and then to early breast cancer. In the US we expect to expand, first of all, as the opportunity goes our markets are in the first line. Right now we have a market share of approximately 27%. And moving to next quarter, next year we expect to expand that even further. We also expect to have an accepted filing by FDA of our PALOMA 3 data this year, which we expect will give us registration for later lines of therapy in the metastatic setting.

In Europe we have a file and our filing was validated. The filing in Europe was based on both PALOMA 1 and PALOMA 3 data, which means that covers the entire metastatic population, not only the first line, as was our submission and current label in US. We're also working to expand our label to earlier phases of breast cancer, as I have indicated earlier, with currently three major Phase 3 studies running that includes basically thousands of patients. The PENELOPE B is a study that includes more than 1,000 patients. The PALACE, it is a study that will include almost 5,000 patients, 4,600. And the PILOT study, which is the first one that was introduced in that setting, is expected to come into primary completion around 2017.

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

Thank you, Albert.

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

Thanks, Albert. Can we move onto the next question, please?

Operator

Your next question is from Chris Schott of JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Great. Thanks for the questions. Just had two here. The first, if we think about business development potentially addressing kind of three broad areas of your business, seems like you're talking about improving top-line growth, driving operating synergies and/or improving your tax rate or

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financial synergies. I know these are all important, but how do you rank order these three in terms importance? Are some of those must haves and some of those nice to haves? Trying to understand as you look at the landscape what you go after, how you're weighing those three broad categories.

My second question was on inversion, which has been talked about a lot. But just in the current political environment where there's a lot of negative headlines around kind of pharma already out there, how do you think about political risk of inversion just in this kind of election season and with a lot of noise around the drug industry kind of already out there? Thanks so much.

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

So I think Chris, the best way to think about this is that we want to target the maximum return on investment and it's a sort of a mix-and-match combination of, as you said, financial, pipeline, growth, financial synergies, cost synergies, and the sort of puzzle is to define the target company whose price and those three combinations allows us the highest rate of return on the disposition of precious capital.

So I won't -- and then on the negative issues of pharma, I'm a little -- I'd like to have a few words about that. I think there has been some negative press on particular pharmaceutical companies. I don't see that society is saying they don't want innovation, and society is not looking for cures for Alzheimer's and Parkinson's and cancer. And so I think our industry continues to remain firmly in good stead in the sense that we remain a low percentage of the healthcare cost. So we are, I believe, the most efficient way of dealing with costs in the healthcare system. And so I think public policy is squarely behind having an innovative industry.

Certainly I think we can make the case that this industry risk-adjusted is appropriately profitable. It's PE and return on capital and return on investments are, I think, appropriate inside the averages of the stock market. So I think the returns for pharmaceutical companies are reasonable in that context. So I do believe that we have a lot of positive arguments to make when having this dialogue with society.

So around the political ramifications, the shareholders of Pfizer expect us to maximize the return, and the employees of Pfizer want to have a robust, successful Company in the future. Their jobs and their careers depend upon it. So part of the leadership of this is to ensure this Company can be successful in the future. To be successful in the future, we need to have a competitive tax rate. So that is why it's an important issue for us.

Chris Schott - *JPMorgan - Analyst*

Thank you.

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

Thanks, Ian. Next question, please, operator?

Operator

Your next question comes from Colin Bristow of Bank of America Merrill Lynch.

Colin Bristow - *BofA Merrill Lynch - Analyst*

I think a lot's been covered, but a couple more on the SGLT2. How should we think about your positioning here, given you'll be fourth to market and you won't have any CV data until the 1920 (sic) time frame. The feedback we've been getting is it's largely a Jardiance-specific benefit until proven otherwise. So to what extent do you rely on a competitor showing CV outcomes data to confer class effect, given you'll potentially be the last to have a CV readout?

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Then second question. Last quarter you stated that you see biotech valuations as priced to perfection in many ways. Clearly there's been a significant adjustment since then. In light of this it would be great to get your current thoughts on valuations and how is this changing how you're thinking about your strategy with regard to M&A and the potential geography of targets. Thank you.

