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PFE - Q1 2015 Pfizer Inc Earnings Call

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OVERVIEW:

Co. reported 1Q15 reported revenues of approx. $10.9b and reported diluted EPS of $0.38. Expects 2015 reported revenues to be $44-46b and reported diluted EPS to be $1.32-1.47.

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PRESENTATION

Operator

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

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

Thank you, operator. Good morning and thank you for joining us today to review Pfizer's First-Quarter 2015 performance. I'm joined here today by our Chairman and CEO Ian Read; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Albert Bourla, President of Vaccines, Oncology and Consumer; Geno Germano, President of Global Innovative Pharma; John Young, President of Established Pharma; and Doug Lankler, General Counsel.

The slides that will be presented on this call can be viewed at our homepage, Pfizer.com, by clicking on the link for Pfizer Quarterly Corporate Performance, First-Quarter 2015, which is located in the investor presentations section in the lower right-hand corner of the page.

Before we start I'd like to remind you that our discussions during the call will include forward-looking statements and that actual results could differ materially from those projected in the forward-looking statements. The factors that could cause actual results to differ are discussed in Pfizer's 2014 Annual Report on Form 10-K, and in our reports on Forms 10-Q and 8-K.

Discussions in the call will also include certain financial measures that were not prepared in accordance with 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. We'll now make some prepared remarks and then we'll move to a Q&A session.

With that I'll now turn the call over to Ian Read. Ian?

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

Thank you, Chuck. And good morning, everyone. During my remarks this morning, I will briefly recap the highlights in the quarter, provide some thoughts about the pipeline and close with a few comments about actions we've taken to strengthen our core businesses.

Starting with the quarter, our performance for the quarter was solid, with good performance on both top and bottom line. Overall revenues grew by 2% operationally, even with a negative impact from the loss of exclusivity of Celebrex in the US and the end of the Spiriva co-promotion agreement also in the US.

In addition, we saw 12% operational growth in emerging markets, driven by both our GEP and Innovative businesses. While a majority of the LOEs and co-promote expiries are behind us, we still face some LOEs this year and next, making it difficult to generate revenue growth despite the strong performance of our newest products. That said, we believe the impact from any remaining LOEs will diminish over time as we continue to see a building revenue base resulting from investments we have made in key growth areas and recent product launches.

I'll touch on some noteworthy areas. Prevnar 13 had a very strong quarter, particularly in the US where revenues increased 80%. This was primarily due to strong uptake amongst adults 65 years of age and older, following the positive recommendation from the US Centers for Disease Control and Prevention's advisory committee on immunization practices as well as the timing of government purchases for the pediatric indication compared to the year-ago quarter. Revenues for the adult indication were approximately $300 million in the quarter.

Physicians' response to Prevnar 13 continues to build steadily, and our strong Q1 sales suggest these physicians are actively vaccinating adults who have never been vaccinated, as well as those who were previously vaccinated with Pneumovax from Merck. Each year, several million people in the US turn 65 who are eligible to receive Prevnar 13. And of those adults in the US who are already 65, there are many millions eligible that have never been vaccinated or were previously vaccinated.

We are increasing awareness amongst adults about the serious seriousness of pneumococcal pneumonia and the importance of talking to their physicians or pharmacists about vaccination to protect them from its devastating effects. We believe our efforts are increasing the sense of urgency to vaccinate and driving consumers to request the Prevnar vaccine. In December, CMS changed their guidance to cover both pneumococcal vaccines which ensures coverage for seniors 65 years and older under Medicare Part D, aligning with the positive ACIP recommendations from August 2014.

Eliquis is gaining significant momentum worldwide as it continues to increase share amongst cardiologists and recently has become the number one oral anticoagulant, that's NOAC, prescribed by cardiologists for new-to-brand patients in the United States and Japan. In addition, Eliquis is now the number one NOAC prescribed by cardiologists for new-to-brand patients for the non-valvular atrial fibrillation indication in the UK and Spain, and we are continuing to see increasing uptake in Germany.

