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PFE - Q3 2016 Pfizer Inc Earnings Call

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OVERVIEW:

Co. reported 3Q16 revenues of approx. \$13b and reported diluted EPS of \$0.21.
Expects 2016 revenues to be \$52-53b and adjusted diluted EPS to be \$2.38-2.43.



CORPORATE PARTICIPANTS

Chuck Triano *Pfizer Inc. - SVP of IR*

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Frank D'Amelio *Pfizer Inc. - CFO*

John Young *Pfizer Inc. - Group President of Pfizer Essential Health*

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PRESENTATION

Operator

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

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

Thank you, operator. Good morning and thanks for joining us today to review Pfizer's third-quarter 2016 performance. As usual I'm joined today by our Chairman and CEO, Ian Read; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Albert Bourla, Group President of Pfizer Innovative Health; John Young, Group President of Pfizer Essential Health; and Doug Lankler, our General Counsel.



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 2016. And this is located in the For Investors section in the lower right hand corner of the page.

Before we start, I'd like to remind you that our discussion during the call will include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. Additional information regarding these factors is discussed under the disclosure notice section in the earnings press release we issued this morning, as well as in Pfizer's 2015 Annual Report on Form 10-K, notably including Part 1, Item 1a, Risk Factors. And this is filed with the Securities and Exchange Commission and available at their website, as well as the Pfizer website. Forward-looking statements during this conference call speak only as of the original date of this call and we undertake no obligation to update or revise any of these statements.

Discussions during the call will also include certain financial measures that were not prepared in accordance with US generally accepted accounting principles. Reconciliation of these 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, November 1, 2016. You may also obtain a copy of the form 8-K at our website Pfizer.com/investors.

Also, any non-GAAP measures presented are not, and should not, be viewed as substitutes for financial measures required by US GAAP and have no standardized meaning prescribed by US GAAP and may not be comparable to the calculations of similar measures at other companies. We will now make prepared remarks and then we'll 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 & CEO

Thank you, Chuck, and thank you for joining our call this morning. During my remarks this morning I will briefly recap the highlights from the quarter and provide some comments on the strength and depth of our pipeline.

Starting with the quarter, we reported another quarter of solid operational revenue growth, marking our eighth consecutive quarter of operational growth. Excluding the impact of foreign exchange and the legacy Hospira operations, Pfizer's standalone revenues grew by 3% operationally.

Looking at each of our businesses. Pfizer's Innovative Health achieved another quarter of strong revenue growth due to the performance of key brands including Eliquis globally, Xeljanz, Lyrica, Chantix, and Ibrance primarily in the US. We continue to be very pleased with the performance of Ibrance. Since our US launch in February 2015 it remains the market leader for treatment of first-line HR positive HER2 negative metastatic breast cancer. As expected, we are starting to see a tempering in new market share growth. However, our total scripts continue to grow and we are focused on reaching additional metastatic patients currently receiving chemotherapy or hormone replacement therapy. Sorry, hormone therapy alone.

We also anticipate the publication of our Phase 3 PALOMA-2 study will occur by year-end and expect that the ability of our dedicated breast cancer field force to then detail on the strength of this data. It should allow us to achieve greater penetration into the later-adopting physicians, many of whom are potentially high prescribers for Ibrance.

A key milestone to grow the Ibrance franchise will be to secure approval in the EU, where we have filed and received a positive opinion from the CHMP in September. We expect the decision from the Commission later this year.

Also of note, both Eliquis and Xeljanz continue to generate attractive growth on a quarter-over-quarter basis. And Chantix in the US is benefiting from the publication earlier this year of the EAGLES study. Prevnar 13, sequentially we saw an increase this quarter in adult indication as flu season approaches and overall, the Prevnar family continues to perform in line with our expectations.

Turning to Pfizer Essential Health business. It achieved operational revenue growth, primarily due to the inclusion of legacy Hospira operations, and to a lesser extent from the Essential Health standalone Sterile Injectables portfolio. Excluding legacy Hospira, we experienced a slight operational revenue decline on a year-to-date basis; however we remain confident that the Essential Health portfolio has the potential to pivot to achieve modest sustainable growth.



We expect this shift to be driven by a combination of anticipated growth across the portfolio, including Sterile Injectables, anti-infectives, biosimilars, and emerging markets. Collectively they may provide an offset to our peri-LOE and legacy products portfolio, which by their nature are robust contributors to cash flow generation, but given they are multi-source generally decline in developed markets. As part of the Essential Health growth strategy, we anticipate continuing to refine the portfolio with business development activities such as the pending acquisition of AstraZeneca's late stage small molecule anti-infectives business and our recent agreement to sell the Infusion Systems unit to ICU Medical.

All in all, the PIH and PEH business are performing well and have been further strengthened by approximately \$40 billion of acquisitions we've done over the past year. This has enhanced our near-term growth potential by expanding our footprint in the highest-growth therapeutic areas including Biosimilars and Sterile Injectables with Hospira, Medical Dermatology with Anacor, Oncology with Medivation, as well as several smaller deals. These additions to our portfolio are bolstering near-term revenue-generation opportunities as our pipeline continues to mature and advance.

Turning to our pipeline, we remain confident that we have built a solid pipeline, targeting areas that have potentially meaningful clinical value for patients and will provide the largest return on investment for shareholders. Of particular note is our oncology pipeline. For Ibrance we have more than 60 research programs in breast and non-breast cancers, including squamous cell and neck cancer, metastatic pancreatic cancer and mantle cell lymphoma.

For Xtandi, the FDA approved the label update on October 20, to include important data from the first comparative trial that demonstrated safety and efficacy of Xtandi compared to bicalutamide. We believe these data will help physicians better understand the difference between Xtandi and bicalutamide for their patients living with metastatic CRPC, that's castration resistant prostate cancer. Similar to Ibrance, we hope to generate new data to drive increased utilization earlier in the treatment paradigm for prostate cancer.

For immuno-oncology we continue to execute our planned IO strategy of 10 programs in the clinic and 30 programs ongoing. Together with our partner Merck KGaA, we are on track to file avelumab for treatment of metastatic Merkel cell carcinoma by the end of this year in the US. And we just announced the European Medicines Agency validated for review our Market Authorization Application in the EU.

Over 3,000 patients have now been enrolled in ongoing avelumab studies. There are studies of avelumab as monotherapy and are completing recruitment in second-line non-small cell lung cancer and other smaller tumor types. However, we believe that doublets and triplets, that is the combination of avelumab and other IO drugs or chemotherapy are the areas of greatest potential for patients. And we are making targeted investments in support of developing clinical data to potentially advance these combinations.

We've initiated avelumab combination studies with chemotherapy and targeted therapies and expect to see updated data next year on Inlyta plus avelumab in first-line renal cell carcinoma. And rituximab plus 4-1BB in follicular lymphoma. We also anticipate data on avelumab plus 4-1BB next year.

In addition to avelumab, for the remainder of the year we have a study underway with other agents in our portfolio, including OX-40 as a single agent in combination with 4-1BB and avelumab in various tumor types. PTK7 ADC is showing encouraging activity in ovarian cancer in Phase 1B and combination studies with avelumab will commence in 2017.