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

Yes Colin, on the biotech I think there has been a readjustment in pricing. As I said, I think it's been a readjustment in the stock price. I'm not sure yet there's been a readjustment in what investors and the leaders of these companies believe their company may be worth in a transactional situation. I think if we have to wait a little while to see if the new stock valuations settle in in the reality in management's belief in the value of the companies. And then the second question was on SGLT2. I think Geno can take us through some of the logic on that.

Geno Germano - *Pfizer Inc. - President Global Innovative Pharma*

Sure. Colin, we're very pleased about the SGLT program and the recent findings from the BI-Lilly program on cardiovascular outcomes. We have a cardiovascular outcome trial underway. In fact, it's fully enrolled already with our SGLT partnership with Merck. In light of the new findings from BI and Lilly, we are considering additional work that we may do to further augment the package that we're pursuing with our program. We have, in addition to the single entity development program, a combination, fixed dose combination with Januvia and with metformin. And of course with the market position of Januvia in the diabetes market, we think we'll be very competitive with our data package and we look forward to entering that market.

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

I'd like to say I'm extremely pleased that Pfizer is doing a partnership with Merck. Two great companies with great heritage in this space, and we look forward to being very successful with this combination product.

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

Thanks, Ian and Geno. Next question, please?

Operator

Your next question is from Steve Scala of Cowen.

Steve Scala - *Cowen and Company - Analyst*

Thank you. I have three. The JAVELIN trial of avelumab in second line non-small cell lung cancer has a primary completion of 2021. So I imagine there are interim looks between now and then. Maybe you could tell us when those interim looks are, or when the first one is perhaps?

Secondly on the CDK4/6 inhibitor landscape, I think the general view is that the Novartis agent is not differentiated but the Lilly drug does look quite unique and potentially a threat to palbociclib. I think the recent breakthrough designation was notable. Would like your view. Lastly, thoughts on the recent baricitinib versus Humira study and its potential impact on Xeljanz. Why isn't this a risk to Xeljanz? Thank you very much.

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

Okay. Perhaps we'll ask Mikael to talk a little bit about the CDK4/6 competitive space and what we know and don't know.

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Mikael Dolsten - *Pfizer Inc. - President Worldwide Research and Development*

Yes, thank you. So I think I will start, and a little bit punctuate what Albert said, that palbociclib is the only CDK4/6 inhibitor studied in multiple randomized control studies, and has such a profound program for advanced recurrent early breast, and multiple indication also beyond breast. It's a highly selective drug for CDK4 and 6. We do think hitting both CDK4 and 6 is preferable. And it's very tolerable, which is important for a drug that is playing in patients from first line up to early breast cancer.

What we have seen from the abemaciclib drug is data from a single arm in very advanced patients through multiple chemo, almost a salvage line. And that's obviously positive for patients being at that very difficult advanced stage. We know that it's a drug that hits much broader than the CDK4 and 6, that characterize as you rightfully said, palbo and ribociclib. So for me it's kind of a different drug class; broader, less specific, and may play very well in this more advanced setting where the data has been currently. And obviously there has been some tolerability issues reported, which may reflect this broader profile. It's very difficult to comment on competitor drugs. So like always, we say let's have data over the next few years and experience from patients guide us. But I thought that maybe gave you an opportunity for us to summarize the status today.

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

Yes, and I think one of the competitive positions we're taking is to accelerate a very broad in-depth clinical trial program behind Ibrance to ensure that physicians have a broad experience with multiple indications and get in early and establish the standard of care there. So I think that's our answer to, if there is a competitive threat, that's how we are dealing with it. Would you, Geno, talk about Xeljanz?

Geno Germano - *Pfizer Inc. - President Global Innovative Pharma*

Sure Steve, the baricitinib data that was recently released showed the superiority on ACR20 and the DAS28 end points. And in our own program, as you know we had a trial including Humira where we showed strong numerical separation, not only on ACR20 but on ACR50 and ACR70, more difficult end points to demonstrate a difference. Now, that trial was not designed as a superiority trial. It's more of a comparative trial. But that led us to initiate a head-to-head superiority study with Xeljanz in RA compared to Humira where we're testing both monotherapy and Xeljanz with methotrexate against Humira with methotrexate. So it's a robust study. We'll be reading out in the first quarter of 2017.