We are pleased with the continued progress Xeljanz has made toward becoming a key product based on approvals in 40 countries in rheumatoid arthritis. Launches in revenue growth for the RA indication and the initiation of filing for the potential second indication in plaque psoriasis. In the US, rheumatologists' satisfaction with the product continues to be positive. Xeljanz now ranks number three amongst rheumatologists in new-to-brand prescription share of self-administrated rheumatoid arthritis therapies and is on track to become the third new-to-brand therapy overall in the US.

We have put significant focus and resources behind building our Oncology business. The portfolio was strengthened with some recent advancements.

In February we received accelerated approval from the FDA for Ibrance and have quickly launched in the US. While it is still very early I'm extremely pleased with this performance. Physicians have been embracing the product. The number of new patient starts have been increasing since the FDA approval and we are seeing early success with reimbursement to date. The Ibrance team has done a remarkable job in ensuring we were able to get the product to patients as quickly as possible following approval.

We also announced this month that our Phase 3 trial of Ibrance current breast cancer had made its primary endpoint for progression-free survival. We will be presenting detailed efficacy and safety results from PALOMA-3 at the upcoming ASCO. In addition, we have several presentations at ASCO including oral data presentations for our immuno-oncology asset 4-1BB and avelumab, the PD-L1 being co-developed through our alliance with Merck KGaA.

Also last week we announced another encouraging development in our oncology pipeline, a Phase 3 trial for inotuzumab met the primary endpoint of demonstrating a higher complete hematological remission rate in adults with relapsed refractory B-cell acute lymphoblastic leukemia compared to that achieved with standard of care chemotherapy. We are discussing these data with the FDA and other regulatory agencies. The trial will continue to evaluate overall survival which is a separate primary endpoint. The data will be submitted for presentation at upcoming medical meetings.

I believe our recent accompaniments and news flow in research and development demonstrate that we are in one of the productive times for our pipeline. We have strong presence in the areas where the science is quickly moving, whether it's market potential where we believe we have clinical differentiation, and most importantly where the patient's needs are the greatest.

Today we published a comprehensive update of the pipeline. You will see that we have a rich modality mix across small and large molecules and vaccines, novel mechanisms and potential new indications. This includes the development of bococizumab, the ongoing development for Xeljanz, a CDK 4/6 platform with Ibrance, a comprehensive immuno-oncology program with our partner Merck KGaA for the first wave of potential single agent monotherapy treatment regimes for several tumor types, and assets to position us for the next wave of potential I-O combination therapies including 4-1BB, OX40 and ADC, vaccines for staph aureus and c. difficile, a next-generation ALK/ROS1 inhibitor, a world-leading Kinase capability with unique JAK drugs in development, a strong rare disease portfolio in the areas of hematology, neuroscience, inherited metabolic disorders and pulmonology, our novel neuroscience work in Parkinson's, and our development portfolio of monoclonal biosimilars continues to progress well with four products now in Phase 3 development.

In total, we have 88 programs in clinical development with 30 programs in late stage development for registration as of today. Over the last several years we have rebuilt the pipeline and transformed our approach to R&D, and we believe we're well positioned to bring forth over the next several years therapies that will significantly improve people's lives.

Now for a few comments about how we continue to take steps to expand our sources of revenue and strengthen our core businesses. As always, we continue to look for business development opportunities that will create value with a bias towards deals with the potential for creating value in the near term. M&A activity in the pharma space has been very active recently and Pfizer regularly reviews potential opportunities but remains disciplined with our shareholders' capital to ensure transactions we may pursue generate an appropriate return for our shareholders.

That is why this quarter you saw us announce two transactions, one to drive greater sustainability of the GEP business over the long term and one to expand the vaccines portfolio. Hospira is an excellent strategic fit in an attractive and growing market segment, including sterile injectables and biosimilars, and we expect the acquisition to accelerate the growth trajectory of the GEP business. We remain on track for closing in the second half of this year.