Our IDO1 inhibitor is also in Phase 1 and we expect combination studies to start in 2017. Our clinical allogeneic CAR T-cell program with Cellectis and Servier is on track for recruitment in the UK ongoing.

In Inflammation and Immunology through our Anacor acquisition we have added Crisaborole to our pipeline for the treatment of mild-to-moderate dermatitis. It is currently under review by the FDA with a January 2017 PDUFA date. If approved, Crisaborole has the potential to be an important first-line treatment for the 18 million patients in the US who suffer from this significant unmet medical need. We are also exploring filing Crisaborole outside of the US.

We continue to see strong potential to expand the label for our anchor asset Xeljanz in diseases beyond RA, such as UC and psoriatic arthritis. We are excited about our next generation of selective JAK inhibitors currently in development. In CVMET in September we recorded positive Phase 3



data for ertugliflozin in partnership with Merck we're on track to submit New Drug Applications to the FDA for ertugliflozin and two fixed-dose combinations, ertugliflozin plus Januvia and ertugliflozin plus metformin by the end of 2016.

As you saw today, we announced the discontinuation of the clinical program for bococizumab. While these decisions are always difficult, we make these assessments in the best interests of our patients and our shareholders and in the context of the both the data defining the potential profile of the drug, as well as our view of the treatment and market landscape for the drug.

The discontinuation decision was made based on the totality of information available to us across two key areas. The first is the emerging clinical profile from our six completed Phase 3 lipid-lowering studies. Specifically, the longer-term efficacy data now in hand, including from two recently-completed 52-week studies in which top-line results were announced today, we had seen an unanticipated attenuation of LDL-cholesterol lowering over time. Additionally, we have observed an unanticipated higher level of immunogenicity and injection site reactions of bococizumab as compared to other agents in the class.

The second is the evolving treatment and market landscape for lipid-lowering agents in the PCSK9 class. In this market, the treatment's ability to impact CV outcomes is a significant value driver which requires long-term efficacy and durability of the cholesterol lowerer. And we have also recently seen payers establish access restrictions to the class which has meaningfully dampened our initial expectations for the market potential.

Taken together, the totality of the emerging clinical profile and the treatment and market landscape led us to the conclusion that bococizumab is no longer likely to provide value to patients or physicians or shareholders. And as a result, we determined the appropriate decision was to discontinue the development program.

In rare diseases, the acquisition of Bamboo Therapeutics complements our rare disease portfolio and enhances our leadership position in gene therapy. And with our partner, SPARK, we have seen data from the first seven patients being treated in our ongoing Phase 1/2 trial which is promising so far and has the potential to be a long-time therapy for the treatment of hemophilia B.

In vaccines we continue to advance the Staph aureus and Clostridium difficile programs which are both currently in Phase 2. We anticipate a C. difficile Phase 2 read out before the year-end. And assuming that it achieves its primary endpoint, we anticipate a potential Phase 3 start in the first half of 2017.

And in biosimilars we remain confident that we'll be well positioned in emerging biosimilars market with our broad pipeline. We recently announced that we would begin shipment of Inflectra to wholesalers in the US in late November. As you can see, we expect to have several key pipeline milestones between now and the end of 2017 across several therapeutic areas.

To summarize, for the remainder of this year we anticipate potential EU decision for Ibrance, avelumab filing in the US for Merkel cell carcinoma, ertugliflozin filing in the US and C. difficile proof of concept read out. In 2017, we anticipate potential US decision for avelumab Merkel cell carcinoma, potential lorlatinib submission in non-small cell lung cancer, potential EU decision for Xeljanz in RA, potential US filings in the first half of 2017 for label extension for Xeljanz in UC and psoriatic arthritis, and potential crisaborole decision in the US.

In addition, between now and the end of 2017, we expect up to 12 pivotal studies with top-line read outs. We have seven from oncology, including the first IO combination data read outs of avelumab, one from rare disease and four from biosimilars.

Over the past five years, we have worked to shape the quality of the assets in our pipeline. I believe we have a mix of competitive assets that are positioned to deliver new therapeutic breakthroughs to patients over the next few years.

Similarly, over the past three years, each of our businesses have gained a sharper focus, increased accountability and a greater ability to capture the opportunities within their unique markets. Today they have the independence and resources of standalone entities within Pfizer to effectively compete in their markets while having the benefit of the operational strength and financial flexibility associated with being part of Pfizer.



For example, we are now managing our Innovative Health business as five therapeutic-focused integrated businesses plus Consumer Health. We think of them as five small biotech companies, each concentrated on targeted areas of science and relevant patient groups. And having a clear focus on delivering value to patients and in turn to shareholders.

In conclusion, our business is performing well. We are taking steps to position Innovative Health and Essential Health for long-term success through competitive portfolios, pipeline investments in key growth areas that address the unmet needs of patients, and thirdly, the financial strength to continue to invest in the growth drivers that will enable both businesses to be key leaders in their markets. Now I'll turn it over to Frank who will go into greater detail and results 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 a reminder, because we completed the acquisition of Hospira on September 3, 2015, Pfizer's financial results for the third quarter and first nine months of 2016 include Hospira Global Operations while the comparable prior-year periods include only one month of legacy Hospira US and do not include financial results from legacy Hospira international operations.

In addition, Pfizer completed the acquisition of Anacor Pharmaceuticals on June 24, 2016. Consequently, our financial results for the third quarter and the first nine months of 2016 include three months of legacy Anacor operations which were immaterial. Finally, Pfizer completed its acquisition of Medivation on September 28, 2016, so financial results for the third quarter and first nine months of 2016 reflect three business days of legacy Medivation operations which were also immaterial.

Now, moving on to the financials. Third-quarter revenues were approximately \$13 billion and reflect year-over-year operational growth of \$1.2 billion or 10%, which was partially offset by the unfavorable impact of foreign exchange of \$224 million or 2%. Legacy Hospira operations contributed \$1.1 billion to Pfizer's third-quarter revenues in our Essential Health business. If you exclude foreign exchange and the contribution from legacy Hospira operations, Pfizer's standalone revenues grew operationally by \$381 million or 3%.

Innovative Health operational revenue growth was 10%, driven by the strong performance of Ibrance in the US, Eliquis globally, and Xeljanz, Lyrica and Chantix, all primarily in the US, which were partially offset by the loss of Rebif alliance revenue versus the year-ago quarter, due to the expiration at year-end 2015 of the agreement to co-promote Rebif from the US, lower Enbrel revenues in most developed Europe markets due to biosimilar competition, and expected lower revenues from Plevion 13 adult in the US, due to the high initial capture rate after its launch in the fourth quarter of 2014, resulting in a smaller catch-up opportunity versus the year-ago quarter.

Essential Health operational revenue growth was also 10% driven by the inclusion of legacy Hospira operations and to a lesser extent, from Pfizer standalone sterile injectables. Both of which were partially offset by the loss of exclusivity and the associated generic competition, primarily for Lyrica and Zyvox in most developed Europe markets.

