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PFE - Q4 2016 Pfizer Inc Earnings Call

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OVERVIEW:

PFE reported 4Q16 revenues of approx. \$13.6b and reported EPS of \$0.13. Co. expects 2017 revenue to be \$52-54b and adjusted diluted EPS to be \$2.50-2.60.



CORPORATE PARTICIPANTS

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Frank D'Amelio *Pfizer Inc. - CFO*

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's fourth-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

Good morning. And thank you for joining us today to review Pfizer's fourth-quarter and full-year 2016 performance, as well as our 2017 guidance. 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, General Counsel.



The slides that will be presented on this call can be viewed on our home page, Pfizer.com, by clicking on the link for Pfizer Quarterly Corporate Performance fourth-quarter 2016, 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 this conference 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, including part 1A, item 1A risk factors, that is filed with the Securities and Exchange Commission, and available at SEC.gov, and on our website at Pfizer.com. Forward-looking statements during this conference call speak only as of the original date of this call, and we undertake no obligation to update or revise any of these statements.

Discussions during the call will also include certain financial measures that were not prepared in accordance with US generally accepted accounting principles. Reconciliation of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's current report on Form 8-K, dated today, January 31, 2017. You may obtain a copy of the form 8-K on our website, Pfizer.com/investors.

Any non-GAAP measures presented are not, and should not be viewed as substitutes for financial measures required by US GAAP, they 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, I will make a few comments about the year and where we see the opportunities for continued growth in 2017. Frank will provide details regarding the quarter, and on our 2017 financial guidance.

2016 was marked by solid execution, which led to another year of operational revenue growth. Both in terms of our overall portfolio, that showed an increase of 11% for the year, and on the Pfizer standalone basis, excluding Legacy Hospira and Medivation, where the annual growth was 5%.

We saw robust revenue growth from both new and mature brands. Pfizer Essential Health established market leading positions in sterile injectables and biosimilars. Our sterile injectables portfolio achieved over \$6 billion in revenue during the year, and in our Biosimilars business we launched Inflectra, the first biosimilar monoclonal antibody available in the US.

Globally, we have three marketed biosimilars and are the leader in total sales, as well as having a robust pipeline of biosimilar assets. We look to the sterile injectables and biosimilar portfolios to continue to generate growth for the Essential Health business. And also expect continued growth of the Essential Health portfolio in emerging markets, which achieved 7% operational growth in 2016.

For Pfizer Innovative Health, Eliquis achieved 88% operational growth for the year, and is the number one prescribed new oral anticoagulant by cardiologists in 12 markets around the globe. Xeljanz grew 78% operationally, and is now nearly a \$1 billion brand on an annual revenue basis.

Chantix grew 27% operationally. In December, the FDA approved updates to Chantix labeling, including the removal of the boxed warning regarding serious neuropsychiatric events, based on the outcomes of the EAGLES study.

Lyrica grew 14% operationally, and our Consumer healthcare business achieved another year of solid performance, with 5% operational growth. Ibrance remains a significant growth driver. Its revenue almost tripled year over year, and grew 17% globally on a sequentially quarterly basis, reflecting its attractive clinical profile and continued acceptance by physicians, payers, and patients.

Ibrance received EU approval in November, and will begin to launch across Europe during the year, resulting in incremental revenues primarily in the second half of the year. We feel very confident about our leadership in the CDK 4/6 inhibitor class.



Our business development activities during 2016 have provided us with attractive revenue growth opportunities, within both of our businesses.

Through the acquisitions of Medivation and Anacor to our Innovative business, we have added Xtandi for metastatic, castration-resistant prostate cancer and Eucrisa for the topical treatment of mild-to-moderate atopic dermatitis in adults and children as young as two years of age. And the addition to AstraZeneca's small molecule anti-infective business to Essential Health, has strengthened our anti-infectives portfolio, which is the industry's largest with more than 60 products.

Each of these acquisitions strategically aligns with our approach to business development which is to look for opportunities that come to immediate and/or near-term revenue growth. As we look at the total company operational growth profile, we see our current in-market products, including our recently-acquired products, as having the ability to deliver and enhance revenue growth rate over time, and more than offsetting continued headwinds from product losses of exclusivity.

In 2017, on an operational basis, the midpoint of our revenue guidance reflects 4% revenue growth, excluding the Hospira Infusion Systems business, which we expect to divest next month. Improved revenue growth is an important driver of valuation, and requires continued solid executions in addition to the ongoing advancement of our key pipeline assets. In 2016 we received five product approvals, achieved six regulatory submissions, and advanced 39 compounds in our pipeline.

Our current pipeline contains 96 clinical programs, half biologics, half small molecules, and about 2/3 of new molecular entities. And is well positioned. And in 2017, we are expecting pivotal top-line study results in oncology and biosimilars.

A few pipeline highlights include, in oncology, we have a very robust lifecycle program for Ibrance. It's being studied in an additional four pivotal studies in early, advanced, or recurrent breast cancer.

In addition, Ibrance is being studied in several non-breast cancer indications, including two sponsored trials in pancreatic and head and neck cancers. Xtandi has provided us with a novel treatment in metastatic prostate cancer. We see a potential opportunity to extend the type of androgen receptor blocker in Xtandi into other indications, and to seek regulatory approval in non-metastatic prostate cancer.

In immuno-oncology, we are making significant progress in building a strong IO portfolio and see avelumab as a core asset. Through our partner, Merck KGaA in the US, avelumab's submission for treatment of metastatic Merkel cell carcinoma was accepted by the FDA with priority review. And we also have announced that the European Medicines Agency validated for review the Marketing Authorization Application in the EU.

We have 11 compounds in the clinic, including anti-PD-1 mAb, the T-cell retargeting P-cadherin T-DART, a small molecule IDO-1 inhibitor, and the allogeneic UCART19 T-cell therapy for pediatric and adult acute lymphocytic leukemia. Our avelumab program with Merck KGaA now has 30 programs ongoing, 10 of which are potentially registration enabling, and over 4,000 patients have now been enrolled in ongoing avelumab studies.

The breadth of our IO portfolio allows us to differentiate with combinations, which is core to our strategy. For example, we have started to deliver data with avelumab and 4-1BB. We plan to initiate by the end of the first quarter a triplet with avelumab, 4-1BB and OX-40.

And we'll have studies with avelumab combined with rituximab and 4-1BB. We'll also have studies with avelumab with lorlatinib, our next-generation ALK inhibitor, and avelumab with Inlyta.

In biosimilars, we recently announced positive top-line results, with both infliximab, a potential biosimilar to Remicade; and trastuzumab, a potential biosimilar for Herceptin; and this month, we announced positive top-line results from the comparative REFLECTIONS study for adalimumab, a potential biosimilar to Humira. This marked the third potential biosimilar molecule from our pipeline to report positive top-line data results during the past four months. This year, we expect readouts in bevacizumab and filgrastim, and we have a total of 14 biosimilar molecules in various stages of development.

In inflammation and immunology, we have one of the strongest JAK franchises in the industry, and have advanced four immuno-kinases, including three selective JAK and one IRAK-4 inhibitor to clinical phase 2 studies. Our phase 2 trials cover 10 different indications from rheumatoid arthritis to gastrointestinal to dermatology.

And in vaccines, we have a robust portfolio that continues to progress.

We achieved proof of concept for our *C. difficile* vaccine, and expect to enter Phase 3 in the coming months. Our *Staphylococcus aureus* vaccine is currently in Phase 2, and we now have a novel pneumococcal vaccine in the clinic in Phase 1, that could potentially cover up to 20 stereotypes.

Of note, during 2017, we anticipate potential US decision for avelumab Merkel cell carcinoma, potential lorlatinib submission for non-small cell lung cancer, potential EU decision for Xeljanz in RA, potential US filings in the first half of 2017 for additional indications for Xeljanz in ulcerative colitis and psoriatic arthritis.

