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PFE - Q4 2015 Pfizer Inc Earnings Call

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OVERVIEW:

Co. reported 2015 reported diluted EPS of \$1.24. 4Q15 reported revenue was approx. \$14b and reported diluted EPS was \$0.10. Expects 2016 reported revenue to be \$49-51b, reported diluted EPS to be \$1.54-1.67 and adjusted diluted EPS to be \$2.20-2.30.



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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's fourth 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 - Senior VP of IR*

Good morning. And thanks for joining us today to review Pfizer's fourth quarter and full year 2015 performance, as well as 2016 financial guidance. 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 this call can be viewed on our homepage Pfizer.com by clicking on the link for Pfizer Quarterly Corporate Performance Fourth Quarter 2015 which is located in the For Investors section in the lower right hand corner of this page.

Before we start, I'd like to remind you that our discussion during the call will include forward-looking statements and that actual results could differ materially from those projected in the statements. Factors that could cause actual results to differ are discussed in Pfizer's 2014 Annual Report on Form 10-K, as well as on our reports in Forms 10-Qn and 8-K. The discussions during the call will also include certain financial measures that were not prepared in accordance with Generally Accepted Accounting Principles. Reconciliation of the 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.

Also, today's call is not intended to and does not constitute an offer to sell, or the solicitation of an offer to subscribe for or buy securities of Pfizer or Allergan. We will now make prepared remarks and then we will move to a question and answer session. With that, I'll now turn the call over to Ian Read. Ian?

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Chuck. And good morning, everyone. We finished 2015 with strong financial and operational performance. For the full year, we exceeded our 2015 revenue guidance and met the top end of our adjusted diluted EPS guidance. And, we achieved our first year of operational revenue growth in five years. Frank will take you through the numbers. Before he does, I have a few brief comments about what is driving our performance, some thoughts regarding where we expect to see pipeline advancements during the year, and I'll close with a few comments about Allergan.

Throughout the year, and especially in the fourth quarter, our business executed flawlessly, despite a challenging operational environment. We entered 2015 with solid momentum in both developed and emerging markets. Specifically, in developed markets during the year, we gained incremental market penetration driven by continued success of products that are early in their life cycles, including, Prevnar 13 in adults, Ibrance, Eliquis, Xeljanz. And we saw steady growth from key inline products in 2015. Specifically, Lyrica in markets where it remains patent protected.

During the year in emerging markets, we saw operational revenue growth primarily due to the performance of Prevnar, Lipitor and Enbrel, as well as from the addition of legacy Hospira products. The integration of the Hospira business into Pfizer Global Established Pharma business is on track. And we look forward to this business being an attractive potential growth driver. This acquisition is indeed proving to be an excellent strategic fit, and we're seeing the expected value contribution to our GEP business that we anticipated.

Frank will speak to our 2016 guidance in a moment. We expect to deliver operational revenue growth in 2016. Our key growth drivers will continue to be Ibrance, Eliquis and Xeljanz. And we believe that Prevnar Adult global revenues will be comparable to the strong results we achieved in 2015. Additionally, we believe our near term pipeline will help accelerate this ongoing growth forward. In looking at the year ahead, we expect our businesses will continue to execute well. They are competitively positioned within their markets, and are performing strongly against their competitive set.

Regarding the pipeline, we anticipate advancing many of our Phase 3 programs during the year. For bococizumab we reported today the first of our six Phase 3 efficacy studies achieved its primary end point. And we expect read outs of the remaining five bococizumab lipid lowering studies to read out during 2016. For ertuglifozin, this year we and our partners Merck, will begin to deliver results from our comprehensive Phase 3 clinical program. In 2016, the alliance expects to submit applications for regulatory approval in the US for both monotherapy, and two fixed-dose combination tablets, using data from eight clinical trials.

For dacomitinib, we expect results in the second half of the year for a Phase 3 study in first-line EGFR mutant non-small cell lung cancer and will discuss our regulatory strategy with the FDA. For Xeljanz, in the first half of this year, we expect top-line results for our Phase 3 program in psoriatic arthritis. We believe Xeljanz can potentially fill a significant unmet need in the psoriatic arthritis market where non-biologic DMARDs do not have proven success. And, where there are currently few alternatives for patients who have inadequate responses to anti-TNF therapy. In addition, in

the first half of the year, we anticipate a decision from the FDA for our once-a-day daily Xeljanz formulation for rheumatoid arthritis. And we remain on track to refile our application for RA in the EU.

For Ibrance, we expect to see the top-line PALOMA-2 study results in first-line advanced breast cancer in combination with letrozole. And we have an April PDUFA date for second and third line treatment for advanced breast cancer based on the PALOMA-3 data. We could also see a regulatory decision for Ibrance in the EU by year-end.

Additionally, in the Oncology business, we have a PDUFA date this year in the US for Xalkori in ROS-1 non-small cell lung cancer. And we expect to file for approval of inotuzumab for acute lymphoblastic leukemia in the US. And in Immuno-Oncology, we now have a broad portfolio of compounds that we believe has the potential to support the development of a strong, deep, competitive market position. We now have five Immuno-oncology assets in the clinic, and expect to have up to ten in the clinic by the end of 2016.

As a result of our partnership with Merck KGaA, as of the end of 2015, we had 28 ongoing Clinical Development programs for avelumab, with seven of them being pivotal, registrational studies. We anticipate some of these studies will give us potential registrations in areas like Merkel Cell, ovarian, bladder, gastric, and lung cancer. Of these seven studies, we expect to present data in Merkel Cell this year and to see data from the other tumor types in the following two years. And, we continue to believe that the winners in this space will be those that have a breadth of portfolio assets to support rational combinations. We have a range of assets to combine with avelumab when compared to other companies' assets and we've already initiated six combination studies with avelumab.

In 2016, we expect to see data from: 4-1BB in combination with Keytruda, and in combination with avelumab in various tumors; 4-1BB, in combination with rituximab in lymphoma; a combination of lorlatinib, our next-generation ALK-inhibitor with avelumab in ALK-positive non-small cell lung cancer; and data from Inlyta with avelumab in renal cell carcinoma. Finally, we may see data from OX-40 as a single agent this year. Taking up all of this into account, we believe we are well on our way to being a leading player in this space.

And now, a few comments about our proposed combination with Allergan. We're excited about bringing two great companies together that have a strong strategic fit. The transaction is about accelerating growth potential in our innovative businesses and strengthening our established business and more efficiently allocating our capital around the world. We are confident that we are taking the appropriate steps so that we can achieve the key milestones needed to complete the transaction, and continue to expect close in the second half of 2016.

Since the announcement, we have been working closely with Brent Saunders and his team at Allergan and have been delighted by the engagement and rapport that is occurring. We see a number of potential opportunities after closing, as we continue to learn more about each other's portfolio. For example, we see complementarity in inflammation and gastroenterology. And we will have a broader presence in cardiovascular disease with Eliquis and Bystolic. In neuroscience, Allergan's work in Alzheimer's, schizophrenia and major depressive disorders will be highly complementary to Pfizer's promising early work in such areas as Parkinson's, Alzheimer's and Duchenne's muscular dystrophy. When you look out over the next few years, we expect both companies will contribute several potential new drugs to launch.

We also continue to be excited about the international potential. And by coming together, we are enhancing category leadership throughout our complementary in-line portfolio, and a combined pipeline with great late-stage and mid-stage assets across each of our key therapeutic areas. Both companies bring a great deal of scientific and product expertise to the proposed combination, and a shared philosophy in our approach to research and development. Upon the close of transaction, the combined Company will be an influential player in the industry, with a competitive product portfolio with several leadership positions, robust pipeline, compelling capital structure and financial position, and aligned cultures that are based on ownership and entrepreneurial spirit, creating shareholder value and meeting patients' needs.

This combination is about investing in our business. It's about accelerating our existing strategy while preserving our options and spitting the Company into an innovative business and an established business if we determine that is the best way to unlock the most value for our shareholders. By the end of the current quarter, our integration team will be fully engaged and we anticipate announcing post-closing leadership positions. Throughout the year, we will continue to keep you updated on our progress.



In summary we're looking at year ahead, we have a sound strategy and a strong business. Our outlook and financial guidance for the year takes into account the benefit of anticipated positive organic growth in key products, as well as the impact from foreign exchange. We have a solid portfolio of market leading in-line products, a healthy pipeline. We expect to further strengthen the growth potential of the business with the pending addition of Allergan. We will continue to have the means by which we can create value for our shareholders and bring innovative medicine to patients by producing expected top-line growth, progressing key pipeline assets, pursuing strategic business development, and returning capital to shareholders through dividends and buybacks. Now I'll turn it over to Frank for additional details on the quarter, and our 2016 financial guidance.