Pfizer's standalone revenue in the Essential Health business, which excludes the contribution of legacy Hospira operations, declined 5% operationally as a result of the 7% operational increase in the standalone Sterile Injectables portfolio which was more than offset by a 15% operational decrease in the peri-LOE products portfolio and the 4% operational decline in the Essential Health standalone legacy Established Products portfolio. It's important to note that in emerging markets Pfizer's overall Essential Health revenues grew 9% operationally, due primarily to the inclusion of legacy Hospira operations and Pfizer's standalone Sterile Injectables portfolio and standalone legacy Established Products portfolio.

Third quarter reported diluted EPS was \$0.21 compared with \$0.34 in the year-ago quarter due to a charge related to the pending sale of Hospira Infusion Systems, decreased operating expenses, product losses of exclusivity and foreign exchange impacts, including the Venezuelan bolivar. All of which were partially offset by revenue growth in certain new, in line and acquired products, and lower asset impairment charges, and lower acquisition-related costs.

Adjusted diluted EPS for the third quarter was \$0.61 versus \$0.60 in year-ago quarter. The increase was primarily due to increased revenues, lower effective tax rate and fewer diluted weighted-average shares outstanding which declined by 105 million shares versus the year-ago quarter due

to our share repurchase program. All of which were partially offset by an aggregate operational increase and adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses of approximately \$1.1 billion, or 16%, which includes the addition of Hospira operations in 2016, a \$0.04 negative impact due to foreign exchange and continuing product losses of exclusivity.

I want to point out that third-quarter adjusted cost of sales as a percentage of revenues increased year over year from 17.4% to 22.7%, primarily due to foreign exchange and the addition of legacy Hospira operations. Also, because foreign exchange increased cost of sales while decreasing revenues at the same time, which is atypical, there was an exaggerated increase of our adjusted cost of sales as a percentage of revenues in the third quarter.

If you'll exclude the foreign exchange impact, third-quarter adjusted cost of sales as a percentage of revenue would have been 20.9%. Although we have experienced this for two consecutive quarters, we continue to view this as an anomaly rather than a trend, and we've narrowed our adjusted 2016 adjusted cost of sales as a percentage of revenue guidance within its original range.

Foreign exchange negatively impacted third-quarter revenues by approximately \$224 million, or 2%, of which approximately \$175 million was attributable to Venezuela. While FX favorably impacted adjusted SI&A and R&D expenses, the previously mentioned significant negative impact on adjusted cost of sales drove the overall FX impact of \$115 million, or 2% of our total adjusted cost. As a result, foreign exchange negatively impacted third-quarter adjusted diluted EPS by approximately \$0.04 compared with the year-ago quarter but approximately \$0.015 related to Venezuela.

As you can see on the chart, we've narrowed the ranges to certain components of 2016 financial guidance. We increased the low end of our revenue guidance range and we now expect 2016 revenues to be in the range of \$52 billion to \$53 billion. I want to point out that this range continues to absorb an anticipated \$1.8 billion negative impact from product losses of exclusivity and an anticipated \$1.4 billion negative impact from foreign exchange versus 2015, of which almost \$850 million is attributable to Venezuela.

I also want to remind everyone that as we previously communicated, there are seven fewer selling days in the fourth quarter of 2016 versus the fourth quarter of 2015. This will impact only the quarterly year-over-year comparisons, given that there are essentially the same number of selling days in 2016 as there were in 2015.

Because of our decision to discontinue the global clinical development program for boco, we now expect adjusted R&D expenses to be in the range of \$7.8 billion to \$8.1 billion and adjusted diluted EPS to be in the range of \$2.38 to \$2.43 which is still within our original range of \$2.38 to \$2.48. It important to note the mid point of our adjusted diluted EPS guidance range was negatively impacted solely to reflect this decision. Excluding this Boco decision, the midpoint of the range would have increased by \$0.02.

Moving on to key take-aways. We achieved our eighth consecutive quarter of operational revenue growth. In the third quarter of 2016 growth was driven by the inclusion of legacy Hospira operations, new products that are early in their life cycles such as Ibrance, Eliquis, and Xeljanz, as well as the solid performance from Lyrica and Chantix. We narrowed the ranges for certain components of our 2016 financial guidance.

We announced and completed the acquisition of Medivation and accomplished several key product and pipeline milestones. And we returned \$10.5 billion to shareholders through the first nine months of 2016 through dividends and share repurchases, including a \$5 billion accelerated share repurchase program. 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. - SVP of IR

Thank you, Frank and Ian. At this point, operator, can we please poll for questions?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - Deutsche Bank - Analyst

Thought I'd start perhaps for John, a two-parter for John. First on biosimilar Remicade. How would you set expectations on the launch in light of rebates and aggressive contracting by J&J? And any legal risk that you see that remains for Pfizer? And separately on the SIP business, which was very strong in the quarter, were there any temporary factors there that helped that?

And then for Ian, following your decision to, for now, not split the Company up, can you speak to your comments in the release that you will now move forward with a focus on strategic priorities to grow and increase operational efficiency to be more competitive and what that means? Thanks.

John Young - Pfizer Inc. - Group President of Pfizer Essential Health

Okay, thanks for the question, Gregg. So let me take the launch of Inflectra, first of all. Obviously we're very excited, very positive about the opportunities that we have. And that's based on the positive uptake that we've seen in the markets where we've already launched Inflectra. In fact, where biosimilars have launched, we have already seen around about a 26% volume share of branded Remicade switched to biosimilars of infliximab.

And so we believe that actually the marketplace, on a global basis, is really beginning to become more comfortable with the introduction of biosimilars. So in the United States we obviously are very positive about the opportunities that represents. And we look forward, as we've already announced, to introducing Inflectra towards the end of this year.

In relation to sterile injectables, obviously as you know, we are very focused on the combination of the legacy Hospira Sterile Injectable portfolio, along with the branded legacy Pfizer portfolio. The strong performance that we've seen in the Sterile Injectable business this quarter really is a reflection of the combination of the strengths of both of those portfolios together, both legacy branded Pfizer portfolio as well as the legacy generic Hospira Sterile Injectable portfolio.

And I think we're seeing, at a customer level, the combination of that much broader offerings to the customers really provides us with the breadth of portfolio that our customers value and provides us with a strong operational offering to customers right across the world. So we're very positive about that opportunity and how the business is performing. Thanks for the question, Gregg.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Greg. To your second question, my comment there really reflects that through this process, we've now established two very strong teams in both businesses. We've established metrics and comparatives. These teams are focused on producing strategies that indicate or ensure they're competitive within their comparison group and focused on generating returns that shareholders require. Thank you.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Ian. Next question please, operator?

Operator

David Maris, Wells Fargo.

David Maris - Wells Fargo Securities - Analyst

Good morning, Ian. Perhaps you could talk a little bit about pricing in the US specifically on Proposition 61. Most recent polling seems to show that if it were held today it would pass. The industry is fighting it. Can you describe what you think the impact would be on innovation and pricing, what the difference between what state agency pay versus VA pay for Pfizer drugs?

And then separately, we've spoken a little bit about this, but some have pointed to the supply chain, specifically PBMs, as being part of the problem in lack of transparency. Do you agree? And do you think if the US is willing to discuss price controls it should be willing to discuss PBM rebate controls? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

So let me take that. This is going to take a little bit longer given the extent of your questions on this. Let's just deal in general with the pricing situation and then we'll come back to the Prop 61.