As we look at the year ahead, Pfizer is well-positioned with our in-market portfolio and our pipeline assets. I also see our Company structure, with its two distinct businesses as affording us a focus and sense of urgency to deliver enhanced revenue growth over time. For 2017 we look forward to working with the new administration, and across the healthcare system. Our efforts will continue to be focused on developing, delivering and providing access to innovative therapies that address areas of unmet medical need and an advanced patient care.

Pfizer has long held a contract with society through our business practices and culture to ensure that patients get the medicines they need. In summary, in 2016, we created significant value for our shareholders with several initiatives, including acquisitions and partnerships that bolster each of our businesses, share repurchases, and an increase to the dividend.

We enter 2017 with strong financial position, products who are leaders in their categories, strong and emerging mid and late-stage pipeline, and an operational structure that gives us the flexibility to differentiate our business in ways that will continue to create shareholder value. Now I turn it over to Frank to provide more detail on 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 full-year 2016 reflect Legacy Hospira global operations for the entire period, while full-year 2015 includes only four months of Legacy Hospira US operations and three months of Legacy Hospira international operations. Our financial results for fourth-quarter 2016 and fourth-quarter 2015 include Legacy for Hospira global operations for both periods. In addition, Pfizer completed the acquisition of Anacor pharmaceuticals on June 24, 2016. Consequently, our financial results for the fourth-quarter and full-year 2016 include three months and approximately six months of Legacy Anacor operations, respectively, which were immaterial.

Finally, Pfizer completed its acquisition of Medivation on September 28, 2016, so financial results for the fourth-quarter and full-year 2016 include three months of Legacy Medivation operations.

Now, moving on to the financials. Fourth-quarter 2016 revenues were approximately \$13.6 billion, and reflect a year-over-year operational decline of \$191 million or 1%. It's important to note that fourth-quarter revenues were negatively impacted by four fewer selling days in the US, and three fewer international selling days versus the prior-year quarter, which unfavorably affected revenues by approximately \$750 million.

If you will recall, the first quarter of 2016, I pointed out that there were nine more selling days versus the prior-year quarter and that this imbalance would be primarily offset in the fourth quarter of 2016, which would have seven fewer selling days. It's important to note that there are essentially the same number of selling days in full-year 2016 as in full-year 2015, so the impact of the quarterly year-over-year comparisons, notably the first and fourth quarters. Fourth-quarter 2016 revenues were also unfavorably impacted by foreign exchange of \$228 million or 2%.

Our Innovative Health business recorded 2% operational revenue growth in the fourth quarter, driven by the strong performance of Ibrance in the US, Eliquis globally, Xtandi in the US with the Medivation acquisition in September, and in Xeljanz and Lyrica, both in the US, all of which were



partially offset by a 23% operational decrease in global Prevnar 13 revenues. In the US, Prevnar 13 declined 33%, due to a decrease in revenues for the adult indication after the high initial capture rate, the eligible population following its successful fourth-quarter 2014 launch, which resulted in a smaller remaining catch-up opportunity compared to the prior-year quarter. And the unfavorable impact on the timing of government purchases for the pediatric indication.

We continue to believe that Prevnar 13, both pediatric and adult indications, will remain very significant products for Pfizer, notwithstanding this decrease in the fourth-quarter 2016, and the expectation that full-year 2017, global Prevnar 13 revenues will remain flat, slightly down. We do expect Prevnar adult launches in international markets, as well as the potential for increased utilization in the 18-through-64 population to temper the expected decline in sales in the US.

Fourth-quarter Innovative Health revenues were also negatively impacted by lower revenues for Enbrel in most developed Europe markets, primarily due to continued biosimilar competition, and the loss of Rebif alliance revenue versus the year-ago quarter due to the expiration at year-end 2016 of the agreement to co-promote Rebif in the US.

Revenues for our Essential Health business decreased 6% operationally, driven by a 20% operational decline from Peri-LOE Products, and a 3% operational decline from Legacy Established products, which were partially offset by operational growth of 3% from the sterile injectable pharmaceuticals portfolio, and 48% in biosimilars. Revenues from Legacy Hospira products declined 1% operationally, however, excluding the performance of Hospira Infusion Systems, these revenues actually increased 2% operationally.

In emerging markets, Pfizer Global Essential Health revenues grew 4% operationally due primarily to 3% growth in the Legacy Established Products portfolio and 9% growth in the sterile injectables portfolio. Fourth quarter reported EPS was \$0.13 compared to the loss of \$0.03 in the year-ago quarter, primarily due to the non-recurrence of foreign exchange losses related to Venezuela, a Protonix-related legal matter, and pension settlements in the prior-year quarter and a lower effective tax rate in Q4 of 2016, compared to Q4 of 2015. These were partially offset by fewer selling days, foreign exchange impacts, higher restructuring costs and losses related to the early redemption of debt, and the pending sale of Hospira Infusion Systems.

Adjusted diluted EPS for the fourth quarter was \$0.47 versus \$0.53 in the year-ago quarter. The decrease was primarily due to fewer selling days, the unfavorable impact of foreign exchange, continuing product losses of exclusivity, and a higher effective tax rate, all of which were partially offset by revenue growth due to certain new, in line, and acquired products, and due to the diluted average shares outstanding, which declined by 105 million shares versus the year-ago quarter, due to our share repurchase program.

As I previously mentioned, foreign exchange negatively impacted fourth-quarter 2016 revenues by approximately \$228 million or 2%, and negatively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate of \$50 million or 1%. As a result, foreign exchange negatively impacted fourth-quarter adjusted diluted EPS by approximately \$0.04, compared with the year-ago quarter, with approximately \$0.03 related to Venezuela.

On a full-year basis, foreign exchange had a \$0.21 negative impact on adjusted diluted EPS, with approximately \$0.10 attributable to Venezuela. As you can see, we achieved or exceeded all elements of our 2016 financial guidance ranges. It's important to note that every major currency, except the yen, weakened against the US dollar in 2016, which negatively impacted our full-year 2016 revenues by approximately \$1.5 billion, of which \$778 million was attributable to the devaluation of the Venezuelan bolivar.

In full-year 2016, we generated 11% operational revenue growth, and excluding Legacy Hospira and Legacy Medivation operations, Pfizer standalone revenues grew 5%, operationally. I also want to point out that 2016 adjusted SI&A expenses were at the top end of our guidance range, as a result of spending to support new products, including Ibrance, Eliquis, Prevnar Adult, Xeljanz and biosimilars.

Now, I'd like to walk you through the 2017 guidance ranges for revenues and adjusted diluted EPS relative to our 2016 actual results. First, it's important to note that our 2017 financial guidance assumes the pending disposition of Hospira Infusion Systems in February 2017, and excludes its \$1.2 billion contribution to 2016 revenues and its \$0.03 contribution to adjusted diluted EPS in 2016.



Also, while our 2017 revenue guidance range reflects anticipated strong growth of certain new, in line, and acquired products, this growth is partially offset by an anticipated \$2.4 billion negative impact, due to continuing product losses of exclusivity and an anticipated \$900 million negative impact due to adverse changes in foreign exchange rates. Consequently, we are absorbing a negative impact of \$4.5 billion related to these three factors.

In addition, I'd like to clarify for modeling purposes that while Xtandi revenues from the US are included in alliance revenues, revenues that are generated outside the US are booked as royalty, and therefore included in Other Income. In summary, we expect our 2017 revenues to be in the range of \$52 billion to \$54 billion. I also want to point out that the midpoint of this revenue range implies another year of mid-single-digit operational growth, excluding the impact of the pending sale of Hospira Infusion Systems and foreign exchange.