Frank D'Amelio - Pfizer Inc - CFO

Thank, Ian. Good day everyone. As always, the charts I'm reviewing today are included in our webcast. As a reminder, because we completed the acquisition of Hospira on September 3, 2015, Pfizer's full year financial results for the year ended December 31, 2015 include four months of legacy Hospira US operations, and three months of legacy Hospira international operations. Financial results for the fourth quarter 2015 include three months of legacy Hospira global operations. By comparison, financial results for full year and fourth quarter 2014 do not include any contribution from legacy Hospira operations. Now moving on to the financials.

Fourth quarter 2015 reported revenues were approximately \$14 billion, and reflect year-over-year operational growth of \$1.9 billion or 14% mainly driven by the addition of legacy Hospira operations, the continued strong performance of products that are early in their life cycles, such as Plevnar 13 Adult, Ibrance, Eliquis and Xeljanz. Lyrica primarily in the US, and 5% operational growth in emerging markets, mainly from legacy Hospira operations, Plevnar 13, and certain other products.

Reported revenues continued to be unfavorably impacted by foreign exchange of \$934 million or 7%. Excluding the inclusion of legacy Hospira operations of \$1.2 billion, the negative impact of foreign exchange, and to a much lesser extent, the inclusion of \$35 million of revenues, associated with vaccines acquired from Baxter, Pfizer's standalone achieved operational growth of \$646 million or 5%, while at the same time, absorbing a \$720 million negative operational impact from product losses of exclusivity.

Fourth quarter adjusted diluted EPS was \$0.53, versus \$0.54 in the year-ago quarter. The decrease is primarily due to an aggregate operational increase, and adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses of \$1.8 billion or 21%, \$0.07 due to foreign exchange, and the continued product losses of exclusivity in certain geographies. These were partially offset by revenue growth of certain new, in line and acquired products, a lower effective tax rate, and fewer diluted weighted average shares outstanding, which declined by 125 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.

Reported diluted EPS was \$0.10, compared with \$0.19 in the year-ago quarter, due to the previously-mentioned factors and the unfavorable impact of foreign currency losses related to Venezuela, increased purchase accounting adjustments, acquisition related cost, restructuring charges, and asset impairment charges versus the prior-year quarter, and non-recurring charges related to pension settlements, which were partially offset by the non-recurrence of a charge associated with the global strategic alliance formed with Merck KGaA in November 2014 to jointly develop and commercialize avelumab, lower charges for certain legal matters, and a lower effective tax rate.

Foreign exchange negatively impacted fourth quarter reported revenues by approximately \$934 million or 7% and positively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate by \$435 million or 5%. As a result, foreign exchange negatively impacted fourth quarter adjusted diluted EPS by approximately \$0.07, compared with the year ago quarter.

Now moving on to the financial highlights of our business segments. In the fourth 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 Lyrica in the US and Japan. Income before taxes increased 17% operationally due to the increase in revenues, and a 5% operational decrease in cost of sales. Cost of sales as a percentage of revenue decreased 1.7 percentage points operationally because of lower royalty expenses and increased alliance revenues with no associated cost of sales. IBT was unfavorably impacted by a 4% operational increase and SI&A expenses as a result of additional investment at Eliquis, Xeljanz and Chantix, and 11% operational increase in R&D reflecting investments in our late stage pipeline, primarily for bococizumab and tanezumab.



Fourth quarter VOC revenues increased 38% operationally reflecting operational revenue growth in each business. Global vaccine revenues grew 53% operationally, driven by 102% increase of Prevnar 13 US revenues due to the strong uptake among adults, Global Oncology revenues grew 61% operationally, driven by Ibrance in the US, and to a lesser extent by Sutent and Xalkori globally. And Consumer Healthcare revenues grew 4% operationally, due to Nexium 24 hour in the US. Income before taxes increased 33% operationally, mainly due to increased revenues and an associated improvement in gross margin, which were partially offset by a 66% operational increase in SI&A expenses, as a result of higher promotional expenses in the US for newly launched Consumer Healthcare products, Ibrance and Prevnar 13 Adult. And the 46% operational increase in R&D expenses, due to increased costs associated with our Oncology programs, primarily our alliance with Merck KGaA and Ibrance.

Fourth quarter Global Established Pharmaceutical revenues increased 5% operationally, mainly due to the previously mentioned inclusion of legacy Hospira revenues contributing \$1.2 billion, which was partially offset by the loss of exclusivity and generic competition for Celebrex in the US, and certain other developed markets. Lyrica in most developed markets in Europe and Zyvox in the US. Emerging market revenues were flat operationally, which reflected the positive impact of the inclusion of legacy Hospira operations and continued strong growth in China, offset by declines in certain markets in the Middle East.

Income before taxes declined 12% operationally, reflecting the unfavorable impact of a 4.7 percentage point operational increase, the cost of sales as a percentage of revenues due to the inclusion of Hospira operations, and the impact of losses of exclusivity. A 24% operational increase in SI&A expenses, driven in part by the addition of Hospira operations, and the 53% operational increase in R&D expenses, due to increased legacy Hospira development programs.

We exceeded the top of our guidance range expectations for 2015 reported revenues by approximately \$400 million. Adjusted cost of sales as a percentage of revenues was 18.5% versus 18.7% at the low end of our guidance range due to increased alliance revenues and sales volumes. And we exceeded our expectation for our effective tax rate on adjusted income as a result of a favorable change in our jurisdictional mix of earnings. We met our expectations for adjusted R&D expenses and achieved the top end of our adjusted diluted EPS. Adjusted SI&A expenses of \$14.3 billion were higher than our guidance range, due to increased expenses for recently launched products such as Prevnar 13 Adult and Ibrance, other in-line products, and certain Consumer Healthcare brands.

We recorded adjusted other income of \$409 million versus our expectation of approximately \$500 million. Finally, reported diluted EPS was \$1.24, versus our expected range of \$1.37 to \$1.43, mainly as a result of increased purchase accounting adjustments, acquisition related cost and restructuring charges primarily related to the acquisition of Hospira, the negative impact of foreign currency losses related to Venezuela, and non-recurring charges related to pension settlements.

Now, I'd like to walk you through the 2016 guidance ranges for reported revenues, reported diluted EPS, and adjusted diluted EPS relative to our 2015 actual results. First it's important to note that our 2016 financial guidance excludes the impact of our pending combination with Allergan. Our 2016 reported revenue guidance range reflects anticipated strong growth of certain new, in-line, and acquired products that is partially offset by an anticipated \$2.3 billion negative impact due to continuing product losses of exclusivity. I want to point out that within this range, and consistent with our previous comments, we expect full year Prevnar 13 Adult global revenues to be comparable with its full-year 2015 global revenue level.

We expect adverse changes in foreign exchange based on mid-January 2016 rates relative to the US dollar, compared with actual foreign exchange rates from 2015 to have an additional \$2.3 billion negative impact on reported revenues, including an estimated \$800 million negative currency impact related to Venezuela. Consequently, we expect 2016 reported revenues to be in the range of \$49 billion to \$51 billion. Reported diluted EPS and adjusted diluted EPS guidance also include the negative impact from product losses of exclusivity, as well as an expected \$0.09 negative impact from foreign exchange rates and the \$0.07 negative currency impact related to Venezuela. As a result, we expect reported diluted EPS to be in the range of \$1.54 to \$1.67 and adjusted diluted EPS to be in the range of \$2.20 to \$2.30.

In addition, I want to remind everyone that guidance ranges for both reported and adjusted diluted EPS incorporate \$5 billion of anticipated share repurchases in 2016, which consist of our previously announced intention to execute a \$5 billion accelerated share repurchase program in the first half of 2016. These repurchases are expected to more than offset the potential dilution related to employee compensation programs. In summary, if you exclude anticipated foreign exchange impacts, including the negative currency impact related to Venezuela, full-year 2016 revenue and

adjusted EPS guidance midpoints, are 7% and 10% greater than actual full-year 2015 levels, respectively. The remaining elements of our 2016 financial guidance are set forth on this chart.