So look, we obviously got pricing affordability an issue that is concerning to us and it's clearly been amplified in this election cycle. There is considerable uncertainty and turmoil about both candidates' positions on these issues. And it's difficult to decipher between campaign rhetoric and legitimate policy views. It's been disappointing that this debate on pricing has completely neglected the other side of the ledger, that is the benefits and value added by the pharmaceutical industry.

So while we understand healthcare costs have increased for many patients, we disagree with the prevailing notion among some politicians that pharmaceuticals are the reason for these rising costs. And we believe that post the election cycle, good public policy will prevail.

So currently in the US, you'll see it's a comparator, we spent 17% of our GDP on healthcare. Yet we only spent 2% on drugs while 12% GDP is spent on inpatient and outpatient services. We compare that to the OECD countries who spend approximately 9% of GDP on healthcare. They spend 1.5% of GDP on drugs and only 5.5% of GDP on medical services.

But for half a point of GDP extra on drugs between OECD and United States, you get a vibrant research-based industry that is producing roughly \$1.3 trillion of value to GDP. I think policy makers are well aware of the importance of maintaining an innovative pharmaceutical business.

Further, if you look at cost increases in the US from 2004 to 2014, hospital service costs have increased 75% while prescription drug costs have increased 35%. While faster than the CPI, they are lagging the overall medical costs of around 40% growth.

I think what's exacerbated the cost problem for patients is their insurance plans on average cover a much lower share, 83% actually, of prescription drug costs, compared to the cost of medical services where they cover 96%. So we're seeing insurance companies are making a choice of subsidizing health services more than drugs. You see this in their actions taken by increasing co-pays and shifting drugs into the overall deductible, which has pushed the issue with patients of affordability, but it's certainly not due to price increases because in 2016, the branded pharmaceutical industry took about a 2.8% on average net price increase.

I think the market is reacting to the fact that in the pharmaceutical business there are two markets. There's a market of branded, patent protected products which increased prices in 2015 to 8% and then a market of difficult-to-make generics or generics that have squeezed them where we've seen certain actors take what society believes is unreasonable price increases. So I think we can have better solutions if we look to how do we fix the policy issues and the regulatory issues that allow single suppliers, single source suppliers, and ease the pathway of those generics. Regardless of the election results, I'm not really concerned -- well, no matter the outcome of the Presidential race, we will continue to work with public officials.



That being said, let's talk to the rebate issue. Look, I think the rebates have served an important contribution to allowing negotiations on volume-related transactions. I think they are now becoming less helpful in getting cost-effective solutions to patients. And in reality, if we could find some way, and I think it would need a legislative fix, that we could find some way of ensuring that the pharmaceutical industry has an ability to moderate price according to volume solved for the cost to customers without rebates, I think that would be in the best interest of patients.

Now coming to the issue on Prop 61. If we voted today on the facts of the case, on the merits of the Proposition, it would be rejected by the California voters. We don't see any particular overall benefit in health care costs for California.

However, we are a highly politicized arena. It's difficult to say exactly what will happen on this Proposition. But once we know the results, the industry will then formulate its public policy and respond to it. I would like to say that what Prop 61 is asking for is basically untenable. It's asking for an industry that has given non-commercial prices to the veterans for a very good reason, they're a special part of our society. And we've given one commercial price to that part of society, you take that and extend it to the rest of government is not a workable economic model. So the Prop 61, between its floating and its implementation of six months, I would expect to see a lot of public policy discussions which we met on this implementation. Sorry for the length of that answer.

Operator

Geoff Meacham, Barclays.

Geoff Meacham - *Barclays Capital - Analyst*

Morning, guys, thanks for taking the question. Just had a couple on the bococizumab discontinuation. Obviously, this could have been a large commercial investment which now you'll save. Ian, can you put this into the context of Pfizer strategy in primary care? And what influence, if any, would this have on your appetite for bolt-on type of deals?

And then on the pipeline for Xtandi, now that you guys have TERRAIN formally in the label, how much of a tipping point do you think this could be for urologist adoption? I'm just thinking about the bigger M-zero population as you move upstream. Thanks, guys.

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

Thanks, Geoff. On the bococizumab, I don't initially have -- it doesn't have that dramatic implications. It's contribution to our EPS was modeled by most analysts as being moderate in the outer years. So per se, it's not an issue that creates a sudden need to change strategies. It certainly does indicate that we want to continue to make our decisions on portfolio based on what we believe will generate return. And we need to look at the substrate we had in cardiovascular to seeing how we strengthen our cardiovascular presence with more substrate. I'll pass it over to Albert to do the Xtandi.

Albert Bourla - *Pfizer Inc. - Group President of Pfizer Innovative Health*

Thank you, Geoff, for the question. For Xtandi going forward, we believe there will be continued momentum in the oncology segment. But importantly, as you ask, we believe there is a large intact opportunity within the urology segment which we believe will be catalyzed by the terrain label update.

Based on facts in Q3, 26% of Xtandi units were prescribed by urologists, up from 20% historically. Right now, we have approximately 2,000 urologists prescribing the product. And the recent market research suggests that 80% of urologists are highly compelled to prescribe Xtandi after seeing the terrain data. So I think terrain data publication and increasing in the label will be an important catalyst for Xtandi.

Operator

Jami Rubin, Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. I have a couple questions. First, Ian, on your decision to discontinue your PCSK9, it sounds to me like the only thing that has really changed is the emerging profile of your specific drug. The evolving landscape hasn't evolved yet because we don't yet have clinical outcomes trials for which we are waiting. I'm wondering if you saw something with your outcomes trials that you can share with us and any additional details on LDL-lowering end events.

And then my second question is back to the pricing question. Clearly Pfizer, along with many of your peers, have taken multiple price increases during the year, Pfizer is no exception. How do you see your ability to take price going forward? How should we think about price competition -- or contribution from price going forward? And also if you could break out what was price versus volume this quarter. Thanks very much.

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

Okay, on the LDL, on bococizumab, we're making a decision based on the profile of our drug, not on the profiles of other drugs. And on our profile, what we saw was that earlier on we did see we had ADAs. But we had data earlier on at 12 weeks and 24 weeks and we saw no substantial impact on LDL lowering. In fact, we continue to see a robust LDL lowering.

It was only recently that we got the data on the majority of our LDL trials out at 52 weeks. And out at 52 weeks, we saw a substantial population reduction in LDL lowering. We correlated that with neutralizing antibodies. And then we have the site rejection in one of our other -- the injection site reaction on some of our trials. So when you look at the total profile of our drug, we don't believe it could be commercially successful or in the benefit of patients for us to continue to bring that to market.

And then on the pricing issue, we have always priced responsibly. We priced to the marketplace the value of our product. And on the affordability issue we always made provisions for patients who have no insurance or poor insurance, to get our product free or nearly free. So I don't believe that there's any reason for Pfizer to change its approach to the pricing of our products, as we sit here today. Thank you.

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

Thank you, Ian. Next question, please, operator.

Operator

Steve Scala, Cowen.