We think that that will help shed more light on the performance of this drug in this setting, this clinical setting. The end point for our head-to-head is ACR50. As you know, Ian mentioned before, we have the once-a-day dossier filed with the FDA now with a PDUFA date of February 2016. And then we have our post-marketing safety study that also has arms with Enbrel and Humira in. So we'll have really good comparative data over the short and medium term to put these drugs into perspective. Frankly, I think that the JAK pathway is a powerful pathway that offers the potential for strong efficacy. And we think that that will play out with both baricitinib and Xeljanz in the long run.

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

I think, Geno, we like our position of having the opportunity to look at with and without methotrexate as well, which is maybe if they ever had to take methotrexate, they'll understand why people don't like to take it. Albert, would you like to discuss the JAVELIN question?

Albert Bourla - *Pfizer Inc. - President Vaccines, Oncology and Consumer*

Yes. Ian, I do not have handy the date of when the interim analysis will happen in this study. And anyway, as you know, these are event-driven so you never know what eventually will happen. What I wish I could tell you, this is as you know, a second line lung cancer study. We are planning to initiate the first line study this year hopefully, and that will have an expected readout much earlier, so around 2017.

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

Thank you very much. Next question, please, operator?

Operator

Your next question is from Vamil Divan of Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

Great. Thanks so much for taking my questions. So I just had a couple, one building on what you were just talking about with the JAK inhibitors and Xeljanz. Can you just give a little more detail on the decision you made to sort of focus your priorities? You said you're stopping development of Crohn's and ankylosing spondylitis, focusing on other indications. Was that something specific to the product? Was it safety, efficacy of the product in those indications? Or is more of a kind of view of the commercial competitive dynamics in those other indications?

And then second. Just one, if I could, on Eliquis. Just wondered if you could give a little more color on what you've been seeing there. Haven't really touched on that on this call yet. And then wondering if you expect any sort of negative impact, given the approval of paroxetine, the universal agent for Pradaxa recently. I was just wondering, do you think that might impact physicians prescribing over the next year or so prior to having an antidote for Eliquis (inaudible) available? Thanks.

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

Geno, those two questions, please?

Geno Germano - *Pfizer Inc. - President Global Innovative Pharma*

Sure. Let me start with Xeljanz. As we continue to see the studies readout, obviously we become more informed about how this agent is working in these various patient populations and various disease states. Our decisions on prioritization are made on the basis of the data that we're seeing, the emerging profile of the drug, again, across different patient populations. And also the timing of and the amount of work that's required to continue these programs. So it's a number of factors that has led to the decisions that we've made.

We are very excited about continuing in the RA and the psoriatic arthritis and the ulcerative colitis areas where we're very encouraged with what we've seen so far. And these are very large, robust market opportunities. So we're looking forward to a bright future for Xeljanz.

With regard to Eliquis, frankly we're continuing to see Eliquis take share in the NOAC market around the world. We're a leading product now in a number of countries. We're a leader with cardiologists in many more countries. We established our foothold in the stroke prevention market and now in the thromboembolism market. We're continuing to make inroads in primary care. So that engine just keeps rolling.

With regard to the antidote, the feedback that we've gotten from the physicians in the marketplace is that it's a nice to have and they welcome it. We don't expect it to have a major disruptive effect in the marketplace.

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

Thank you, Geno.

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

Thanks, Geno. Next question, operator?

Operator

Your next question is from Andrew Baum of CRTI.