Now, moving on to key take-aways. We had a very strong financial performance in 2015 and we achieved operational revenue growth every quarter, including 14% operational growth in the fourth quarter. For the full year 2015, we achieved 6% operational revenue growth that was mainly driven by new products that are early in their life cycles. And we achieved this growth despite a \$3.2 billion negative impact from product losses of exclusivity. Our full year 2016 reported revenue guidance range of \$49 billion to \$51 billion absorbs a \$4.6 billion combined negative impact of product losses of exclusivity, adverse changes in foreign exchange rates, and the negative currency impact related to Venezuela. And the adjusted diluted EPS guidance range includes an anticipated \$0.16 negative impact from foreign exchange, including Venezuela.

We announced our proposed combination with Allergan and continue to expect the transaction to close the second half of 2016 and we continue to create shareholder value through prudent capital allocation. In 2015, we returned \$13.1 billion to our shareholders through dividends and share repurchases. And we expect to execute a \$5 billion accelerated share repurchase program in the first half of 2016. Finally, we remain committed to delivering attractive shareholder returns in 2016 and beyond. Now, I'll turn it back to Chuck.

Chuck Triano - Pfizer Inc - Senior VP of IR

Thanks Ian and Frank. Operator, can we please poll for questions?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Your first question comes from Colin Bristow from Bank of America.

Colin Bristow - Bank of America - Analyst

Good morning and congrats on the solid finish to the year. So, a couple of product specific questions if I may.

On the Prevnar franchise, you posted strong Q4 numbers. Could you just talk about your expectations for the trajectory going forward? On Ibrance there's been a lot of discussion around Abemaciclib or Lilly's Abemaciclib and the potential there for a threat to Ibrance. What's your view here?

And then just lastly on biosimilars? Can you update us on the status of your biosimilar candidates? And when we should expect any data read outs, thanks.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you Colin, I'll ask Albert to manage the Prevnar and Ibrance and then pass it over to John for biosimilars.

Albert Bourla - Pfizer Inc - Group President, Vaccines, Oncology & Consumer Healthcare

Thank you very much for the question, Colin. Let me provide some insight to help you understand the situation moving forward.



In the years, obviously, we have done an excellent job with the catch up opportunity. We have achieved 86% market sale, 92% at retailers, we have 90% awareness of the recommendation of healthcare practitioners. And as a result, of the 45 million adults eligible at the time of recommendation for vaccination, we have already captured about a third of them.

Now, while many adults remain, this cohort is more difficult to capture, as the low hanging fruit is gone. It will require more innovative strategies that we all have in place. But even if we assume a similar or higher penetration rate this year, it will be on a much smaller pool of adults.

However, we expect this will be mitigated by Europe, which has a very different growth profile. Even with prices lower than US, the demographics are very favorable, with a much larger eligible population. And we have already received pneumonia in our label in 2015. And we are working to obtain broad recommendations and following that, reimbursement from the authorities.

Now, this will be faced likely over two years window period because in Europe this is done country by country, and sometimes region by region within the same country. But all-in all, we expect very strong growth in Europe next year.

Now, let me move on Ibrance and to your question about competition or particularly Lilly's drug. Look, Lilly's drug, while the same class, is for any indication. The refractory patient population for which they have received Breakthrough Designation, is a very small population with few options available. In fact, the average refractory patient undergoes seven lines of treatment, so it's in high need.

Now speaking generally, on competition. There is only limited clinical data on the public domain. And we need to see more efficacy and safety data to make comparisons.

What I can tell you is about our strategic position. We are the only company with a registered product in the US, and six other countries, and an accepted filing in Europe, where we may obtain registration as early as next year. We have very good clinical experience with the product.

Ibrance has been prescribed by 5,000 physicians and more than 20,000 patients. And so far, feedback is very positive, particularly, on patients' quality of life.

We are having a very heavy clinical program. We have two pivotal studies in first-line metastatic breast cancer. Two studies in recurring metastatic breast cancer. And three in early breast cancer, PENELOPE-B, PALLAS and PALLET.

Ibrance is part of 88 investigational initiated trials. Approximately 15 breast cancer and 30 in other tumor types. So, as you can see we are investing heavily to stay ahead of the competition.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Albert. I think just on Ibrance, you mentioned next year for Europe. You meant this year late this year we may be able to get registration.

Albert Bourla - Pfizer Inc - Group President, Vaccines, Oncology & Consumer Healthcare

Correct, in 2016 I mean. I apologize.

Ian Read - Pfizer Inc - Chairman and CEO

Go ahead.

John Young - Pfizer Inc - President, Global Established Pharma

Okay, so thanks for the question on biosimilars Colin. So then, we're obviously very excited to be able to bring together the combination of Hospira's current in-line biosimilars, which are already in the market. So we have three assets, as you know which are already in the market in Europe. Nivestim, Retacrit, and Inflectra. And to bring that together, along with the legacy Pfizer monoclonal antibody pipeline, plus some additional assets that Hospira have.

So in total, when you look at the pipeline, we have nine distinct biosimilar molecules in different stages of development: infliximab outside of the EU, adalimumab, trastuzumab, bevacizumab, rituximab, pegfilgrastim, ranibizumab, denosumab, uztekumimab. So overall, we have a very strong pipeline.

A number of those assets are in Phase 3, late phase development. And the first data set that you'd be seeing from our Phase 3 studies, would come from the legacy Pfizer infliximab program where we would expect to produce data from our Phase 3 towards the end of this year.

Colin Bristow - Bank of America - Analyst

Thank you, John.

Ian Read - Pfizer Inc - Chairman and CEO

Thanks, John.

Operator

Your next question comes from Jami Rubin from Goldman Sachs.

Ian Read - Pfizer Inc - Chairman and CEO

Jami? Okay Jami, we may come back if we can correct the technical issues. If not let's go to Alex.

Operator

Your next question comes from Alex Arfaei from BMO Capital Markets.

Alex Arfaei - BMO Capital Markets - Analyst

Good morning and thank you for taking the question. Frank, your gross margin for 2016 is better than we expected considering you're integrating a lower margin business in Hospira and losing exclusivity on some high margin products.

Can you help us understand what's driving that, and should we expect additional margin expansion going forward given that your innovative business is growing at a faster rate? And then, on Hospira's contribution this quarter, it doesn't seem to reflect much revenue synergies. Obviously it's too early, but how should we think about Hospira's contribution next year and also revenue synergies going forward? Thank you.

Frank D'Amelio - Pfizer Inc - CFO

So Alex on the gross margin, let me run the numbers and then I'll answer the question.



So we ended the full year at 18.5% in terms of cost of sales. So I'll do the cost of sales, the reciprocal obviously, is gross margin. We guided for next year cost of sales number of 21% to 22%. So, if you take the mid point of that 21% to 22%, just to make the math easy, that's 21.5% from our 18.5%. That's at 3%, 300 basis point increase in our cost of sales as a percentage of revenue.

By the way, that's being driven by a few factors, but one of which clearly is Hospira. In terms of, I think your question, which is why was it even more? I think the answer is our ongoing productivity and cost reduction initiatives. When you think about our factories, our manufacturing capabilities, we really manage that from a cost perspective.

First of all, we focus that on quality, service, and cost. If you think about that as a triangle, quality is at the top of the triangle. But there's four major buckets right?

There's the number of facilities, there's the numerous quality initiatives we have within each facility, there's the purchasing that we can get from a leverage perspective. And finally, there's the center cost that resides outside of the factories. We manage all of those very aggressively, to basically manage our cost structure and manufacturing. But that gives you a feel for what the numbers were, and why they are what they are.

John Young - Pfizer Inc - President, Global Established Pharma

So thanks, Alex. So obviously, again we're very excited by the opportunities afforded us by the combination of our two businesses. And, I think I've talked about biosimilars already, and the opportunities we see in that marketplace. So let me just touch briefly on sterile injectables.

It's a large growing market. It's somewhere between \$50 billion to \$70 billion currently globally. And one of the features of that market is it's very concentrated, particularly in the US, but also in a few ex-US markets, such as Western Europe and particularly China.

So one of the things that we are very focused on is going to be revenue synergy. We obviously have a strong commercial presence in China. And also in the hospital segment in developed Europe and emerging Europe.

So essentially, the lag time since September, when we closed this transaction, we've been focused on making sure that we have our blocking and tackling in place. To be very systematic with our highest value molecules that really meet market needs most appropriately. To be very focused on registering and bringing those molecules to market.

So in the biggest opportunity that we have in China, that is going to take time. As you are very well aware, drug lag in China is a significant issue, but we're very encouraged by the progress that the CFDA are making to accelerate access to important new medicines in China. But that will take time. But we do see opportunities both in the short-term, as well as medium long term to deliver significant growth ex-US through the sterile injectable business and the combination of Hospira's portfolio into our commercial footprint.