Steve Scala - *Cowen and Company - Analyst*

Thank you. I have three. On Prevnar 13, year-to-date the franchise is down modestly in part due to the Q3 government purchases. To hit the full-year guidance of comparable to slightly down, it implies Q4 will also be slightly down. Is that how to look at it? That does seem better than the cautionary commentary that the Company provided, particularly that in August.

Secondly, now that Pfizer has had a chance to see Novartis's CDK4/6 inhibitor data, how would you compare and contrast the profile to that of palbo? And then lastly, the CTLA-4 from Oncolmmune is described in the press release as potentially differentiated. I'm wondering if you could elaborate on its potential differentiation. Thank you very much.



Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Steve. I'll ask Albert to answer the Pevnar question and then Mikael will handle the evolving profile of competitive products and our evolving profile and also the CTLA-4 question. Thank you.

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Thank you, Ian. The statement is exactly the same as we did it last time. Overall we expect the total full year Pevnar franchise revenues to be slightly down compared to 2015. As you said, we were down 2% operationally and that was driven primarily by the adult indication, which as expected, was down approximately 26% in the US. Notably the quarter sequentially grew 37% versus second quarter because we're entering a high flu season. And then in the international markets, and in the US pediatric, excuse me, in the third quarter we were up 21%. But this was driven by the volatility we see in this case. The CDC orders were much higher in this quarter.

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development

Yes, we are very excited and appreciative on the Ibrance profile that's been taken up extremely well by patients and physicians. It's viewed as an effective, really well-tolerated therapy and has had a profile for both metastatic breast cancer patients that has been great, and we see the profile being very suitable for what's early breast cancer and many other indications.

Now, we tend to not comment on other products. And as you know, it's difficult to compare across trials, but in contrast to other products, we have not seen issues with elevated liver tests, no issues with cardiovascular or QTC, nor issues with EI. Our product has been really well behaving and we think its profile works across the breast cancer segment, as well as in many other indications.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Mikael. CTLA-4 question, Mikael?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development

On the CTLA-4 differentiation. So when it comes to CTLA-4, our view --.

Ian Read - Pfizer Inc. - Chairman & CEO

I think he's referring to potential license and opportunity we have.

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development

Oh, okay. Well, thank you for that. As you know, the CTLA-4 agents are quite powerful, but have been limited by quite some systemic adverse events. We do look at having the most comprehensive IO portfolio combination portfolio in the industry. And as you know, we're quite excited about some of our existing assets like 4-1BB, as a great partner to PD1, PDL1, OX-40, IDO1, all of these advancing in our portfolio.

We do obviously assess the CTLA-4 class but the type of drugs we are looking at would be a CTLA-4 variant that would have some best-in-class properties that would retain efficacy but attenuate the [addressmental] function. Ad those are the ones we are looking at evaluating and that would fit with our view of immuno-oncology product to be efficacious but easy to administrate and well tolerated.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Michael.

Operator

Jeff Holford, Jefferies.

Jeff Holford - Jefferies LLC - Analyst

Hi, thanks very much for taking my questions. First of all, on Enbrel, I wonder if you could give us a bit more color on the market dynamics there for pricing and switching in markets where you have biosimilars.

Second, on Ibrance, I guess the prescription data is beginning to suggest that in the United States, at least, you may have reached a duration of therapy out there in the market. I wonder if you could give us a bit more color of what duration of therapy looks like in first-, second- and third-line patients.

And then in general, sounds like you remain pretty committed on cardiovascular as a therapeutic area. Just how and when will we see you build that out further in terms of developing pipeline assets there? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you. I'm going to take cardiovascular on first. As we sit here today, we have good assets in cardiovascular. We think it's an important area and we'll continue to look for ways of strengthening our position there to ensure that we can be part of cardiovascular.

Of course, like all of our therapy areas, we review these on an annual basis and make decisions on where we want to go and how much we want to invest. None of this will be an exception this year when we once again look at our long-term strategies in all of our therapeutic areas.

I can ask Albert to answer the Enbrel and Ibrance question, but I'd like to point out with Ibrance in the marketplace, we're very pleased with the reaction from patients and physicians for the treatment of Ibrance and it's relatively benign side effect profile. Go ahead.

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Thank you, Ian, and thank you, Jeff for the question. In the third quarter revenues for Enbrel were down 12%. This decline reflects the negative impact from biosimilars in Europe that were launched late in Q1. We have been preparing for biosimilar competition for quite some time. And to try to continue to differentiate Enbrel by generating new data, by enhancing the patient experience, and of course by leveraging our expertise in inflammation.

For the remainder of the year, we expect continued modest uptake of biosimilars. But due to our limited long-term safety and efficacy data, we anticipate the usual primarily in new patients, as physicians look to gain experience with these problems.

On your question on pricing. So far, of the limited pricing we have seen to date for Benepali, the discount letters are in line with our expectations and we expect Enbrel's pricing to be competitive. In Norway or in Denmark, where Benepali won national tenders, let me say no idioms, top is the outcome of their tender and Benepali won the tender with a 47% discount, while Enbrel provided a 41% discount. But it is important to note that the tender process in Norway is not indicative by any means of the pricing practices, entrance, typically seen in other markets across Europe.



Now, let me speak about Ibrance. Ibrance had a terrific launch and has quickly become the standard of care. Since launch, has been prescribed by more than 8,500 physicians, reaching more than 40,000 patients. This rapid uptake is a testament to its efficacy and its outstanding safety and tolerability profile. Very low rate of grade 3 or 4 GI side effects such as fatigue or diarrhea.

Now as expected, given this performance, we are starting to see some tempering of growth. But let me clarify that recent reporting changes at IMS due to some specialty pharmacy consolidations, might be modeling the orders and not showing an accurate picture. Based on our data, we continued to grow in scripts by 9% in the third quarter versus the second quarter of 2016, sequentially, which aligns with our own net sales growth of 7% quarter after quarter.

Now moving forward, our strategy with Ibrance is evolving. So far growth of Ibrance has come from establishing the product to early-adopting physicians. We believe growth in the next three years in the US will come from late adopters, but have limited prescriptions so far. We are now moving to the second phase of our strategy and building a dedicated sales team and fee-based medical organization to maximize this opportunity. In addition, the publication of our Phase 3 PALOMA-2 study data, which we anticipate to occur by year-end, will be important additional data for these late-adopting physicians.

Now, outside the US, additional growth will come from our geographical expansion. As you know, Ibrance is registered in the US and now in 20 more countries. And we have received positive opinion from CHMP Europe and expect registration later this year. And last but not least, in the mid-term the growth will come from the many studies currently running to move to earlier lines of breast cancer.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Albert.

Operator

John Scotti, Evercore ISI.

John Scotti - Evercore ISI - Analyst

Hi thanks for taking my questions. Initially for Ian, so I wanted to ask a corporate strategy question. I wanted to get your sense on appetite potentially for other actions, from a corporate strategy perspective, in addition to M&A, given that you decided not to split, et cetera. So things like spin-outs of business units, such as consumer, shock and awe, buy-back.

And then, of course, also any color on the M&A environment right now. Are you still in the market for a transformative deal? And what are your therapeutic added categories of interest?