Adjusted diluted EPS guidance, as I mentioned, excludes the contribution from the Hospira Infusion Systems and includes the negative impact of product losses of exclusivity, as well as an expected \$0.05 negative impact on foreign exchange. In addition, the guidance range for adjusted diluted EPS incorporates \$5 billion of anticipated share repurchases in 2017, which are expected to more than offset potential dilution related to employee compensation programs. As a result, we expect adjusted diluted EPS to be in the range of \$2.50 to \$2.60. The midpoint of this range implies operational growth of approximately 10%, excluding the impact of the pending sale of Hospira Infusion Systems and foreign exchange.

Moving on to key takeaways. We finished full-year 2016 with 5% standalone operational revenue growth, excluding Hospira and Medivation. We issued 2017 financial guidance, excluding the pending sale of Hospira Infusion Systems and foreign exchange, the midpoint of the revenue guidance range implies another year of mid-single-digit operational growth, and the midpoint of the adjusted diluted EPS guidance range reflects approximately 10% operational growth.

We accomplished several key product and pipeline milestones, including the European Commission's approval of Ibrance in the treatment for women with HR-positive HER-2 negative locally advanced and metastatic breast cancer, and the FDA's approval of Eucrisa for the treatment of mild to moderate atopic dermatitis in patients two years of age and older. We returned \$12.3 billion to shareholders through dividends and share repurchases. Finally, we remain committed to delivering attractive shareholder returns in 2017 and beyond. Now, I'll turn it back to Chuck.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you. Operator, at this point, can we pull for questions, please?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Tim Anderson, Bernstein.

Tim Anderson - Bernstein - Analyst

Thank you very much. I'd like to ask you about immuno-oncology and the commitment to the agreement on avelumab and with your partner Merck KGaA. As you outlined, you have a lot of registration-enabling trials ongoing and lots of combinations.

Should we interpret that as meaning that you are fully committed to that partnership and to avelumab, or is it in the realm of possibilities that in this fast-changing world of IO, where the landscape continues to shift, you have to be more open-minded to continually reassess the way and try to become a leader in this area, and maybe Merck KGaA and the assets you have in development don't quite get you there?



And a second question is on border tax. Can we just get your perspective for how you think this whole issue might play out, both in the near and longer term? Do you think this proposal has legs? My understanding is that it could clearly be a potential negative for multinational drug companies.

Ian Read - Pfizer Inc. - Chairman & CEO

Tim, thank you for the question. Regarding avelumab and our partnership with Merck KGaA, I believe avelumab is a very highly competitive molecule, and we are focused along with our partner on delivering its promise, as both monotherapy and in combination with other agents.

In the IO area, we believe that having a backbone of PD-L1 compound is necessary, but insufficient in the future competitive environment. But we see avelumab as potentially competitive in selective first-line settings. We believe the true value will be in combinations, potentially with targeted agents such as Inlyta and antibody drug conjugates, oncolytic vaccines and other I/O agents, such as OX-40, 4-1BB, IDO-1 and drugs in Pfizer's pipeline.

I think that addresses most of the risk and concerns you have about our strategy. Everybody needs, I think, a PD-L1, but that's just the shift to the entry. After that, you need an extensive portfolio around combinations to really open up the value in immuno-oncology.

On the issue of border tax. The tax codes are complicated, the tax suggestions are complicated. I think the Republican leadership has overall tax changes. They are overall favorable for the pharmaceutical industry. Certainly it would allow us to create more jobs in the United States. And I don't really think that we would feel those changes as being proposed are negative for our industry. Frank, you want to add something to that?

Frank D'Amelio - Pfizer Inc. - CFO

I would just punctuate what Ian said, which is, I don't think you can look at one individual, one potential individual part of the reform. You have got to look at what the total package would look like. So, that would include what's going to be corporate taxes? What are going to be the impact on future foreign earnings?

Base erosion, which is where our border adjustability comes in. Accumulated foreign earnings. Interest expense deductibility. I think what we will need is, we need the full picture, the full puzzle, instead of just trying to comment on one individual piece of it.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Frank and Ian. Next question, please, Operator.

Operator

Chris Schott, JPMorgan.

Chris Schott - JPMorgan - Analyst

Great. Thank you very much, just two questions. First, on appetite and priorities for business development from here, and as you're thinking about that, would a repatriation tax holiday or broader tax reform affect any of your capital deployment or business development priorities?

Could that make deals that did not make sense previously make sense, given the new capital structure? Second question was just maybe talking a little bit more about Prevnar. We had a step-down in sales this quarter.

You talked about sales to be flat to maybe modestly declining in 2017. Just elaborate a little bit more.



Where are we with regards to the adult bolus in the US, and how should we think about this ramping in Europe offsetting potential further erosion of the US opportunity? Thanks very much.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Chris. I will make a few comments on the BD. Frank may want to add something, and then we'll go over to Albert for a discussion on the Prevnar vaccines.

To the extent I'd like to point out that the most impactful thing of tax reform will be to level the playing field between US companies and foreign companies in the regards of the foreign companies not having the tax advantage of acquiring companies and then taking to a low tax location. That would be a fundamental change in competitiveness to the extent that tax changes would make it cheaper for us to access financing. You're quite right, some deals that previously would not have been affordable may now be affordable.

But the lens we look at it is always from a point of view of creating value for shareholders. So, per se, I don't see that the tax reform alters our approach to doing BD, which is, are we going to generate above our cost of capital in making this investment, and is it both short and long-term the right thing for shareholders. Hopefully that answers on BD. And then we will go over to Albert to talk about vaccines.

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

Prevnar 13 is expected to continue to be a significant product. Overall this year, we expect Prevnar 13 to be flat to decline. And this is a result of complex movements in the marketplace.

As discussed previously, in the US we have already vaccinated approximately 50% of the 65-plus population, so we expect to continue to see a decline here in the adult indication as we exhaust the catch up opportunity. These would be offset by international adult growth and growth of adult vaccinations in the 19-to-64 age range.

And you'll also see a modest growth in pediatric indication. From our perspective, moving forward in the US and in the EU, in the US, we're focused on protecting the remaining 50% of the 65-plus population and expanding uses to 19-64 age range. We are aware that vaccinating the remaining 50% is more challenging than it was to vaccinate the first half and to realize the full potential of 19-64, we need an ACIP recommendation, but we are moving forward with plans, given the current situation.

In Europe, as you know, it's all about recommendations and reimbursements. We continue to advocate with vaccine technical committees for recommendations and payers for reimbursements. The timing of the success varies country by country, and in some cases region by region within the same country.

Thus, couple of data in 2016, we had relatively limited number of recommendations and reimbursements. We had in Denmark and we had one region in Spain, Madrid region. In 2017, we expect funding decisions in a number of important markets, like France, Italy and Belgium.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Albert. As I think we've said in the release, we expect, given the pressures on the ability to get into the individual (inaudible) adult markets, we expect flat to slightly down for the overall Prevnar franchise next year.

Chuck Triano - Pfizer Inc. - SVP of IR

Operator, can you move to the next question, please?



Operator

Vamil Divan, Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

Great. Thank you so much for taking my questions.

Going back to the business development of some of the D.C.-related comments you made earlier. I'm just wondering in terms of, given there's a lot of uncertainty around how everything is going to play out in terms of corporate tax and border taxing -- border pricing, all of these issues, is it fair to say there may be a little bit of a pause in Pfizer? Is it going to do larger-scale business development until these issues are sorted out, presumably later this year?

And my second question I had relates to Xtandi. I'm curious on that product.

Your expectations given how much you paid for that asset in your acquisition last year. J&J commented a little bit last week around some market contraction that they're seeing in that space, and I'm just curious if you can give a little bit more color in terms of what you're seeing in terms of volumes and pricing from Xtandi.

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

On BD, I don't see it as a pause, we're going to play the cards we get dealt. As I said, the change in the tax code may reduce competition for assets from external buyers. It may alter, somewhat, the overall cost to make an acquisition, but it's not dramatic in the sense of we're going to take a year pause as we see what the tax code is going to do.