Chuck Triano - Pfizer Inc - Senior VP of IR

Operator let's see if we can get Jami Rubin back.

Operator

The next question comes from Jami Rubin from Goldman Sachs.

Jami Rubin - Goldman Sachs - Analyst

Thank you. Sorry about that don't know what happened on my end. But anyway, a few questions.



Frank, can you tell us what your Venezuela revenues are? We in consensus are surprised by the size of the hit. Can you all hear me?

Ian Read - Pfizer Inc - Chairman and CEO

Yes, we can hear you. You're a little static but we can hear you.

Jami Rubin - Goldman Sachs - Analyst

Okay sorry about that. Anyway, so Frank if you could just provide more color on Venezuela.

Frank D'Amelio - Pfizer Inc - CFO

Sure.

Jami Rubin - Goldman Sachs - Analyst

And, why such a big hit?

And then Ian, a couple questions for you. Back on this whole breakup thesis and the timing. I think investors initially were disappointed by the timing you laid out at the time that you announced the Allergan deal. I think you said you'd make a decision by the end of 2018.

I want to put out there that the stock has pulled back quite a bit since you announced the Allergan deal. And I would think, despite clearly the market is excited about this, but I would think the even growing gap in valuation between where your stock is in an SOTP, should help you to accelerate your decision to move in that direction. And if you could just comment on that please?

And then, thirdly, on revenue growth. Clearly, there have been tons of pushes and pulls in your numbers. Mostly currency and patent expirations.

Can you remind us when you expect, and this excludes the acquisition from Allergan, but when you expect your reported revenue growth? Or just talk about operationally revenue growth. When we should start to see a positive inflection point?

Because it has, when I look at my models revenues have been in decline for many years. And some of that is divestitures and spins, but, since 2013 we've had revenue flat to down. When is that going to change, or what drives that change talking from Pfizer standpoint? Thanks very much.

Ian Read - Pfizer Inc - Chairman and CEO

Let me just do the revenue growth first. Well, as I said, 2015 was the first year when we saw revenue growth. 2016 operationally, we expected it to be Hospira and Allergan, we expected it to be flat. And that's because we had a huge growth from Adult Vaccine in 2015 and will hold that franchise, we won't grow it again.

We'll have good growth from our in line products and our newly launched products. But we still deal with a couple of billion of LOEs.

So I think you can begin to see, as we begin to get more traction with more clinical trials in Ibrance, as we begin to see the ertugliflozin launch, and we begin see our next wave of products get approved. You'll see us returning to very robust growth. But obviously, Jami one of the reasons for doing the Allergan deal, was in fact to ensure that we had robust growth in our innovative business. So we're aware of that issue.



Now, vis-a-vis the breakup timing. Number one, I'd point out that while the stock is down, I don't think it's specifically down more than the DRG. In fact, I think it's roughly the same as a DRG. And in fact, given the arb pressure that one would expect in the stock, I'm actually well, one never like to see the stock go down, it certainly was expected to come under pressure from the arb community.

Now the breakup timing, is an issue of, we are focused on integrating this Company and the two companies together. And we have laid out the four questions that we need to answer. And I think any shareholder would want those questions answered. So, can we run the businesses successfully inside Pfizer?

And, we have bought Hospira, you're seeing sterile injectables. You've got the biosimilars. You're beginning to see if you'll strip out the LOEs, the stabilization of the core business, which we expect to return to growth. But that being said, we can run it well inside Pfizer.

Can it be run better outside Pfizer? Is there trapped value and can we unlock the trapped value in a tax efficient manner? And these are very serious questions. These are very large companies.

And, I think that by the end of 2018 we will be well positioned to make that decision in the best interest of our shareholders. And frankly, don't particularly see a way of short circuiting that, just because of the amount of work that has to be done and integration, and getting the transaction with Allergan right. I do understand your wish for more speedy decision, but I think we're taking the right approach for shareholder value here.

Frank D'Amelio - Pfizer Inc - CFO

Venezuela?

Ian Read - Pfizer Inc - Chairman and CEO

Yes.

Frank D'Amelio - Pfizer Inc - CFO

So Jami, Venezuela revenues -- that were, I'll call it initially projected for 2016 were about \$800 million. Roughly the same size as 2015. And if you look at the adjustment we took, we changed the exchange rate from 6.3 Bolivar to the dollar to 200 Bolivar to the dollar. We went to the Simadi rate for Venezuela.

That change in the translation is what causes the adjustment that we made for 2016. And we thought that the timing of that adjustment was appropriate. Given oil prices, given what's going on in Venezuela economically. Given the dollars that are coming out of Venezuela.

We thought the timing for this was appropriate. But it's really the 6.3 Bolivar to 200 Bolivar to the dollar conversion that's really causing the adjustment for 2016.

Ian Read - Pfizer Inc - Chairman and CEO

Now Jami, ongoing, when Venezuela passes through this crisis and they reestablish a normal economy, we would expect Venezuela to grow back to be in the \$200 million to \$300 million -- between \$200 million and \$400 million a year. So the actual delta medium term is the \$400 million between what was an overvalue in currency. Thank you.

Chuck Triano - Pfizer Inc - Senior VP of IR

Thanks Ian and Frank.

Operator

Your next question comes from Andrew Baum from Citi.

Andrew Baum - Citigroup - Analyst

Three questions please, two of them very short. Firstly, perhaps you could just outline the sequential growth for China (inaudible) the last quarter. Second, do you anticipate a third notice from the Treasury on conversion? And obviously, we are not at the point where the (inaudible) notice. But how restricted do you see any notice, if it does impact your potential to complete the Allergan transaction?

And finally, just returning to Abemaciclib the patients in their ongoing Phase 2 trial, which they intend for an accelerated approval, have not seen palbociclib in earlier line of therapy. Is that an approvable setting given the design of that trial? Given the fact you are approved for their indication, or does that in your view, preclude any regulatory approval for the drug? Thank you.

Ian Read - Pfizer Inc - Chairman and CEO

Okay, I'm going to do the notice first. We, at the moment, understand the Treasury are working on formalizing and regulating the first two notices they issued. Which are not, in many ways, applicable to our transaction as we are at the below 60% ownership.

I really can't speculate if there's going to be a third notice or not. We feel confident the transaction is fully within the US law, and fully within accepted interpretation of that law. And expect the transaction to close in the second half of next year. With that I'd go to growth with Frank and then ask I would ask Mikael to talk about palbociclib.

Frank D'Amelio - Pfizer Inc - CFO

It was China.

Ian Read - Pfizer Inc - Chairman and CEO

China.

Frank D'Amelio - Pfizer Inc - CFO

So, on China for the quarter, China grew 10%. Full year, China grew about 10%. Nice numbers.

Somewhat moderated from 2014. In 2014, China grew at about 15%. So we saw some moderation in the growth in China.

That said, Andrew we remain very bullish on China. It has an increasing population, increasing personal wealth. Government is committed to healthcare, we see increased spending in the government. And the GDP rate is still very healthy. Not as high as it's been in past, but still quite healthy. So, we remain bullish on the China market on a going forward basis.

Ian Read - Pfizer Inc - Chairman and CEO

Mikael?



Mikael Dolsten - Pfizer Inc - President, Worldwide Research & Development

Thank you Andrew, for a good question here. Two things.

First, I want to just point out that Abemaciclib it's somewhat different from Palbo and Novartis CDK drug in that it seems to be less selective, and has a different adverse event profile. Likely due to hitting multiple CDKs, particularly being reported significant GI issues. So it's a different profile, and we, as Albert very well pointed out, have been extremely pleased with a favorable profile that allow patients to benefit from Ibrance with very good tolerability.

Now, you asked about this late stage population studies by Abema, and how that population in the future will evolve. We anticipate, as Ibrance is having a very nice uptake in the marketplace, in first-line metastatic, and some also more advanced lines. And hopefully with PALOMA-3 approval Ibrance is likely to be used in multiple lines. Hence, monotherapy with another CDK, will of course, have the potential to face a patient population that have seen a CDK inhibitor.

And that's why we are developing a strategy for how we can see patients benefit from a drug like Ibrance, at various stages with different anti-hormonals and also now studying Ibrance in triple therapy. So I think you can see that multiple drugs is likely to be the preferred, as patients become more advanced.

Chuck Triano - Pfizer Inc - Senior VP of IR

Thank you.

Operator

Your next question comes from Vamil Divan from Credit Suisse.

Vamil Divan - Credit Suisse - Analyst

Morning, everyone. Thanks for taking the question.

Just, again, on the biosimilar front. There's a been a couple questions, but a couple more if I could.