And then finally on IO, I wanted to ask what your thoughts are in the probability of success of your study in the first-line PD-L1 positive setting for avelumab reading out next year? Do you have the ability to change the PD-L1 cutoff?

And then based on your current thoughts on how the market will play out, do you intend to move IO-IO combos or chemo combos into Phase 3? And when should we expect those registrational trials to start? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, John. On the corporate strategy issue around the use of our cash flows, we have always had a combination of use of cash flows between buy-backs, dividends, investment in our portfolio, also business development. That combination is what we continue to try to maximize.

So I would say today on the M&A part of it, on the business development part of it, our appetite for continued acquisitions or investments in business development remains firm, that if it can improve the return to shareholders, we would act on it. And I don't believe that we're limited in the size of the deal we could do.

That being said, clearly, if you do it in therapeutic areas you're already well established in, you tend to get more value because you get the value of the synergies in that area. So you tend to be looking to do deals in the areas where you're already strong.

Secondly, I do think that the whole industry is on pause right now in major business development while we wait to see the consequences of primarily, I would suggest, tax policy on the results of the elections. Thank you, I'll pass it over to Albert to deal with the other questions. Not Mikael, sorry, I apologize. It's Mikael.

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development

Thank you, Ian. I think the way we approach clinical trials is always to be agile and adapt to new information. Clearly, we have taken notice about the impact of high PD-L1 for response in first-line lung cancer. We are reviewing how to best execute the design of our trial and you can be certain that we will incorporate the most appropriate design to maximize likelihood of success. Certainly we are encouraged that our drug and the class will do well in PD-L1-high lung cancers.

Now when it comes to opportunity to advance the class further, I really appreciated your question because I think in 2017 and 2018 you'll see Pfizer propel us among the leaders when it comes to combination therapies. We aspire to have up to six triple therapies in the clinic by 2018 and up to four of them in the clinic by the end of this year. That will include treatment IO agents such as 4-1BB, avelumab and OX40.

It will include doublets and triplets with chemo and IO agents. It will include also combinations with other emerging drugs in our pipeline, whether targeted drugs, as well as combination drugs such as antibody drug conjugates, small molecules like IDO. I think what you will see is across many solid tumors, some of the larger tumor cases, lung, ovarian, gastric, as well as in blood cancers, a large set of trials that will be doublets and triplets and will address the need to further augment the promising results of immuno-oncology as well as deal with the colder tumors that [inaudible].

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Mikael. I'd like to add to that the commercial importance is that we have all of those agents in house and will enable a more efficient and focused relationship for the payers.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks Mikael and Ian. Our next question, please.

Operator

John Boris, SunTrust.

John Boris - SunTrust Robinson Humphrey - Analyst

Thanks for taking the questions. First question for you, Ian. It's been bantered about that there could be a repatriation bill. If there was one, what would the dynamics of that repatriation bill need to look like for you to consider repatriating some of the \$80 billion that you have trapped offshore, that you might potentially like to bring back to the States to put to use?

Second question on pricing. I don't think you answered Jami's question on price-volume and the contribution there. But delving on pricing a little further, certainly McKesson and Cardinal have indicated they expect significantly less price increases next year. Is your innovation product group and your established health group anticipating a similar level of increases to what they took in 2016? Or less of increases as have been evidenced by what McKesson and Cardinal have said?

Then lastly on Xeljanz. Any update on the European review on Xeljanz and the timing for potentially supplementing that with ulcerative colitis and the psoriasis data. Thanks.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, John. Albert, could you deal with the Xeljanz question first?

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Yes. Let me say first of all that the Xeljanz continued robust growth. This growth is primarily due to increasing confidence as a monotherapy agent and includes Xeljanz in the ACR guidelines, introductions for Xeljanz XR, and growing brand awareness among patients.

Now, to your question. We are expanding Xeljanz both geographically and therapeutically. Geographically, we are moving it to Europe. As you're aware, in March the EMA accepted our application for the treatment of moderate to severe RA. The application provides additional information to the original submission.

It includes data from the oral development program which consisted of six completed Phase 3 clinical trials, plus two open-label long-term expansion studies, one of which is still ongoing. While we cannot speculate what would be European authorities' decision, we are very confident on the strength of the data. The discussions are going very, very well.

On the UC and psoriatic arthritis, we are continuing the development of those three indications. We have high, they represent high unmet medical need, and as a result high potential commercial potential. And we plan to file in 2017, is the answer.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Albert. Frank, do you have the numbers on pricing?

Frank D'Amelio - Pfizer Inc. - CFO

Sure. As you mentioned before, Ian, we have been and we are and we expect to continue to be, responsible players when it comes to pricing. In terms of the absolute numbers, if you look historically on a total Company basis, enterprise-wide, our price impact on any given year is plus or minus a range of low single-digits.

And that's what we are seeing again this year on the plus side, a low single-digit increase. That's what we've seen historically, that's what we are seeing again this year. And obviously for 2017, John asked about 2017, when we provide our 2017 guidance in January, we'll also talk about major assumptions relative to pricing.

Ian Read - Pfizer Inc. - Chairman & CEO

And John, as I've said before, on pricing, we're going to continue to use the philosophy we've always used, which is to look at the value of products, look at it in the context of the marketplace, handle the affordability outside of insurance by our programs that allow people without insurance or



poor insurance to get it for free from Pfizer. So I don't see any, and I don't expect at this moment in time, that there's going to be any dramatic change in Pfizer's policies there.

Now on repatriation, I would hope that Congress, with the administration, will reform the international tax code as soon as possible next year. I think it is highly uncompetitive and negative to business and jobs in the United States. So I would hope they would reform it in terms of not only repatriation, but going to a territorial system or another title system that permanently puts us on a level playing field with foreign companies. I can't really speculate on how they are going to do exact mechanisms, but we would evaluate the law they pass and we would make the appropriate decisions and we'd see what they're proposing. Thank you, John.

Operator

Richard Purkiss, Piper Jaffrey.

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

Hi, thanks. Two quick questions, if that's okay. Could Frank just run through if there are any specific FX moves that are driving higher COGS in the third quarter?

And then just a question on biosimilars for John. Do you think the branded injectable industry is as complacent now as the branded pill industry was in the first half of the last decade? Thanks.

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

So I'll take the FX question first, which is there's really two things driving the impact on, I'll call it gross margin. I know you used cost of sales, it's easier to do FX. One is FX negatively impacted revenues by \$224 million or 2%. It also negatively impacted COGS by \$189 million.

Now typically FX, it operates like an ocean tide. Everything rises, everything falls, in the same direction. But we had an atypical move this quarter. We actually had it last quarter too, very unusual, where revenues were down, COGS were up.

So if you look at our cost of sales as a percentage of revenue this quarter, 22.7%. If you remove the impact of foreign exchange, that 22.7% becomes 20.9%. So FX had a material negative impact overall on cost of sales.

By the way, this kind of atypical relationship between revenues and cost of sales and we don't expect it to continue in 2017. We do expect it to continue next quarter. And it's really being driven primarily by Japan and within Japan, obviously the yen, based on what's going on there relative to the currency fluctuations of the yen and the amount of in-market inventory that we have there. But net net 22.7% becomes 20.9% for the quarter.