We are going to continue to do BD where we see value for our shareholders. We think we have the flexibility and the balance sheet to do that, so I don't see a dramatic pause. Frank, you want to add anything to that?

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

Just that since September of 2015 with the current cards we have been dealt, with the current tax laws as they are written, we have done approximately \$40 billion in deals, all of which obviously we believe are or will create shareholder value. And to Ian's point, if we get dealt a new set of cards, a new hand, then obviously, we will play that hand, and once again, it's the compass that never changes, the compass is always creating shareholder value.

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

Albert, on Xtandi.

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

Let me provide some insight of the market dynamics, and then also provide our expectations for the product. Xtandi revenues in Q4 declined 8% versus Q3 of the same year, and 13% versus the same quarter of last year. However, Xtandi demand as measured by specialty pharma, was up, increased 4% in Q4 versus Q3, and over 9% versus the same quarter of last year.

The same inconsistency between revenues and demand is also observed on the full-year basis, where revenues were up by 8%, while total prescriptions were up by 15%. This inconsistency, it is due to changes in the demand mix, with a significant increase in patient assistance program last quarter, which impacted revenue. This spike in PAP program is unprecedented compared with prior experiences.

We remain confident in the growth potential of Xtandi in the metastatic prostate cancer market for the following reasons. We expect to continue to grow (inaudible) with both oncologists and urologists. Urologists is where the largest growth potential exists.

Currently, the number of oncologists prescribing the product is almost 4,000 of the universal 6,500. The number of urologists prescribing Xtandi now grew to around 1,400 in this quarter. However, there is still a great opportunity with over 5,500 urologists prescribing Casodex.

The publication of the positive data from TERRAIN, which is the only study demonstrating superiority against Casodex head to head will have a significant impact. The recent market research shows a significant increase in prescribing intent by both oncologists and urologists that were aware of TERRAIN data versus those that were not aware.

Beginning of January 1, this year, we put a strong commercial management team in place from Pfizer. Given our strong reputation and experience in both oncology and urology, together with our good partner Astellas, we expect to accelerate the Xtandi growth.

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

Thank you, Albert. Next question please, Operator.

Operator

Jami Rubin, Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. My question is for you, Ian. As you know, President Trump is meeting with a group of industry executives right now as we speak, and he said he wants to bring drug pricing down.

Do you think that the industry is doing enough to quell concerns out there? And if this comes to a head -- how do you think it does come to a head? How are we going to get closure on this drug-pricing issue?

Will the industry have to give something up? How do you look at it, and just specifically on your price increases, which you announced January 1, are you holding to one price increase a year? Can you comment on that?

I think it's interesting that a number of distributors this morning said that they are expecting that drug companies will raise prices again in the June and July time period. So, your overall views on how this is all going to come to a head. Thanks.

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

Okay. Thank you, Jami. On our price increases, I don't want to get into the rhythm of when we increase prices, for simply competitive reasons. We are not changing our philosophy, vis-a-vis how we price our medications and when we take those price increases.

Regarding the meeting with President Trump, which I could not attend because I am on this analyst call, I would like to sort of broaden exactly and look at what he said. He said, number one, you need to get manufacturing back to America. That falls squarely in the side of getting tax reform, which allows us to reinvest in the United States and create jobs.

I think we can be a very positive part of the story of creating jobs in the United States, if we get the tax reform. Regulations, we've got to cut up to 80% to help streamline the approval process. That will help with drug prices, because it will induce more competition.

We have been advocating for a long time to speed up the approval of generics and remove the barriers to their approval, because that will help with drug prices. Regulations. The way insurance is delivered.

Cost to consumers, which is really I think what the president is talking about. Cost to patients is driven by the fact that the out-of-pocket expense on average for a patient to visit a hospital is 3%, but on his drug bill it's 15%. We would like to see regulations that would allow that unfair playing field to be squared up.

It would be positive to get a new FDA head and very positive if the young companies and companies can get to the market quicker and that would be good for the whole system. So, I think the complexity of drug prices involve all of the other comments he made, and I think there are lots of ways, like changing regulations to allow a value-based contracting between the industry and the health system.

That would also be very helpful. We have a regulation that was created for fee for service, and now we have regulations in a new world of value-based pricing.

So, I think there's lots of ways we can work with the administration to ensure that patients have affordable drugs, or more affordable drugs in the United States. I think that covered most of what you asked.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Jami. Next question please.

Operator

Mark Schoenebaum, Evercore ISI.

Mark Schoenebaum - Evercore ISI - Analyst

First of all, I'd like to thank the Pfizer organization for all the help while I was gone. Especially Chuck, Ryan and Bryan helping my team. Thank you.

I wanted to ask again about the possibility of a repatriation holiday. Maybe this is a question for Frank, but I want to understand if I'm doing this right. Your OUS cash is at least \$14 billion, I think is what you said publicly, not updated for the 4Q.

Your leverage ratio right now total debt to EBIDTA is around 1%, 1.3%, somewhere in there. I believe you said you'd be willing to go to at least 2%, and I'm wondering if you're able to repatriate cash, it'd probably alleviate some of your needs for short-term paper in the US. So, in the event of a tax repatriation holiday, how high, Frank, would you allow your leverage ratio to go?

And would you consider borrowing, maximizing your borrowing to maximize cash on hand? And second of all, if you don't mind, the 5% operational growth for the year in revenue, can you break out price versus volume?

Ian Read - Pfizer Inc. - Chairman & CEO

Mark, I'm going to direct most of the questions to Frank. I think he can give you the answers you're looking for. I just wanted to say welcome back, it's good to have you back on the calls.

Frank D'Amelio - Pfizer Inc. - CFO

Welcome back, Mark. I wanted to also say that, too.

Listen, on capital structure. The real punchline to the question was, how high would we go? Let me run a few numbers and then answer the question, which is, at the end of last quarter we had about \$24 billion in cash. We say at any point in time up to \$10 billion of that is in the US, so that \$24 billion minus that \$10 billion that we disclosed is how you got to your \$14 billion.

At the end of last quarter, we had give or take about \$44 billion in debt. So, if you put your debt of \$44 billion and put that on our EBITDA number, you get a number that's close to 2%. If you do a net debt number, which is probably the calculation that you did, you get to a leverage ratio that's about 1%, 1% and change, which is I'm assuming how you got to the basis of your question.

In terms of how high would we go on leverage? The answer is, it depends on what we are doing. And quite frankly, to lock myself in on a number, really, to me is an inappropriate thing. It really depends on what is the use of capital?

And the compass on capital, whether it's business development, whether it's buybacks, whether it's dividends, whether it's investing in our business, but the compass is, how do we maximize capital deployment to maximize shareholder value? So, that's how we think about it to the extent that we needed to lever up, because we think it will be an opportunity that made sense, we would lever up. But to lever up just to lever up, isn't what we're all about.

That's how I'd answer that. On price, I think the answer is, I believe for the full year, our operational revenue growth all in was 11%. Then you took out, you made a couple of adjustments to get the 5%.

But I look at the 11%, the majority of that 11% was volume. Low-single digits, approximately 2% of that was price.

Chuck Triano - Pfizer Inc. - SVP of IR

Next question please, Operator.

Operator

David Risinger, Morgan Stanley.

David Risinger - Morgan Stanley - Analyst

Yes, thanks very much. I have a couple questions. First, with respect to pipeline news flow in 2017, could you just highlight what the top two or three read-outs are in your mind that we should be focused on?

Second, with respect to future business development, you've obviously commented on it in some detail, but it would be helpful to get some more perspective on what your expectations are for potential timing on large transactions. It would seem that it would be most beneficial to Pfizer to have clarity on the likelihood of tax reform and/or repatriation before pursuing a very substantial transaction.

But I would love to get your comments on that, Frank. Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

Well, you know, on the -- I'll ask Mikael to do the pipeline flow and then myself and Frank will answer your BD question.