One, specifically on Enbrel. And if you could discuss, in terms of 2016, how you're viewing the impact of biosimilars to your performance for that product?

And then second, now that Hospira has closed, this is a question for John. In terms of the value of having a biosimilar business under the same broad umbrella as your innovative business, so you can leverage that commercial infrastructure, for areas like Oncology and autoimmune disorders. Does it in anyway make more sense then to keep Pfizer as a single entity as opposed to splitting up and then needing to rebuild a commercial infrastructure for your biosimilars in those similar areas where you do have innovative products? Thanks.

Ian Read - Pfizer Inc - Chairman and CEO

Vamil, I'll ask Geno to talk about Enbrel and the impact to biosimilars in Europe.



Geno Germano - Pfizer Inc - President, Global Innovative Pharma

So, the first biosimilar for etanercept has been approved in Europe. And we've been watching the situation very closely, and evaluating adoption of biosimilars across each of the countries throughout Europe for awhile now.

Our overall expectation is that there will be somewhat modest impact in 2016. The biosimilar landscape is clearly still developing. There are different approaches taken by different countries. And we have a very clear detailed road map for how to address each of the dynamics that exist in these different countries.

So we're fairly confident that we'll continue to have a strong Enbrel business throughout Europe. We think the new patients would be probably most at risk of being exposed to the biosimilars. And hope that the availability of lower cost biologics will expand the market. So, overall, we see this as again, a modest impact to our business in the initial period of time.

Ian Read - Pfizer Inc - Chairman and CEO

And then, Vamil, a very interesting question on the connectivity between the biosimilars and the other space. I would say that would be taken into account if there was any such linkage that was positive in our TSAs, the way we set up the separate companies to insure that as overall, we maximize the value of that between both companies in the contracts we would sign, if we decided to split.

Operator

The next question comes from Steve Scala from Cowen.

Steve Scala - Cowen and Company - Analyst

First, apologies if I missed the explanation, but the 2016 guidance includes roughly an incremental \$4 billion in revenue and \$0.08 in earnings from Hospira, implying down to significantly down underlying sales for the legacy Pfizer and flattish to down EPS. And it seems that generic exposure and currency cannot be the explanations, because the predicted \$4.6 billion hurdle in 2016 from these factors is well less than the \$6 billion plus predicted in 2015 at this time last year.

So, actually the comparison on generic exposure and currency is improving. And more than offsets the year-over-year increase in Prevnar. So any thoughts on that would be appreciated.

And one more. How should we think about the long term outlook for Sutent particularly given the competition from Immuno-Oncology agents? Do you think Sutent will soon become a declining asset or do you see growth in the future? Thanks.

Ian Read - Pfizer Inc - Chairman and CEO

I'll ask Albert to talk about Sutent and its possible combinations. And the other studies we have reading out on Sutent. And then I'll ask Frank to come back on your questions about growth rates.

Albert Bourla - Pfizer Inc - Group President, Vaccines, Oncology & Consumer Healthcare

We remain very confident in our position in the RCC space. Especially, and that includes both Sutent and Inlyta. Because they are very well known by physicians and other stakeholders.

There is an approval in RCC for immunotherapy, but this doesn't affect Sutent. It is in the second line. Sutent is used primarily in first-line.

And we have also, as we have previously disclosed, we are studying Inlyta plus avelumab and Inlyta plus other PD-1 inhibitors very aggressively, so we can see better results in monotherapy in RCC second line.

Ian Read - Pfizer Inc - Chairman and CEO

Frank?

Frank D'Amelio - Pfizer Inc - CFO

Yes, Steve. Let's see if I can answer the question.

So first, we don't give a specific number for Hospira revenues for 2016. With that said I believe I can still answer the question.

So, the way I think about this is, if you went to the mid-point of the guidance prior to foreign exchange in Venezuela, which was part of the basis of your question. The mid-point of the guidance would be 52.3, we'll use the midpoint. If you take 52.3, compare that to the 48.9 that we printed in 2015, all now at the same foreign exchange so purely operational, that's an increase of about \$3.5 billion. We said, Ian said when he answered Jami's question, that revenue excluding Hospira on a year-over-year basis was essentially flat operationally while absorbing \$2.3 billion in LOEs for 2016.

The other data point I think to help answer the question is, remember, we did \$1.5 billion in Hospira sales this year. So, when we say the bulk of the growth is from Hospira you understand it's incremental growth on top of the \$1.5 billion that we printed in 2015. So that's how you get to the numbers we said and why we said operationally, the numbers were essentially flat if you left Hospira out of the equation.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Frank.

Operator

Your next question comes from Mark Schoenebaum from Evercore ISI.

Mark Schoenebaum - Evercore ISI - Analyst

Hi guys. How you doing? Thanks for being so clear on the communications in the quarter.

I have one question that's been danced around, but maybe let me just ask it again in hopes that I won't annoy you, but I'll try again. So the first is do you believe there's anything, Ian under the current US statute that would allow Treasury to block and/or materially delay the closing of the Allergan deal? So I'm not asking if there will be a third proposed notice, but if under the current law do you remain very comfortable that there's nothing that Treasury legally could do to block the deal or to materially delay it like into 2017 when there will be a new Congress and a new President?

And then I'd also just, for Frank perhaps, just like you talked a little bit about your leverage ratio. If my math is right, the leverage ratio of the combined Company the NewCo, should it close, would be around one. By my math, you could take that to maybe three without affecting credit ratings in a big way, but that's my math and I'm not very good at math. So I'd love to hear your general thoughts around leverage ratio of the NewCo and where you might be willing to take that should the deal close, thank you.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you Mark, for the compliment on the clarity of the communications. We strive to make them clear. So, on your question, which I don't think we danced around, under current law, I do not believe there is any reason why this deal will not close. Full stop.

Frank D'Amelio - Pfizer Inc - CFO

Mark, let me run some numbers. On leverage, let me run the Pfizer numbers based on third quarter. We haven't issued a balance sheet for the fourth quarter, we'll do that when we file the K.

We had about \$37 billion of cash and investments. We had about \$39 billion of debt, short and long term debt. So, to your point, call that one-to-one essentially.

And what we said when we announced the Allergan deal -- what I said, was we could take the leverage ratio to your point up to about 2.5 to 3. And, obviously once we took it there we would want to see what kind of rhythm that created relative to the Company. The operations supporting the Company, and that we take it there but that we would still want access to commercial paper.

We would be willing to take a one notch down grade, but still want to have access to commercial paper. But in terms of your math, and your calculation that 2.5 to 3, that's right. That is basically what I talked about when we announced the Allergan deal so your math was good.

Operator

Your next question comes from Marc Goodman from UBS.

Marc Goodman - UBS - Analyst

A few things. One is, can you tell us what the key products are in Venezuela if there are any massive ones we need to be hitting the model on.

Second, Frank, maybe you could go through some of the push/pulls on SG&A, and how you're thinking about the spending this year. And then third, can you just give us an update on the IL-6? Thanks.

Ian Read - Pfizer Inc - Chairman and CEO

So key products. I don't think there's any outstanding products. Probably Enbrel is the biggest product that contributes. John would you want to add anything?

John Young - Pfizer Inc - President, Global Established Pharma

Enbrel is the biggest product, and in addition we have a portfolio of mature, established products. So, Lipitor and Norvasc would be other key products for us in Venezuela. So really just think about the basket of established products and that fit in that marketplace.

Ian Read - Pfizer Inc - Chairman and CEO

SG&A?

Frank D'Amelio - Pfizer Inc - CFO

So Marc, on SG&A. Let me just talk to the quarter and then I'll talk to the rhythm of the numbers.

So if you look at the quarter, we had a big spend in SG&A. It was \$4.6 billion all-in, and three major factors there. One, obviously the inclusion of Hospira which added a couple hundred million.

Two was, sequentially, if you're thinking about the fourth quarter compared to the third quarter, we had a lot more selling days in the quarter. So internationally we had six more selling days, domestically two more selling days. So sequentially, Q3 of 2015 to Q4 of 2015, we had more selling days. So obviously that helps revenue, it also increases the spend on our line items.

And then we had, obviously I alluded to in my comments increased promotional spend in many areas of the business. Now, if you take that \$4.6 billion and you annualize it. Times 2 is what, \$9.2 billion times 2 is \$18.4 billion. If you look at the guidance we gave for next year on SI&A, it's \$13.2 billion to \$14.2 billion.

So you can't take that Q4 number and annualize it. You get to a number that's nothing close to our guidance for 2016. It was just a combination of the Hospira numbers, the selling days, and then increased spend in the quarter. But when you look at it for next year, we have a number that on an annual basis is significantly lower than what that annualized number will be.