John Young - *Pfizer Inc. - Group President of Pfizer Essential Health*

So Richard, thanks for the question. I certainly wouldn't characterize the industry or specific companies as complacent, but I think we would always say, obviously, the life blood of any Company is its ability to innovate. But where there are important treatments that are coming towards the end of their period of patent protection, we, as you obviously know, are very positive about the opportunities that biosimilars represent to be able to bring treatment options to patients that actually can add real value to the healthcare system. And so we are very focused on what we can do to bring that value to healthcare systems and patients and depositions in the US and around the world.



Ian Read - Pfizer Inc. - Chairman & CEO

Yes, I don't accept the comparison to small molecules to sterile injectables. Sterile injectables is an incredibly complex process and it's high-capital and needs constant focus on quality. The FDA is very active in ensuring that they meet those qualities. So I really don't think that the risk and return on capital in the sterile injectables could be compared to the small molecule business.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Ian.

Operator

Chris Schott, JPMorgan.

Chris Schott - JPMorgan - Analyst

Great, thanks very much. Just two questions here. The first coming back to Ibrance. Is there any numbers you can put around how large the opportunity is for this next cohort of physicians that you're planning on targeting post the PALOMA-2 publication? What percent of market does that represent or percent of physicians does that represent?

And the second was just staying on Ibrance as well, when we think about the EU opportunity for the drug, how should we think about both the launch and size of that opportunity relative to what we've see in the US? How would you compare and contrast the uptake we've seen here versus what you hope to see as we roll out in Europe?

Ian Read - Pfizer Inc. - Chairman & CEO

Albert?

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Yes. I will try to give you magnitude of elevation. We do have very high penetration among target physicians in the US. So many of them in the range of 20% are prescribing. But the vast majority only prescribing one to three prescriptions so far. So they are just testing the waters for the product. This is where the opportunity is coming. And this is why we have developed a specific force and this is why I think the publication of PALOMA-2 data will catalyze this.

In terms of the EU markets, I cannot obviously give you a forward-looking statement on our focus. But we aim for leaders with Ibrance there. And we think that we've had very robust plans. We have built our sales forces. We are expecting the approval now with one of the most comprehensive compassionate-use products that Pfizer's ever launched, more than 1,000 patients on Ibrance. And we are looking to the future with a lot of optimism.

Ian Read - Pfizer Inc. - Chairman & CEO

I'll just add to that to your question on the EU and the US and the only sort of thing I could say to you is if you look at our experience with Sutent, or perhaps the industry experience, you normally see that the European markets are once you have the endorsement can be as robust as the US market in specialty high-value drugs.



Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Ian.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - Leerink Partners - Analyst

Thanks very much for the question. So just a couple here. First off, can you guys talk a little bit about the scale in the Consumer business as it sits today? And your interest in expanding and building out those assets, as well as the argument for its fit inside the Innovative business rather than the GEP business?

The second question is excluding product-specific issues, if you were looking at the PCSK9 market and the class with fresh eyes today, given your comments about the market itself, would you still view this as an attractive area for new investment for Pfizer? And then the last question is as we look at and consider the market opportunity and your considerations in IO, I would argue that it implies either a unique ability to displace existing players or a larger market opportunity. Can you give us your thoughts on which of the two you see for Pfizer going forward? Thanks.

Ian Read - Pfizer Inc. - Chairman & CEO

So on the IO, there is both opportunities. You're going to expand by the combination therapies tumors that today we call cold, they don't react, they don't benefit from PD-L1 therapy. And you also see a replacement ability because we expect to have our efficacy with these combinations in triplets. So I think on the IO we'll get both of those if we're successful.

On the PCSK9 question, if you ask me would I today begin a new PCSK9 program, the answer is no. We're too far behind. And on the Consumer business, it's a valuable business. It's growing well. We're investing, we've made acquisitions, but like all other businesses, they are all -- we all look at them and we subject them to tests of are they worth more inside or outside of Pfizer? And we'll continue to run those tests. Thank you.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Ian.

Operator

Marc Goodman, UBS.

Marc Goodman - UBS - Analyst

Yes, on Ibrance, can you give us the penetration rates for first, second and third line so we can figure out where we are and how much is more to go? And then second question, remind us what the next milestone is for the Medivation PARP. And third, can you give us an update on China and how that's doing in the quarter and year-to-date and what the trends are there? Thanks.

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Okay. For Ibrance, belated, but I saw them today in my office, we have about 50% in first line and 50% in second line of markets there.

Ian Read - Pfizer Inc. - Chairman & CEO

Okay, thank you. Medivation, Mikael?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development

Yes, thank you for asking about the PARP inhibitor. I think it's really a growing drug class which was fueled by very promising data that was presented at ESMO. And within that class we are very excited about talazoparib because of its very strong potency and also that it has a potentially unique differentiation with what is called PARP trapping.

When it comes to the near-term opportunities, we have a Phase 3 trial called EMBRACA, which is in BRCA-mutated breast cancer that has a read out due next year, possibly middle of the year. We look forward very much to see that data set as we think that the talazoparib and PARP class in these types of sensitized tumors with DNA repair deficiency, can perform very well and supplement other therapies.

I wanted just to punctuate that the existence of this BRCA and other DNA repairs deficiency now goes into a number of cancers and opportunity is likely much larger than earlier anticipated. It's not just breast, ovarian, but also increasingly seen in prostate and lung. And these tumors often carry a high mutation burden which allow us uniquely to combine talazoparib with the immune-oncology product. And of course that can include doublets like avelumab and potentially even triplets. So I think you should really keep an eye on what we may be able to do with our really comprehensive opportunity to move this asset standalone and in combination.

Ian Read - Pfizer Inc. - Chairman & CEO

Thanks.

Frank D'Amelio - Pfizer Inc. - CFO

And the numbers on China. For the quarter, operational revenue growth, 16%. Year-to-date operational revenue growth, 10%. And we remain bullish on China, decreasing population, increasing personal wealth, increased government commitment to healthcare spending, strong GDP, although moderated somewhat. But net net, doing very well there and we remain bullish.

Operator

Andrew Baum, Citi.

Andrew Baum - Citigroup - Analyst

Couple of questions, please. First, going back to the PBMs which are clearly striving to deliver value for their shareholders. CVS pulled Xtandi and Taigna two oral cancer drugs from their 2017 formulary. Given and following your acquisition of Medivation, plus your existing compounds, the contribution from all cancer drugs in your portfolio is going to be highly significant as we go out five years. Within those categories, there's going to be three CDK-6s, probably five ALKs. Xtandi, as we mentioned, is already gone. I guess what I'm driving at is, what do you see the risk that PBMs will alight upon oral cancer drugs and therefore their vulnerabilities given your exposure in that area.

And then second, on ribociclib the toxicity that's been reported for ribociclib, Mikael you mentioned that yours is behaving very well. There's been case reports of hepatic failure with palbo. What do you see more broadly in the real world practice? Do you think what you're seeing or what Novartis is seeing with the ribociclib is due to CV6 activity? Or just simply off-target activity of their particular molecule? Or are you seeing anything to suggest that may be mechanism and may in fact impact your molecule as well? Many thanks.