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

Thank you for the question. I think we are in a really good rhythm with the pipeline. Actually, over the last six years, we've had over 20 key approvals, with an average of 3 to 4 approvals per year.

And the pipeline, the quantity and the quality that we have of the pipeline of more than 90 (inaudible) in clinical development will have a similar flow or even more. Actually in 2017 and 2018, we expect about five approvals every year. Concerning read-outs, and I will focus mainly on pivotal studies that are registration-enabling, we will have about 15, 1-5 pivotal read-outs in 2017 and 2018.

Particularly in 2017, more near term, I can mention read-outs expected for dacomitinib, lorlatinib, avelumab in certain indications, and also two of our biosimilars. And there will be continuous flow-up to 50 pivotal readouts in total, 2017 and 2018.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Mikael. Frank, would you like to add --?

Frank D'Amelio - Pfizer Inc. - CFO

And, Dave, you commented specifically, you mentioned large transactions. The way I would answer the question is, and Ian and I have both said this before. We always thought we were agnostic to start when it comes to business development.

Our compass is we'll continue to build shareholder value. In terms of the other part of your question, access to overseas cash or easier access to overseas cash. Clearly, that would be beneficial.

That would be favorable, all other things being equal. In terms of does that make it easier to do deals? The answer is, it depends. For example, what happens to the valuations of all the companies?

If it is easier to have access to overseas cash, does that drive valuations and prices up? The compass has to continue to be shareholder value, return on capital, relative to our cost of capital. That's what we've always done.

That's what we will continue to do. At a macro level, all other things being equal, does easier access to our global cash help us, is it more favorable? The answer is yes, but there are other factors that we will have to understand as we work our way through business development.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Frank. Next question please, Operator.

Operator

John Boris, SunTrust.

John Boris - SunTrust Robinson Humphrey - Analyst

Thanks for taking the questions. First question just has to do with a very broad question --

Ian Read - Pfizer Inc. - Chairman & CEO

John, we can't hear you, you need to speak up, sorry.

John Boris - SunTrust Robinson Humphrey - Analyst

Can you hear me now?

Frank D'Amelio - Pfizer Inc. - CFO

Much better, John. Loud and clear.

John Boris - SunTrust Robinson Humphrey - Analyst

Great. Thank you. The first question is just a very broad question on how fragmented the pharmaceutical industry is relative to other industries.

Can you give your thoughts on consolidation, and especially in light of the pricing pressures, just your thoughts on the need for the industry to consolidate. There's a lot of manufacturing inefficiencies out there. Just a lot of inefficiencies in the industry, in general. So, that's the first broad question.

Second question in 2006 you made a decision to sell your Consumer business. Is there any way of giving some quantification as to what kind of earnings contribution you currently get from the Consumer business, and if you were to consider externally selling it, how would you offset that dilution? Would you add to that \$5 billion share repurchase?

Third question, Ibrance, was there any outperformance, great performance on the brand in the quarter? Was there any additional product put into the channel on Ibrance? Was that all sell-through? Lastly, Ian, applaud your highlighting the 96 clinical programs you have, but one thing I hear a lot from investors is that you haven't had an R&D meeting in a long time.

I would love to see that innovation displayed in front of the investment community. Any thoughts about doing an R&D meeting?

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, John. Four good questions. On the issue of fragmentation.

From a society point of view, society has to decide, do they want continuing (inaudible) of innovation with lots of shots on goal? If they do, they need to continue to support that and support it through the robust market-based system in the United States. To the extent that that would change and we don't have a robust ability to cover our value, then I do think you would see the fragmentation disappear and innovation would go down.

So, it's a macro decision that the government has to make or society has to make as to how much progress and how fast they want to see progress, and how much resources they are willing to put behind it. And that would dictate, I think, the fragmentation and then fragmentation of the industry. Vis-a-vis the Consumer business, we don't give out obviously our profits for our sub-businesses, but we see it as an actor that is valuable to us, valuable to our shareholders.

And would like all of our portfolio and all of our assets, if there is a better mix, we are always open to it, but it has to be for strategic reasons rather than cash. On Ibrance, I will ask Albert to talk a little bit about Ibrance. Before he does, you asked about the R&D portfolio.

R&D day. Let's look at it. We haven't had one for some time.



I haven't often found them that productive. We give you a lot of visibility by publishing our (inaudible) to clinical.com. Mikael is available to analysts whenever they want to talk about the science.

We are more than willing for you to come in and talk to Mikael, John. I'm not sure that a big R&D day is really worth the disruption in the focus on getting it done, vis-a-vis explaining what we're doing, but we will take a look at it. Okay.

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

It was a great performance for Ibrance, John, as we said. Exceeded \$2 billion a year in the second year of its launch, and it was almost 200% growth. And this excellent financial performance is driven by underlying demand, and there was no abnormal [contractions] in inventories.

Ian Read - Pfizer Inc. - Chairman & CEO

And, Frank, why don't you add some more on the consumer revenues?

Frank D'Amelio - Pfizer Inc. - CFO

John, to run some numbers to help you in terms of answering your questions, so for the quarter, consumer sales, consumer revenues, \$950 million plus 4%, operationally. For year, \$3.4 billion, up 5% operationally. We don't give specific margins, but one of the things we do say about the consumer business is that the margins are lower than the pharmaceutical business, because it's a less risky business.

That gives you enough information, I think, to be able to really ballpark what the number is. By the way, in terms of just the theory of the case of when we divest in asset. How do we deal with it from a dilutional accretion perspective? The answer is, it depends.

But think about the levers. We did a big buyback. We did a share exchange, and so even though we divested what was a very good and very profitable company, we wound up making that transaction accretive.

There's lots of ways for us to do that. You mentioned share buybacks, and yes, that's clearly one of the ways when we divest assets, that we can deal with accretion and dilution

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Frank. Our next question, Operator.

Operator

Geoff Meacham, Barclays.

Geoff Meacham - Barclays Capital - Analyst

Good morning. I wanted to dig a little bit on the biosimilar franchise. What can you guys tell us about the Inflectra experience so far in the US, and what is the Pfizer view of the new interchangeability guidance and what it means to speed to market?

And at a higher level, when your biosimilar franchise scales to add more assets, do you think about gross to net any differently? In other words, is a long-term value here biased to more margin contribution or more revenue growth? Thanks.



Ian Read - Pfizer Inc. - Chairman & CEO

John, would you like to comment on that?

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

First of all, I think we obviously are very positive about the opportunity that we have with biosimilars. First of all, our commercial opportunity provides real value to our shareholders. But also the opportunity that biosimilars represent, to continue to bring some of the competition that Ian referred to to the healthcare system, and to bring efficiencies and savings.

We think the opportunities in both regards are very significant. It's obviously very early days with Inflectra in the US. We are literally in the second month of launch, so it's early days.

We anticipate that the uptick in the first few months in the US will be slow. That represents our progress in Europe. Where we've seen that actually after the first few months as physicians get comfortable with biosimilars, we've seen the rate of uptick really begin to accelerate.

Just to give you data points to compare in Europe, the uptick of biosimilars overall for infliximab in Europe, is something like 28%, 29% in the second year. We're actually very satisfied with what we've seen about the progress that biosimilars can make when we begin to get information about how a high-quality biosimilar in our data can really, actually, deliver significant value to the healthcare system.

In regard to your second question about the portfolio, we certainly continue to have, as you heard from Ian and Frank, a bias to shareholder value. Our compass, whether it's in BD, as Ian and Frank had talked about, or when it comes to the individual contribution of product portfolio, such as biosimilars, will always be around shareholder value. And so, we certainly are very positive about the opportunities for revenue growth, but our compass is always going to be shareholder value, as we determine how to invest in that portfolio going forward.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, John. Next question please.

Operator

Steve Scala, Cowen.

Steve Scala - Cowen and Company - Analyst

Many thanks. I have two questions. First, for Ian.