Ian Read - Pfizer Inc - Chairman and CEO

Mikael Do you want to discuss IL-6?

Mikael Dolsten - Pfizer Inc - President, Worldwide Research & Development

Yes thank you for your question. So we tested IL-6 antibody in Lupus and Crohn, and while the antibody did show some activity, we found that the overall profile did not compete as well as many other real interesting immunology agents and odd opportunities we have in our very rich pipeline of 90 clinical programs. So this is part of prudent portfolio prioritization within Pfizer.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you.

Operator

Your next question comes from John Boris from SunTrust.

John Boris - SunTrust Robinson Humphrey - Analyst

Thanks for taking the questions, and for all of the clarity that you've given on the 2016 guidance. Ian, first question, on the timing around the breakup. I think you've indicated that integration of Allergan is very important. You've also indicated that you've had time to look even deeper into the Allergan portfolio.

As you think about integration, can you give us some more commentary around how you're thinking about mapping out integration? Some look at Wyeth and the massive amount of synergies that you're able to extract out of the Wyeth transaction, and are somewhat puzzled as to why you can't do that here. So any commentary around that.

Two additional questions, one on CDK 4/6 this one's for Mikael. Mikael, when you look at preclinical models, is there any argument or hypothesis around a drug that has to be given intermittently, that it might have less efficacy than one that's given on a continuous dosing? And is that supported by any preclinical models?

And then the last question just has to do with Xeljanz. Obviously a very important asset for you, not only in the US, but on the EU timing for filing. I think you indicated you wanted to have that filed before the end of the year. Just any update on what Europe is looking for within that filing to secure approval in Europe?

And then on psoriasis in the US? Any developments there? And on the modified release from a regulatory standpoint? And then, obviously with Enbrel seeing generic competition what have you done with your infrastructure in Europe to still keep some infrastructure in place to support Xeljanz if and when it gets approved?

Ian Read - Pfizer Inc - Chairman and CEO

Okay, so let's just quickly the last one first. We still have very strong expectations from Enbrel in Europe. As Geno was discussing, we aren't removing our support from Enbrel. So we expect to have full support for Xeljanz when it launches in Europe.

There was a somewhat of a slippage from, as you say, the end of the year to the beginning of this year on the Xeljanz application in Europe. We wanted to get it right, and make sure that it was in the best shape we could. And these things happened so there was a slight slippage on time on that.

Mikael, do you want to deal with this hypothetical on CDK 4/6?

Mikael Dolsten - Pfizer Inc - President, Worldwide Research & Development

Yes, thank you for the questions. And of course always, we would caution you can't speculate on things that haven't been studied in humans in comparative aspects.

But, we think it's important to hit CDK 4/6 hard for breast cancer. And when you do that with high doses, you'll get efficacy on the tumor, but also see some neutropenia. And that's why we chose the intermittent schedules, particularly seems effective for combination therapy with multiple agents such as anti-hormonals in breast cancer.

For other tumor types, we may explore various schedules for various combination of drugs. But, for breast cancer we think the chosen schedule with the combinations we have studied is very effective and works well.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Geno do you want to deal with the other questions that John asked on Xeljanz?

Geno Germano - Pfizer Inc - President, Global Innovative Pharma

Yes, John. I think the question in EU, as Ian already alluded to, we're now expecting our filing to be in the first quarter of this year. We're actually meeting with rapporteurs at this point.

We did generate additional data on immune function as a result of the discussions that we had with the regulators in the first submission. So, we feel that we have a strong package that we have responded to the information request that they had, and we're just tidying up the last few details and expect to put that filing in imminently.

Ian Read - Pfizer Inc - Chairman and CEO

And then psoriasis? There's a question on psoriasis.

Geno Germano - Pfizer Inc - President, Global Innovative Pharma

So psoriasis, as you probably know we received a complete response letter from the FDA on psoriasis. We have provided a backgrounder to the FDA, and we expect to meet with them also this quarter to follow-up on the components of the complete response letter. And once we know in more detail what their issues and concerns are then we'll determine the best way forward from there.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you. Frank do you want to deal with the synergy number?

Frank D'Amelio - Pfizer Inc - CFO

Yes, so we said when we announced a deal more than \$2 billion we gave you the timing in terms of when we would get that. Couple comments, John to your question.

I think first, why more than \$2 billion, why not a higher number? I think these are two companies that have done a lot on the cost reduction front. Significant reductions at both companies. I think efficiently run companies.

Two, not a lot of therapeutic area or overlap. Which is always kind of a trigger for synergy opportunities.

Third, if you look at the Allergan cost of goods sold, 2/3 of that from our perspective from a synergy perspective was unaddressable. It's their ANDA business and royalties. So not a lot we could do there.

But all that said and done, we're working now with the Allergan teams, with Brent, with Bob Stuart with Tessa. Ian, myself our leadership team here at Pfizer we've already launched a couple of operational teams. And we're starting to dig into this in much more detail, and if there's more there please know we're going to get it and we'll tell you about it. So, on a synergy front, there's more to come.

Ian Read - Pfizer Inc - Chairman and CEO

John, the purpose of this deal was not huge cost synergies. It was about driving revenue. Growth in the Innovative Business. Driving reasonably young portfolios, taking the products internationally, and then getting excellent capital allocation over the world.

So, we will get the synergies we can get but our focus is on growth, and a lot of questions on the call have been about growth. This is part of the solution to that, and also on really a good capital allocation.

Chuck Triano - Pfizer Inc - Senior VP of IR

Thanks, Ian.

Operator

Your next question comes from Tim Anderson from Bernstein.



Tim Anderson - *Sanford C. Bernstein & Co. - Analyst*

Thank you if I could go back to the revenue guidance, the mid-point is about \$2.5 billion below consensus. You flagged FX as a major headwind. I know that we spend a lot of time trying to incorporate FX, and I imagine consensus does too yet, that's still a very big delta. So, my question on this is when you look at analyst models are there particular revenue line items for products or divisions where you think consensus is too high unrelated to foreign exchange?

Second question, you mentioned the 4-1BB with Merck in showing combination data with Keytruda and that's Phase 1 data, so, as such it's unblinded. I'm wondering if you can give us a preview of the tumor types you think are most promising? And also any preliminary safety findings? And then last pipeline question. Last year you mentioned having an oral PCSK9 approaching human development and I'm wondering if that is now in the clinic, when I look at your pipeline chart I see a new compound has been advanced into Phase 1.

Ian Read - *Pfizer Inc - Chairman and CEO*

Okay, Frank if you could deal with the first question? And Mikael with the remaining two.

Frank D'Amelio - *Pfizer Inc - CFO*

Tim let me run the numbers and then I'll answer the question. So, your numbers are right.

So, consensus numbers give or take on revenue for 2016 about \$52.4 billion. The mid-point of our guidance \$50 billion, the math there is roughly \$2.5 billion that you alluded to -- to nail the numbers.

Two major pieces in terms of the gap. One is, clearly the Venezuela adjustment we made in 2016 wouldn't have been in the \$52.4 billion. So that's an \$800 million adjustment. That would take the \$52.4 billion to \$51.6 billion.

And then, I think when you look at the line items, the big difference if you ask me to point out one single place it's Prevnar 13. The growth expectations in Prevnar 13, 2016 versus our modeling for 2016 where I said in my comments and Albert punctuated in some of his detailed remarks, about we're expecting that to be essentially comparable to 2015 levels. Those are the two things that I would point out that make up the majority, big piece of the difference in terms of your \$2.5 billion.

Mikael Dolsten - *Pfizer Inc - President, Worldwide Research & Development*

So thank you for asking about 4-1BB. And as you know we believe that combination therapy will move the Immuno-Oncology field to the next level. We are very pleased with the 4-1BB monoclonal antibody that we have.

We have studied it in combination with rituximab, in lymphoma and with PD-1 Keytruda in a small study across various tumor types. And now also, initiated combination study with avelumab. The 4-1BB antibody -- the Pfizer antibody, shows very good tolerability when combined with other biological agents. And its clinical performance suggests also a very interesting favorable clinical activity on top of other biologicals, such as rituximab and PD-1 Keytruda.

We will share the data from this first cohort this year likely at ASCO. We are quite excited about 4-1BB and also look forward to that in our pipeline. And you will see 4-1BB avelumab data likely late this year as well as OX-40 monodata and early next year several doublets and triplets which makes me very enthusiastic as I look forward, how we advance this strategy of combination therapy.