Andrew Baum - *Citigroup - Analyst*

It's Andrew Baum from Citi, actually. Three questions, short ones. First, Mikael, do you have a SERD anywhere near the clinic? Second, with regard to biosimilars, I'd be interesting in Pfizer's view on interchangeability. Is it economically desirable within the US landscape, given there's a much likely rapid erosion of revenues as a consequence? Finally for Ian, in relation to inversion, I note that Medtronic after inverting and said Covidien seemingly have had to import $10 billion worth of offshore cash with only $500 million tax bill. Given this did not fall at 60% level, does this mean that there's still surprising amount you can do despite being higher than that threshold?

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

Well, let's answer the questions in the order they were taken.

Mikael Dolsten - *Pfizer Inc. - President Worldwide Research and Development*

So yes, I assume you're considering what else in our pipeline could combine with Ibrance. And we do have, as you know, the PALOMA 3 with a SERD, fulvestrant. We have some internal activities on (inaudible) SERD, but nothing that allow me to give you a date when it could or could not get to the clinic. I wanted, though, to say that we have exploration in the clinic with a PR3K emptor inhibitor that we have ourselves that have a unique tolerability profile because it's given intermittently. We do explore with internal and potential partner drugs how you could combine, but I would probably be more keen to go beyond the estrogen receptor blockade and look for mechanisms that could be more much additive, synergistic, when we develop the CDK4/6 franchise further.

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

Thank you, Mikael. John, could you discuss the interchangeability issue?

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

Yes, Thank you. So I mean, first of all, let's just say that we view biosimilars as playing a key role in the future of healthcare, and they can address the evolving needs of patients, physicians and payers. On the interchangeability question specifically, I think our view as a Company is that interchangeability should be based on science and under physician supervision since biosimilars are not the same as the reference products. The traditional paradigms that you might see in a small molecule of interchangeability and automatic substitution just don't apply.

We believe that regulators and also payers should and will look at the data specific to each individual biologic molecule. That's why we have comprehensive development programs for our biosimilars, so that we can actually help physicians and patients to be able to make informed decisions about how to appropriately use those molecules. Our key point here is that we realize there's a need for more scientific progress to make interchangeability feasible, and for that to really be driven by the data for individual molecules.

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

Thank you. Frank, on the various flavors of inversion?

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

Yes, I think the best way I'll answer this, Andrew, is your question I think is actually a good example of what I said before, which is it's really target-to-target specific in terms of how much of the benefit you can preserve of an inversion if you're an in betweener, in terms of less than 80% and greater than 60%. The example you gave is, I think, a good example of where benefit is being preserved. But it just punctuates my point before about it's really target-by-target, company-by-company specific.

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

I'd like to point out that these rules are proposed rules. They have not been triggered.

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

Thanks, Ian. Operator, if we could take our last question, please?

Operator

Yes. Your final question comes from Alex Arfaei of BMO Capital Markets.

Alex Arfaei - *BMO Capital Markets - Analyst*

Good morning, and thank you for taking the questions. And congratulations on a strong quarter. Ian, just building upon your earlier comments on trapped value and the split decision, is it fair to say that the ongoing strong performance of your Innovative business strengthens the split argument, since there does appear to be a significant trapped value there? So in terms of a go/no go decision, I guess, is it fair to say that the split argument is strengthening from your perspective? And then on immuno-oncology, given your focus on combinations, how are you thinking about pricing in the current environment, given how the first generation products have priced? Thank you.

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

I think on the split, to the extent of both businesses are doing well and can command premium PE ratios, if those PE ratios aren't being seen in the combined stock, then it would be an argument to say that this trapped value could be released by a split. I think we'll look at that and look at how the market is pricing the Pfizer Inc. stock compared to what would look -- what the individual stock should trade at if their PEs were unfettered, so to speak, by being on their own.

And then I do think you're right, that I believe that one of the competitive advantages will be if a company owns the sequence of treatments and the combination products. So I really see in oncology, it becoming a chronic disease where you move from one combination to the next to the next to the next. And so the ability to both price those combinations individually and price if you have enough in your portfolio to also price a longer period of different treatments is going to be extremely important in -- as a competitive ability.

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

Thanks Ian, and thank you everybody for your attention on the call.

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Operator

This concludes today's Third-Quarter 2015 earnings conference call. You may all disconnect.

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