As someone who has been in the industry for a long time, I would be interested in how you view the current potential threat from government intervention on drug pricing versus that sporadically over the last 20 or 30 years. Would you say it is now among the most significant threat you've ever seen? Would you say it's similar to past periods, or not as severe?

And then a question for Dr. Dolsten on JAVELIN 100. The study is similar to KEYNOTE-024 and CheckMate 026, reads out this summer. The PD-L1 expression threshold is 1%.

Is Pfizer amending the protocol to use a higher threshold, since otherwise it seems that this study is unlikely to be successful? So, thank you.



Ian Read - Pfizer Inc. - Chairman & CEO

Steve, on the role of threat, it's a good question. I think the misinformation is far greater than I've ever seen before out of the marketplace. And we are seeing, added onto previous price discussions, the behavior of companies that work in the generics sector who are moving to change their prices in a more volatile manner, hence creating a negative perception there.

But if you actually look at the price increases of the branded pharmaceutical companies, as a whole for 2015, it was 2.8%. So, if you separate the hysteria, frankly, in the media which often the examples are companies that are in the generics market, then I think it's really a huge amount of misinformation out there that we and the pharma as an organization needs to begin to start dealing with.

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

Great to get the question on our clinical strategies. We always carefully monitor new learning and clinical science to make sure we try and incorporate them into our studies, and this is true also for the JAVELIN first line lung cancer study, where we are obviously incorporating the best way to define the patients concerning PD-L1.

You can be certain that our patient population, we've optimized for what is the best knowledge how to get likely maximum response to a PD-L1 inhibitor such as avelumab. Finally, I wanted to add, beyond the monotherapy, which we think would be a productive profile for initial monotherapy, we worked on doublets and triplets with 4-1BB and OX40 that will over time, we think, be able to move the needle even further, including indications such as lung cancer.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Mikael. Next question please, Operator.

Operator

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - Deutsche Bank - Analyst

Thank you. First, for John Young. John, do you think the Essential business can grow without deals and without the benefit of innovative products coming over the wall over time? Can you also give us a road map for what biosimilar launches Pfizer might have in the next two to three years? And comment on your Copaxone ANDA status in light of the legal ruling.

Over to Ian and Frank, rather than asking you to predict what replaces the Affordable Care Act and when, can I ask you to quantify the effect you think the ACA has had on Pfizer, industry feed, donut hole, increased volumes potentially, biotech exclusivity, these are the things that come to mind. But how do you quantify what ACA has done for Pfizer as we think about where that may go in the future? Thanks.

Ian Read - Pfizer Inc. - Chairman & CEO

Please, John.

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

Okay. Thanks for the question, Gregg. I think we've been fairly consistent in terms of saying that we really believe that we have a strategy and a portfolio that can return the Pfizer Essential Health business to some sustainable growth.

After the impact of LOEs has begun to lessen. We certainly still have an impact of some LOEs in our portfolio, as you know, but that impact will lessen over the next few years. And I think we believe that just strategically at a high level the strength that we have in our emerging-market business, that would be typically in most of the large emerging markets, number one or two in most of those countries

We have the leading sterile injectable business, leading biosimilars business, and within our what we think of as our global brand portfolio, we actually also have the largest portfolio of anti-infectives in the business. So we believe that those core areas of strength really provide an opportunity for us to drive this business to sustainable growth.

Just to run some numbers for you. It was in the fourth quarter this year the growth of the business overall was minus 6%. If you adjust for the impact of LOEs, giving you a sense of what is actually happening to the core business without that headwind, the answer was flat.

But if you adjust for and equalize the selling days, which I think Frank highlighted in his opening comments, that core business grew by 6%. I think that hopefully gives you a sense that actually we are actually growing those portfolios that we believe will be the positive drivers of growth going forward. We will continue to look at opportunities to strengthen those portfolios, and certainly our aspirations to return this business to a sustainable growth remains undimmed.

In terms of biosimilar launches, as you know, we are also very well-positioned to be the leader that we are today in terms of revenues, but actually a leader over the next 5 to 10 years, given the strength of our portfolio. And the relatively near term, we anticipate that in the 2018, 2019 time frame, we will be able to file around about five biosimilar products. I think you are aware of the products that we have in our pipeline.

We certainly have potential biosimilars for trastuzumab for cancer. For bevacizumab, also for cancer. For adalimumab, which is an anti-TNF product, and one of the biggest products in the world.

And rituximab, as well as EPO, which we filed in response to the complete response letter that Hospira had previously received. And we filed that response in December of last year.

So, when you look at all of those drivers, with combining that with early stage pipeline that we have, we believe we are really well-positioned to have a rich platform of biosimilars in the marketplace over the medium term. Thanks for the question, Gregg.

Ian Read - Pfizer Inc. - Chairman & CEO

Gregg, thank you. I'm going to point out some of the -- I'll let Frank go through the costs of ACA.

I'd like to make a point that there was no windfall for our industry from the expected 20 million more patients, because most of these patients were not treated with the type of, given the level of insurance they had, they did not really have access to innovative drugs. So, there was very little revenue growth from the exchanges for Pfizer. And now let's get into the expenses of the ACA.

Frank D'Amelio - Pfizer Inc. - CFO

The donut hole in the fee on pharma sales this year for the full year, Gregg, \$722 million. The thing to add to that is the Medicaid component. Although it's very hard to come up with that number now, because many states have moved to managed Medicaid.

But if I just ballpark that number and assume it has been roughly the same as it was a couple years ago, that number grosses up to about \$1.25 billion. You divide that by call it \$80 million per share, pre tax, that \$1.25 billion, \$0.15, \$0.16 a share. Thank you.

Chuck Triano - Pfizer Inc. - SVP of IR

Can we move onto the next question, please?



Operator

Marc Goodman, UBS.

Marc Goodman - UBS - Analyst

Good morning. It looks like another year of flat spending. Can you talk about the push and pulls, specifically on SG&A for this year? But also just more broadly, just philosophically, it looks like R&D, SG&A the past couple of years have been flattish.

Should we be thinking flattish for the next couple of years as we model and basically however the top line drives the bottom line? And second of all, just on Ibrance, you mentioned there was no unusual inventory, but you on the quarter usually give us some metrics, how many patients are on the product, and what kind of penetration rates you have got in first line and second line.

That would be helpful. Thanks.

Ian Read - Pfizer Inc. - Chairman & CEO

Why don't you do the Ibrance, Albert, and we will get back to the R&D and SI&A.

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

Let me give you a brief overview of the performance of Ibrance. And let me start by saying how happy we are with the success. Ibrance has been prescribed in the US by approximately 9,500 physicians.

This is up from 8,500 that were in Q3. Has been given to approximately 50,000 patients. Our initial strategy was to establish Ibrance as the standard of care with early adopting physicians.

Moving forward, we believe the growth will come from late adopters. Many of whom have already prescribed Ibrance, but in a limited number of patients. 20% of the approximately 12,000 prescribing physicians in the US have not yet prescribed the product.

From those already prescribing it, approximately 30% have only one or two patients on Ibrance. With the publication of PALOMA-2, we think this is important data for these late-adopting physicians. Let's not forget what the study demonstrated, more than two years PFS making it the first and only treatment of this population to do so in a randomized Phase 3 study.

And then the last part of your question, our internal market sales are approximately 45% in first line for the quarter. 40% in second line, and 25% approximately in the third line.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Albert. I want to make a couple comments on your questions from the strategic point of view of our expense for R&D and SG&A, and then I'll ask Frank to give you more analysis. We spend in SG&A and R&D according to the opportunities we see, and how we can create value.

So, that layer is always there and expectations of R&D and SG&A are related to the opportunity we see in the marketplace. Underneath that, though, we have consistent programs to look for efficiencies in how we do R&D, and how we deliver our SG&A, and perhaps Frank can comment on some of those efficiencies. So, right now looking at it I'm satisfied with the level of support we have in SG&A and R&D, and each budget cycle we look at it, look at the opportunities and the growth we can get from those opportunities.