We have an oral PCSK9 in Phase 1. It's too early to have any definitive interpretation of that data, and we also have a PCSK9 vaccine in late preclinical development.



Chuck Triano - Pfizer Inc - Senior VP of IR

Thanks, Mikael.

Operator

Your next question comes from Richard Purkiss from Piper Jaffray.

Richard Purkiss - Piper Jaffray - Analyst

Oh, thanks I had a couple of questions for Mikael. Just on Ibrance, can you flag any upcoming data for tumor types outside of breast cancer that we should look out for? Also, can you update on how well the adjuvant breast cancer studies are enrolling? Thanks.

Ian Read - Pfizer Inc - Chairman and CEO

Mikael would you like to?

Mikael Dolsten - Pfizer Inc - President, Worldwide Research & Development

Yes, I could say a few words. So, as Albert alluded to, there is a large number of Ibrance studies, the great majority by investing in initiated research. So we will have to see as these studies reach out report emerging.

I can say that we also have sponsor-lead studies outside breast, that includes pancreatic cancer and head and neck. And we are also looking at triple therapy in breast cancer.

I remain optimistic and excited about Ibrance performance. And think we will see interesting data sets coming from several of these new tumor types.

Ian Read - Pfizer Inc - Chairman and CEO

Enrollment? It's going well?

Albert Bourla - Pfizer Inc - Group President, Vaccines, Oncology & Consumer Healthcare

Yes actually, I can only add here that likely the mantle cell lymphoma and the head and neck. We may see data even this year. And then many of the areas that Mikael discussed, including lung we may see next year.

Ian Read - Pfizer Inc - Chairman and CEO

Okay thanks Albert and Michael.

Operator

Your next question comes from Geoff Meacham from Barclays.



Geoff Meacham - *Barclays Capital - Analyst*

Good morning guys thanks for taking the question. Just a couple of quick ones.

On Bococizumab, given Pfizer's experience in cardiovascular, I was just curious what your thoughts of the demand trends were looking peripherally at the PCSK9 class today. I know a lot, looking forward to outcomes data, but just curious about whether there's a tipping point, and position adoption.

And on biosimilars in the US, just want to get your view on where you think the FDA is with respect to extrapolation? When we're looking at the upcoming Remsima panel next week. Thanks.

Ian Read - *Pfizer Inc - Chairman and CEO*

Geno any comments?

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

Yes, I think I'd reinforce the comment that you made. It's been our contention all along that this class becomes a real class in managing patients with the cardiovascular outcome data that we'll be seeing either late this year or starting next year. Our program is advancing nicely.

We have, as you know, two cardiovascular outcome trials. And the ASPIRE-2 trial which is in the high risk patient population, we've now reached a point where we discontinued screening. We're almost completely enrolled, and that trial is moving along very rapidly.

And ASPIRE-1 trial will be completely enrolled by the end of this year, or early next year. So we're looking forward to these data and the impact we think it will have on the marketplace.

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

So on the Inflectra AdCom as you know it scheduled for February 9, next week. I think it will probably be premature to speculate on the view that the FDA will take. We certainly think that this will be extremely informative as to the FDA's views and perspectives on extrapolation.

I think, obviously the product is being filed by Celltrion so specific questions about the AdCom really should be directed to Celltrion. But what I would say is that while we obviously await the resolution of the advisory committee and certain other factors, we're certainly moving ahead with the preparation for launch plans in 2016.

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

Thanks Geno and John.

Operator

Your next question comes from David Risinger from Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Yes, thanks very much. I have three questions.



First, Ian besides the likelihood of closing, what do you think investors most under appreciate about the Allergan merger?

Second, these are two financial questions. One is with respect to Enbrel ex-US, could you just give us a sense for the percentage of revenue that is in countries where biosimilars are launching in 2016 so that we have a sense for the percentage of Enbrel revenue that's exposed to biosimilar threats?

And finally, Frank if you could just run through the cash flow outlook for 2016? The operating cash flow and then the planned use of funds? Thank you.

Ian Read - Pfizer Inc - Chairman and CEO

David your question on Allergan, our interactions with the shareholders both sell-side and buy-side have been very positive. I don't think in reality there's anything under appreciated other than the street's perception of risk around the close.

I would direct you back, of course, to the excitement I have about the products that Allergan have that they just launched. About their Phase 3 products, both in depression, and in diabetic gastroparesis, and they just got breakthrough status. And the combination of our information knowledge, and our TAs with Xeljanz around their area, our JAKs around their expertise in that area, I think perhaps the street is right now hung up on this close issue.

Geno Germano - Pfizer Inc - President, Global Innovative Pharma

David on the question regarding percentage of Enbrel business, potentially exposed to biosimilar competition, I don't have a figure on the top of my head. I would say more than 50% of the ex-US business would be in the European Union, where we expect to see biosimilars. We aren't expecting to see it in Japan, Australia and several of the Latin American countries, but I would say it's more than 50% of the business.

Frank D'Amelio - Pfizer Inc - CFO

The last question was on 2016 operating cash flow. The way I'll answer this Dave, is, if you look at our operating cash flow through three quarters, it was about \$10 billion. We expect the fourth quarter to be healthy in terms of the operating cash flow for the year. And then obviously 2016, we want to continue to grow that operating cash flow number.

And then in terms of the uses from our perspective, the uses of how we deploy our capital haven't changed. Obviously, investing in our business and our returning capital to shareholders. I mentioned in my remarks we returned \$13.1 billion to our shareholders in 2015 through a combination of dividends and share buybacks. And obviously looking at some bolt on acquisitions, if those make sense.

So, no change would be how I'd answer the question on capital allocation.

Chuck Triano - Pfizer Inc - Senior VP of IR

Thanks Frank.

Operator

Your next question comes from Gregg Gilbert from Deutsche Bank.



Gregg Gilbert - *Deutsche Bank - Analyst*

Thanks, also a three-parter. First, Frank what level of detail should we expect in the proxy in terms of your long term projections? Similar to the Pfizer Weyth documents or any differences and caveats you'd like to let us know about before folks start slapping accretion percentages on those numbers?

Secondly, going back to something you'll said earlier, taking your leverage to 2.5 to 3 times for NewCo, if you were to apply that capital to buybacks that would create EPS accretion that is far beyond what you've suggested. So would like your thoughts on what you'd be doing with that leverage or is that a hypothetical?

And third, for John do you still see the benefit of the Hospira device business alongside the drug business as you originally thought, thank you.

Ian Read - *Pfizer Inc - Chairman and CEO*

John could you deal with Hospira first please?

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

Yes sure. So I think we would say that in the Hospira infusion systems business, which comprises pumps, consumables, large volume solutions. We believe we acquired a very valuable asset that provides novel capabilities in an adjacent area. And it adds significant value to the customers and the patients. We are committed to insuring its success in short, medium and longer term.

Ian Read - *Pfizer Inc - Chairman and CEO*

Okay Frank on the leverage and then the level detail?

Frank D'Amelio - *Pfizer Inc - CFO*

Yes, so I think on level of detail, we'll be providing revenue details, EPS details, projected out I believe it's several years -- five years. So there will be information out there relative to projections on the Company.

On the leverage number the 2.5 to 3, in my mind that's what's possible. In terms of what we did on buybacks, we tried to provide information when we announced the deal to give you all of the data you needed so that when you connected the dots you could model what the buyback numbers would be, right?

So we started out with the accretion dilution. We said neutral in year one, modestly accretive in year two, more than 10% in year three, and high teens in year four.

We gave what the beginning share count number of the combined Company would be. It was 10.6 billion shares we said we would have 5.9 billion and Allergan would have 4.7 billion. And then we gave the tax rate which was 17% to 18%.

So with those data points we thought we provided the information that you needed in order to model what the buybacks would be. And just to the 2.5 to 3, clearly there could be some extra juice if we took the leverage ratio up to that level.

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

Thanks, Frank.

Operator

Your next question comes from Chris Schott from JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Great, thanks, just two quick ones here. First, more broadly on emerging markets, can you talk about the growth outlook here? Maybe on China just given the current economic environment we're seeing has there been any change in your growth expectations there?

And then the second question for Ian, I know you've had a very large deal pending right now. But how are you thinking about Business Development given the recent volatility and value ratio reset we see in the market?

What's the size and scope of assets that you could be interested at this point given the upcoming Allergan transaction? And maybe how quickly post the Allergan transaction could this Company start considering larger deals if there was an attractive opportunity in the market?

Ian Read - *Pfizer Inc - Chairman and CEO*

John do you want to talk about China?