Ian Read - Pfizer Inc. - Chairman & CEO

On the PBM question. You know, Xtandi was being managed by Medivation and we probably have more extensive and deeper relationships with the payers than Medivation, so that's one. Two, while I think that PBMs will take a hard look at what they can achieve, you have to realize that there's a huge emotional content around oncology and a huge impact on lives saved, value of life months added.

And even in countries like the UK, you've seen them have to react to outrage from the population of lack of access. So I think you'll see a good balance in our society between access and pricing and the efficacy of the drugs. So with that, I think we have the Ibrance question and Medivation and we go to Mikael?

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development

We are always careful to comment on other companies' drugs, but I hear you saying that ribociclib has had reports on cases with liver and also with cardiovascular. And as you heard from Albert and myself, Ibrance has performed extremely well. It has a very nice tolerability appreciated by patients and physicians. We haven't seen these type of issues with our drug, so I'll likely conclude it doesn't seem to be related to CDK4 and 6. But I'm careful to comment on other companies' drugs.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Mikael.

Operator

Tim Anderson, Bernstein.

Tim Anderson - Bernstein - Analyst

Thank you. A few questions. On Xeljanz can you talk about the US reimbursement outlook heading into 2017? It's a crowded category, lots of moving parts in that marketplace.

Second question on PBM, going back to the very first question you got, but asked differently. Do you think that there's going to be a material change in the relationship between pharma companies and PBMs going forward over, let's say, the next three years? Whether it's a good relationship or not, do you foresee that there's actually going to be a material change?

And then a last quick question on CTLA4 again, and I know it's pre-clinical but you did call out differentiation. You're not in humans yet. I'm wondering what gives you the basis to think that that might have a differentiated clinical profile?

Ian Read - Pfizer Inc. - Chairman & CEO

Okay, Xeljanz.

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

The current growth of Xeljanz, this is very impressive, 86%, is driven by primarily by the increasing confidence for Xeljanz as monotherapy, inclusion in the ACR guidelines. There is an introduction of Xeljanz XR and growing brand awareness among patients. All of these reasons, plus our extensive



relations with payers are driving to us having increasing in access. Right now, we think that the access is going to be much higher in 2017 than it is in 2016.

Ian Read - Pfizer Inc. - Chairman & CEO

On PBMs, we work with PBMs. They had played up-to-date a role in improving access and reducing cost for patients. I think the issue of the size of the rebates and the net pricing and the general focus on getting pricing transparency could have a marked change, but it would require legislative change.

I don't think absent legislative change, I think the market will be stable around the PBMs. So just depends what happens when the new administration, Congress is in and how much they want to get rid of this issue of having high gross prices and low net prices, which I think today we would say it's a disservice to patients, especially those not insured or poorly insured.

Mikael Dolsten - Pfizer Inc. - President of Worldwide Research & Development

I really appreciate, Tim your interest in how we try to build an industry-leading combination portfolio. And as you know, we have up to 10 different immuno-oncology products. And as I stated, we will have six triplets by 2018, multiple doublets in 2017, and four triplets.

Among the many opportunities, given that we think there are ample potential to expand IO beyond what we've seen with single therapies, we do evaluate and defeat a full monoclonal antibodies that you came back to. I tried to stay at the high level because I don't want to, in detail, reveal what type of approaches we are considering. But basically, we think there are opportunities to potentially see a second generation also of CTLA4 that will deliver the benefit that you see in the tumor, but possibly have a better safety profile. And we do look at CTLA4 that could have this differentiated profile.

As you have noticed our agreement with Oncolmmune as one example. And then maybe several opportunities to tailor next generation of CTLA4 antibodies to potentially have such a differentiated profile. So that's why we are eager to try to add this to our nice collection of IO agents. But I have to obviously be careful in not revealing what we think are the unique opportunities that we are assessing. As our portfolio matures, we'll talk more about them.

Operator

David Risinger, Morgan Stanley.

David Risinger - Morgan Stanley - Analyst

Yes, thanks very much. I have two questions. First, with respect to biosimilar Remicade, do you believe that the NOR-SWITCH trial will be relevant at all to US payers or the US medical community? And then second, for Frank, could you comment on the operational efficiency opportunities that you foresee in the future for Pfizer? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

Okay, John?

John Young - Pfizer Inc. - Group President of Pfizer Essential Health

Okay, so thanks for the question, David. So obviously we think that the increased data on biosimilars and the utilization in appropriate patient populations is going to be helpful to make sure that patients, that physicians, that payers can gain confidence in how to use them appropriately.

NOR-SWITCH is a significant additional add to the data that we have for Inflectra. As you know, it was a randomized double-blind parallel group study with almost 500 patients. And importantly it was funded by the Norwegian government. The study found no significant difference in disease worsening between patients who underwent a single switch to Inflectra, CT-P13, versus those who remained on Remicade. It also found that the incidents of anti-drug antibodies and the frequency of reported adverse events between Remicade and Inflectra CT-P13 were similar.

So we think that the impact of that data is that it certainly will be helpful and informative in helping to make sure that physicians, patients and indeed, payers, can make an informed choice about the role that biosimilars and Inflectra specifically, can play in that patient population.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you. Frank?

Frank D'Amelio - Pfizer Inc. - CFO

On operational efficiency, Dave, I think two comments on this. One, obviously with the two separate businesses we have running within the Company, separate leadership teams, separate accountability, really managing their businesses in a very detailed way. We see that as a potential for operational efficiency.

And then as a Company, we're always looking at every dollar, every dollar of capital that we deploy always with the intent of how do we maximize, how do we optimize the capital that we spend. So given that, that's what we meant when we talked about operational efficiency.

Chuck Triano - Pfizer Inc. - SVP of IR

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

Operator

Vamil Divan, Credit Suisse.

Vamil Divan - Credit Suisse - Analyst

Great thanks so much for getting me in. Just two questions, following up on topics that came up before. One, on your decision to not split. I'm wondering if you can give any sense around timing for when you may reassess that decision. Is there an ongoing review? Or should we not assume anything is going to be looked at again for the next several months or several quarters.

And then second one, on the Consumer side, which came up a couple times. Ian, you mentioned it's been growing. But looking back at the numbers, really it doesn't look like it's grown that much since 2013. So I'm curious, internally are there opportunities such as Rx to OTC switches? Or other things that could drive the growth beyond what we've seen over the last two or three years here? Thanks.

Ian Read - Pfizer Inc. - Chairman & CEO

I see growth in Consumer today. It's not a market that grows that much for us. Albert could talk to that.



Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

It would be this quarter we grew 2% but the year-to-date growth is 5%. And we expect to be -- which is beating the market growth and we expect to stay there.

Ian Read - Pfizer Inc. - Chairman & CEO

It's a very valuable asset inside our Company. As I said, we look at all of our businesses to continue to test if they're generating the right return for shareholders.

On the split issue, I think we've made a decision. It was a major undertaking to look at it. I don't expect us to revisit that on a quarterly basis, as you suggested. I think it will be reviewed in the context of strategic decisions on a longer time frame than that.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you and thanks, everybody, for your time this morning.

Operator

Ladies and gentlemen, this concludes Pfizer's third-quarter 2016 earnings conference call. You may now disconnect.

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