Frank D'Amelio - Pfizer Inc. - CFO

I will give you some of the puts and takes, Marc, and see if that helps. I will run some numbers first. Let's do SI&A.

Last year, the SI&A actual number for 2016 full-year was \$14.7 billion. Our guidance for 2017 is \$13.7 billion to \$14.7 billion, with a midpoint of \$14.2 billion. There is a lot going on underneath those numbers.

If you look at the \$14.7 billion compare it to the \$14.2 billion, just in terms of the midpoint of the guidance, what's going on there? One is ongoing cost reduction programs that I alluded to. Two is, the benefit of the sale of Hospira Infusion Systems. That comes out.

And foreign exchange actually helped SI&A to the tune of about \$200 million, we call that out. Think about that as things that are helping the number, but then there's offsets against that. For example, look at the full-year effect of Medivation next year.

Launch costs for that. Launch costs for Eucrisa. Spend on some of our other areas.

Those are the kinds of things that are going on in terms of \$13.7 billion, \$14.7 billion, with the midpoint relative to next year, there are items that are driving the number down. There are items that are driving the number up. If you look at R&D, same kind of puts and takes.

Last year, 2016, \$7.8 billion. Guidance for this year, \$7.58 billion, so the midpoint is roughly the same as last year, which is part of the basis of your question. Again, lots going on there.

For example, a large boco charge we had in the fourth quarter comes out, so that would reduce spending, all other things equal. On the other hand, we have got the Medivation acquisition, and we're actually increasing our investment in things like Ibrance immuno-oncology and some of our late-stage pipeline assets.

So when you put that all together, you get to that range of \$7.5 billion in there. Just kind of the rhythm of the numbers.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Frank. Next question please, Operator.

Operator

Andrew Baum, Citi.

Andrew Baum - Citi - Analyst

A couple of questions, please. It seems as if the new administration is proposing lower drug prices in exchange for accelerating development timelines for drugs. Do you really believe that that is the underlying issue with economics in the pharmaceutical industry? Does that represent fair trade to you?

And second, in terms of the industry group highlighting other players in the healthcare value chain who may be contributing to drug price inflation, perhaps you might like to comment both on the role of PBMs, as well as on the 340B hospital program.

And very quickly on biosimilars. In relation to your oncology biosimilars, could you outline what you think the anticipated adoption rate and market impact will be, how fast, and in particular to which customer groups in the US you think are going to be most accessible in the initial launch periods? Thank you.



Ian Read - Pfizer Inc. - Chairman & CEO

So, your question on the administration, I would look at it this way. I think to the extent, and I would hope this is how the administration is thinking of it, to the extent they can remove regulations and make it easier and faster to bring drugs to market, that will make the marketplace a lot more competitive which will then, in turn, help to bring down drug prices. I believe that this is the philosophy of the administration to ensure there's competition in the marketplace, and that would be one way of ensuring that drug prices are modified some way.

Regarding your comment about the difference between our price and the list price, I think there's a study recently came out indicating that the things we get are the list price. We have gone into a marketplace and the way the marketplace is developed, that we have list prices but then rebates are negotiated to give us a net price.

I believe there are alternative systems, where we could have just as an efficient system where the list prices could be lower, and the net prices could stay substantially the same or might drop slightly because of the middleman not making so much money in the middle. That is very complex, and they need to come up with a competitive marketplace solution to that. But I do believe that's one of the problems in the market today.

People without insurance or through the deductibles are hit with a list price rather than the net price to the insurance company. Maybe there are ways we can work with the insurance company administration to get rid of this big difference between list price and net price. And the last question was --

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

Thanks for the question, Andrew. Publicly, there are no currently available oncology product biosimilars, either from our portfolio or any other company's portfolio in either the US or Europe or any other major market around the world.

To some extent, it's very early days to conjecture what the rate of uptick might be. What I can say is we're very positive about the pipeline that we have. As I mentioned earlier, we have bevacizumab, a potential biosimilar to Avastin.

We have rituximab, a potential biosimilar to Rituxan, and we have a potential biosimilar trastuzumab to Herceptin, and we're very positive about the way that those clinical programs are unfolding. I think in oncology, it's very likely that biosimilars will be used initially for new patients.

I think it is probably unlikely that oncologists will choose to change a patient's therapy. But given the particular dynamics where a patient by definition start and finish courses of therapy, more often we don't see that as being an inhibition in any way to the uptick. Once physicians actually see the clinical data for a biosimilar, and can then make an informed decision along with their patients around how to most appropriately manage their course of therapy.

Chuck Triano - Pfizer Inc. - SVP of IR

Next question, please.

Operator

Tony Butler, Guggenheim Securities.

Tony Butler - Guggenheim Securities - Analyst

Thanks very much. Three very brief questions. Frank, have efficiencies in gross margins actually been totally wrung out to date?

And number two, to John Young, again, on biosimilars. Do you believe in the US that overall demand is dependent upon formulary positioning, all the pushing the brand back to a higher tier for where your biosimilar may be at a lower tier, as opposed to physician pull through?

And finally, to Mikael Dolsten on first-line lung, but once again, do you wait until JAVELIN 100 completes before moving forward with the combination studies? Or are you already underway with those?

And I noticed or cannot find any trials other than in head and neck, which has radiation, which may involve chemotherapy plus avelumab. I'm curious how you and/or Pfizer think about that in combination, specifically for lung. Thanks very much.

Ian Read - Pfizer Inc. - Chairman & CEO

Okay. Frank.

Frank D'Amelio - Pfizer Inc. - CFO

Tony, I will answer it by using cost of sales, which is basically the same thing. Think about it this way. Our cost of sales in 2016 was 22% of revenue for the full year.

Our guidance for 2017 is 20% to 21%, so the midpoint to that guidance 20.5%, so we're actually down from 22% to a range of 20%, 21% for 2017. A couple of things going on there.

One is more Alliance revenue. Alliance revenue we book we the revenue based on net gross profits, so there's no COGS there, that obviously helps as a percentage. But also ongoing cost reduction programs taking place in our factories and throughout the Company.

And then there's the offset to that is we have got \$2.4 billion of LOEs next year, some of which obviously have a negative impact on the cost of sales. When you put that together, the short answer is we are going down year over year and, no, the short answer is no, we have not wrung it out completely. There's always opportunities to continue to improve in everything that we do.

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

Okay, thanks for the question on biosimilars, Tony. Just to hit on a couple points I made already, which is clearly one component of ensuring appropriate uptake for biosimilars in the marketplace is physician education, making sure that they're familiar with your clinical data, the strength of your program, and we also believe, actually, the importance of the Company profile and our experience in biosimilars.

That said, plainly, access is a critical component as well. We're absolutely clear in ensuring that we can negotiate appropriate patient access, and we take the steps necessary to ensure that patients can have access to high-quality biosimilars is equally important.

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

Yes, great to hear about your interest in how we will evolve the IU combinations. As we have optimized JAVELIN Lung 100 for PD-L1 monotherapy, and I think based on current experiences across the field of PD-1 and PD-L1 antibodies, one can assume that monotherapy may be particularly robust in the PD-L1 high stage section of tumors, but likely of less magnitude in PD-L1 lower lung cancers. We have several Phase 1 studies ongoing, where we start a combination of avelumab, such as JAVELIN Lung 101, which contains avelumab plus ALK-inhibitors Xalkori, lorlatinib for ALK-positive lung cancer.

And we also have JAVELIN Medley, and so the tumor basket studies that contain avelumab with 4-1BB, avelumab with OX40, and we're planning this quarter to start a triple avelumab, 4-1BB, OX40 would likely to the best of my knowledge, will be the first (inaudible) with this agent. I should

say that although you cannot predict outcome of combination drugs, it has been the history of oncology to evolve to that as we learn about single-agent activity.