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

Sure, as we always say Chris, on emerging markets we'll always see quarter-to-quarter volatility. But at the same time, we continue to expect to see growth numbers in the mid-single digit -- mid to high single digit range.

Frank's already talked about China. We continue to be positive about the prospects in the short, medium and longer term in China. It's obviously not just the world's largest country -- it's 1.3 billion to 1.4 billion population. But we continue to see a strong government commitment to expanding access to quality healthcare.

We're very encouraged by steps that we see the government taking in the regulatory environment to really enhance quality standards in the marketplace. And whilst there are a few headwinds, GDP growth is slowing but still positive, still mid-six single digit percentages. We are seeing some pressure in pricing. But overall, when you put all of those factors together, we continue to see China being a very positive growth driver.

Ian Read - *Pfizer Inc - Chairman and CEO*

Thank you, John. And on BD, Chris, we see it would be more focused to smaller deals than larger deals right now. But once we close, we'll look at the opportunities and we still have substantial flexibility.

And of course, it will be measured against the alternative uses of that cash which, right now, are scheduled for buybacks and the accretion equation. So we'll make the decisions that we believe are best for shareholders, and we'll take into account what the assets are priced at, at the time we close.

Frank D'Amelio - *Pfizer Inc - CFO*

And Chris, the only thing I'd add is we Pfizer standalone today generate a lot of operating cash flow. The combined new Company, we said by 2018, will be generating in excess of \$25 billion a year in operating cash flow. So the new Company will generate significant amounts of operating cash flow.



Ian Read - Pfizer Inc - Chairman and CEO

Thank you.

Chuck Triano - Pfizer Inc - Senior VP of IR

Last question please, Operator?

Operator

Your final question comes from Manoj Garg from Healthco.

Manoj Garg - ABR-Healthco - Analyst

Hi, it's Manoj. Thanks for taking the question. A couple on the pending Allergan transaction and one on next Tuesday's panel.

On Allergan -- one, if you can just highlight what some of the levers that would dictate whether the deal would close in early second half of 2016 versus later in the second half? Two, just for Frank, on the \$2 billion synergy number, if you could just quantify as we fine tune our pro forma model, if that's a gross number or a net number?

Ian Read - Pfizer Inc - Chairman and CEO

Okay on the levers, Doug Lankler could you indicate what you see the levers are for the close?

Doug Lankler - Pfizer Inc - General Counsel

Sure. So, Manoj, we're working closely with regulators. We're pleased with the process that we're making. We like the standpoint from the complimentary nature of the businesses, and as a result we continue to expect to close the transaction during the second half.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you.

Frank D'Amelio - Pfizer Inc - CFO

It's a net number. The synergy number is a net number. He asked whether it was gross or net and the answer is it's a net number.

Chuck Triano - Pfizer Inc - Senior VP of IR

Okay. That should do it thank you very much for your questions.

Ian Read - Pfizer Inc - Chairman and CEO

Thanks for your time everybody.



Operator

Ladies and Gentlemen this does conclude today's Fourth Quarter 2015 earnings conference call. Thank you for participating. You may now disconnect.

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IMPORTANT ADDITIONAL INFORMATION WILL BE FILED WITH THE SEC

In connection with the proposed transaction between Pfizer Inc. (“Pfizer”) and Allergan plc (“Allergan”), Allergan will file with the U.S. Securities and Exchange Commission (the “SEC”) a registration statement on Form S-4 that will include a Joint Proxy Statement of Pfizer and Allergan that also constitutes a Prospectus of Allergan (the “Joint Proxy Statement/Prospectus”). Pfizer and Allergan plan to mail to their respective shareholders the definitive Joint Proxy Statement/Prospectus in connection with the transaction. INVESTORS AND SECURITY HOLDERS OF PFIZER AND ALLERGAN ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS AND OTHER RELEVANT DOCUMENTS FILED OR TO BE FILED WITH THE SEC CAREFULLY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT PFIZER, ALLERGAN, THE TRANSACTION AND RELATED MATTERS. Investors and security holders will be able to obtain free copies of the Joint Proxy Statement/Prospectus (when available) and other documents filed with the SEC by Pfizer and Allergan through the website maintained by the SEC at www.sec.gov. In addition, investors and security holders will be able to obtain free copies of the documents filed with the SEC by Pfizer by contacting Pfizer Investor Relations at Bryan.Dunn@pfizer.com or by calling (212) 733-8917, and will be able to obtain free copies of the documents filed with the SEC by Allergan by contacting Allergan Investor Relations at investor.relations@actavis.com or by calling (862) 261-7488.

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Pfizer, Allergan and certain of their respective directors, executive officers and employees may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of the respective shareholders of Pfizer and Allergan in connection with the proposed transactions, including a description of their direct or indirect interests, by security holdings or otherwise, will be set forth in the Joint Proxy Statement/Prospectus when it is filed with the SEC. Information regarding Pfizer’s directors and executive officers is contained in Pfizer’s proxy statement for its 2015 annual meeting of stockholders, which was filed with the SEC on March 12, 2015, and certain of Pfizer’s Current Reports on Form 8-K. Information regarding Allergan’s directors and executive officers is contained in Allergan’s proxy statement for

its 2015 annual meeting of shareholders, which was filed with the SEC on April 24, 2015, and certain of Allergan's Current Reports on Form 8-K.

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This communication contains certain forward-looking statements with respect to the proposed transaction between Pfizer and Allergan. These forward-looking statements can be identified by the fact that they do not relate only to historical or current facts. Forward-looking statements often use future dates or words such as “anticipate”, “target”, “possible”, “potential”, “predict”, “project”, “forecast”, “outlook”, “guidance”, “expect”, “estimate”, “intend”, “plan”, “goal”, “believe”, “hope”, “aim”, “continue”, “will”, “may”, “might”, “would”, “could” or “should” or other words, phrases or expressions of similar meaning or the negative thereof. Such forward-looking statements include, but are not limited to, statements about the benefits of the proposed transaction, including anticipated future financial and operating results, synergies, accretion and growth rates, Pfizer's, Allergan's and the combined company's plans, objectives, expectations and intentions, plans relating to share repurchases and dividends and the expected timing of completion of the transaction. There are several factors which could cause actual plans and results to differ materially from those expressed or implied in forward-looking statements. Such factors include, but are not limited to, the failure to obtain necessary regulatory approvals (and the risk that such approvals may result in the imposition of conditions that could adversely affect the combined company or the expected benefits of the transaction) and shareholder approvals or to satisfy any of the other conditions to the transaction on a timely basis or at all, the occurrence of events that may give rise to a right of one or both of the parties to terminate the merger agreement, adverse effects on the market price of Pfizer's common stock and on Pfizer's operating results because of a failure to complete the transaction in the anticipated time frame or at all, failure to realize the expected benefits and synergies of the transaction, restructuring in connection with the transaction and subsequent integration of Pfizer and Allergan, negative effects of the announcement or the consummation of the transaction on the market price of Pfizer's common stock and on Pfizer's operating results, risks relating to the value of the Allergan shares to be issued in the transaction, significant transaction costs and/or unknown liabilities, the risk of litigation and/or regulatory actions, the loss of key senior management or scientific staff, general economic and business conditions that affect the companies following the transaction, changes in global, political, economic, business, competitive, market and regulatory forces, future exchange and interest rates, changes in tax and other laws, regulations, rates and policies, future business combinations or disposals, competitive developments and the uncertainties inherent in research and development. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The factors described in the context of such forward-looking statements in this communication could cause Pfizer's plans with respect to Allergan, actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements. Persons reading this communication are cautioned not to place undue reliance on these forward-looking statements which speak only as at the date of this communication. Pfizer assumes no obligation to update or revise the information contained in this communication (whether as a result of new information, future events or otherwise), except as required by applicable law. A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-

Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

Applicability of the Irish Takeover Rules

As the transaction constitutes a "reverse takeover transaction" for the purposes of the Irish Takeover Panel Act, 1997, Takeover Rules, 2013, (the "Irish Takeover Rules"), Allergan is no longer in an offer period and therefore Rule 8 of the Irish Takeover Rules does not apply to the transaction from the date of the announcement of the transaction and therefore there is no longer a requirement to make dealing disclosures pursuant to Rule 8.

Statement Required by the Irish Takeover Rules

The directors of Pfizer accept responsibility for the information contained in this communication. To the best of the knowledge and belief of the directors of Pfizer (who have taken all reasonable care to ensure that such is the case), the information contained in this communication for which they accept responsibility is in accordance with the facts and does not omit anything likely to affect the import of such information.

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