Both 4-1BB and OX40 show some single agent activity, whether in clinical activity, or important (inaudible). Finally, I should say that we also are starting studies where we combine avelumab with our own PDL4 inhibitor for (inaudible) mutation, which is a growing segment.

We will review those data (inaudible) and with the first half of the year, particularly avelumab 4-1BB and the quarter (inaudible) Avelumab, and take rapid decisions together with our partner Merck Serono how to leverage those data. We will certainly not wait to see an outcome of JAVELIN 100, I actually think the design of combination studies can also continue to expand and supplement the position we can have in monotherapy.

Chuck Triano - Pfizer Inc. - SVP of IR

Next question please.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - Leerink Partners - Analyst

Just a couple of quick ones. Ian, maybe you can comment on the fact that I/O investment overall seems wildly inefficient.

In that context, can you discuss the general efficiency of pharma's investments into this area? And in oncology, if you think the industry should really be looking to consolidate more of that spend over time, or should companies really be taking these independent paths, chasing the same targets?

And the separate question is just for Frank. On the tax rate, can you help us understand a little bit more the relative to your current repatriation thresholds, what would the tax rate need to be in order to maximize your free flow of capital?

Obviously 15%, I think, would get us there, which is the current proposal for a territorial tax system, but would 20% get us there? Would 22% get us there, relative to forecasting your current pro forma tax rate, which typically runs between 22% and 25%? Thanks.

Ian Read - Pfizer Inc. - Chairman & CEO

Regarding your question, I think you can see that clearly we will see the way investors have treated initially BMS and Merck and those are the front runners on I/O. They think it's a very effective investment strategy. The question you're really asking is, is there value to multiple shots on goal and multiple combinations, and there are a lot of combinations that you can try.

So, I think that these (inaudible) consistency, and it implies some lack of efficiency that we explore for leads and different ways to take these drugs forward, which will over the medium term shake out. Now, whether you want people chasing, only one person chasing one target, well, that would be the result of not spending as much on research by not supporting prices and not supporting innovation. Okay.

Frank D'Amelio - Pfizer Inc. - CFO

On taxes, let me run a few numbers and then I will answer the question, which is, there is the proposals from the administration, there's the proposals from Paul Ryan and the rest of the Republicans. Think about it this way. You need to think of foreign earnings in terms of accumulated earnings to date and then future earnings.



On future earnings, the administration has a proposal I believe of 15% minimum tax, where Paul Ryan has a proposal that's basically a total territorial tax system that would bring it back at zero. That comes, by the way, with base erosion call it border adjustability. I like that total territorial at zero, that is really good.

To Ian's point, in terms of a level playing field with our competitors. If you look at accumulated earnings, everything that's been accumulated already to date, the administration has a proposal of 10%, Paul Ryan has a proposal of I believe it's 8.75% on the cash, 3.5% on the non-cash, and then it's payable over eight years. My short answer is, the lower the better.

Obviously, you want to have easier access to our overseas cash in terms of maximizing shareholder value. The lower that number is for us, the better it is for our shareholders. So, my threshold is low.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Frank. Next question please.

Operator

Alex Arfaei, BMO Capital Markets.

Frank D'Amelio - Pfizer Inc. - CFO

Good morning, Alex.

Alex Arfaei - BMO Capital Markets - Analyst

Good morning. Thank you for taking the questions. First, Ian, thank you for prioritizing investors and being on the call as opposed to the White House.

This morning, the president said that foreign countries must pay their fair share for drug price development, excuse me, for drug development. This may not be a fair question to you, but do you think that is actually achievable, and if so, how could it be achieved?

And then also, forgive me, I'm not sure if I understood your earlier comments regarding the connection between US manufacturing and tax reform, if you could clarify that. And then, finally, on the business, Hospira operational growth was a little bit lower than expected at 2%, given all the ex-US launches. Can you provide some commentary there? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

Okay. On the stopping free riding, that economies free ride on innovation paid for by Americans. Clearly, it's trade policy.

It's how we interact and how we do our trade policies and how we negotiate. I think the president has been clear he thinks that they haven't been negotiated hard enough, and with regards to free riding on American innovation in pharmaceuticals, I totally agree with him, and hopefully we will get something done on that.

And certainly he declared his intentions to do so. And I will hand over the other question to John.



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

Thanks for the question. We continue to be very positive about the contribution that Hospira has made to our Business, both in terms of strategic fit, but also its operational performance. Just to run some numbers by you, our sterile injectable business for Hospira on the quarter as we printed it was flat.

Our biosimilars business grew by 48%. The infusion systems business, which had some softness in the fourth quarter, declined by 9% and the total was minus 1%.

To come back to the selling days true-up, but if you adjusted those for selling days and equalized between 2015 and 2016, the numbers become 9% growth for the sterile injectable business, 61% growth for the biosimilars business, infusion systems would be minus 2% compared to the minus 9%, and the total business would be 8% compared to the minus 1% when you adjust for selling days. Overall, we remain very positive about the organic performance of that business.

Ian Read - Pfizer Inc. - Chairman & CEO

Regarding the connection between tax reform and manufacturing bringing jobs back, we are not as an industry, we're interested in highly qualified workforces that have been trained and driven by the tax code today to manufacture outside of the United States. If there is no penalty by the border adjustment for manufacturing inside the United States to supply your markets outside the United States, that would encourage us to put more jobs in the United States.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Ian, and Operator, if we can take our last question, please.

Operator

Richard Purkiss, Piper Jaffray.

Richard Purkiss - Piper Jaffray & Co. - Analyst

Thanks, I had a couple of quick product questions. Firstly, for Albert on Bosulif do you see the results on the before study allowing you to expand into the first-line setting in the face of Gleevec generics? And for Mikael or Albert on Ibrance, can you tell us when you expect to see the neoadjuvant breast cancer data from the PALLET study, and can you give us a quick update on how enrollment is going in PALLAS?

Chuck Triano - Pfizer Inc. - SVP of IR

Can you repeat the first question, Richard?

Richard Purkiss - Piper Jaffray & Co. - Analyst

Was a question for Albert on Bosulif, the before study allowing you to expand into first-line in the face of Gleevec generic.

Ian Read - Pfizer Inc. - Chairman & CEO

I think we will ask Mikael to make some comments on that, and then the second one was on Ibrance, so you can take this too, Mikael.



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

Thank you for noting the very strong performance of Bosulif in the before study that was run with the venture group Avillion supporting us in developing in two early lines. We were really pleased with the data that I think has been released on a first type of high level that showed that it outperformed Gleevec and showed superiority. So we think it will certainly give Bosulif an opportunity to be a major drug across all lines in chronic myelogenous leukemia. Thank you for noting that.

When it comes to Ibrance, we have had a solid enrollment for our early breast cancer trials, which I think reflect, as Albert has alluded to, they are very favorable tolerability profile for a drug like Ibrance to be used and we have both as you know PALLAS and PENELOPE.

PALLAS is the broader study that covers both high-risk and intermediate-risk patients that will be treated with Ibrance for two years. The smaller PALLET trial, which is a Phase 2, more than any regular trial may read out later this year or possibly in 2018. Always difficult to have a firm projection. We anticipate data could come this year.

That's a study that in some way will give additional data from a Wash-U university study that was earlier shown at ASCO, which did show on Ki67 as a positive mark of [SG] receptor positive cancer cells, as well as on clinical responses that Ibrance was very active in this equivalent of early breast cancer.

These are the endpoints, but in a larger trial, Phase 2 of PALLET, we look forward to the date and I think if we just add more aspect of Ibrance and its activity across many segments of breast cancer, whether advanced or recurrent or here, earlier breast cancer.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Mikael, and thank you everybody for your attention this morning.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, everybody.

Operator

Ladies and gentlemen, this does conclude Pfizer's fourth-quarter 2016 earnings conference call. You may now disconnect.

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