And our deal for Redvax expands our vaccines development portfolio by giving us access to our promising vaccine in preclinical development for human cytomegalovirus, a virus that can lead to serious disabilities in infants when passed from newly infected mothers to their newborns. We now have a broader market in vaccines portfolio for preventing serious illnesses, which includes the most widely used pneumococcal conjugate vaccine in the world, Prevnar 13, with more than 750 million doses distributed. Trumenba, recently approved to prevent invasive disease caused by Group B meningitis in people aged 10 through 25, and vaccines to protect against disease caused by Group C meningitis and to help prevent tickborne encephalitis through acquiring Baxter International's marketed vaccines.

As you've heard us say on several occasions, business development is not a strategy. It is one lever of several we have available for strengthening our two basic businesses, the Innovative Products business and Established Products business.

This year is off to a good start with momentum in the pipeline growing, market penetration for our newest in-line products and strategic additions to the portfolio. Our focus for the year will continue to be on supporting our recent new product launches, in particular Ibrance and Prevnar 13 Adult, accelerating the differentiating key programs in the pipeline to deliver breakthrough products, continuing to look for attractive business development opportunities that strengthen our businesses, and doing all of these things while we deploy our capital in a way that yields the greatest value to shareholders.

I will now turn it over to Frank.

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

Thanks, Ian. Good day, everyone. As always the charts I'm reviewing today are included in our webcast.

First-Quarter 2015 reported revenues were approximately $10.9 billion, and reflect operational growth of $250 million or 2% year over year, mainly driven by the strong performance of Prevnar 13 and Eliquis in developed markets and Lyrica, Nexium 24 Hour, Xeljanz and Viagra, primarily in the US, the launch of Ibrance in the US in February of this year and 12% operational growth in emerging markets, which were more than offset by the unfavorable impact of foreign exchange of approximately $739 million or 7%, the loss of exclusivity in immediate multisource generic competition for Celebrex in the US in December of 2014, other product losses of exclusivity, and the termination of the Spiriva co-promotion collaboration in certain countries.

Adjusted diluted EPS was $0.51 versus $0.57 in the year-ago quarter. The decrease was primarily due to a $0.04 negative impact due to foreign exchange, and a $0.03 negative impact due to the $295 million upfront payment to OPKO during First-Quarter 2015.

Adjusted diluted EPS was favorably impacted by a lower effective tax rate and fewer diluted weighted average shares outstanding, which declined by 184 million shares, versus the year-ago quarter due to ongoing share repurchases which includes the partial quarter impact of our $5 billion accelerated share repurchase agreement effective February 2015. Reported diluted EPS was $0.38 compared with $0.36 in the year-ago quarter due to the previously mentioned factors and the favorable impact of lower legal charges, which were partially offset by a higher effective tax rate.

Foreign exchange negatively impacted first-quarter reported revenues by $739 million or $0.07, and positively impacted adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses in the aggregate by $462 million or 7%. As a result, foreign exchange negatively impacted fourth-quarter adjusted diluted EPS by approximately $0.04 compared with the year-ago quarter.

Now moving on to the financial highlights of our business segments, in the first quarter, Global Innovative Pharmaceutical revenues increased 7% operationally year over year due to the strong operational growth from Lyrica, primarily in the US and Japan, and the performance from recently launched products including Eliquis globally and Xeljanz primarily in the US. Although operationally revenues increased 7% and cost of sales decreased 1%, income before taxes declined 9% operationally mainly because of a 59% operational increase in R&D expenses, primarily due to the previously mentioned upfront payment to OPKO Health, and, to a lesser extent, an 11% operational increase in SI&A expenses due to increased investment in products in certain in-line brands.

First-Quarter VOC revenues increased 29% operationally due to the 51% operational revenue growth, from our global vaccines business, as a result of Prevnar 13, which grew 80% in the US and 15% in internationally, and the inclusion of Baxter's marketed vaccines in Europe, Nexium 24 Hour in the US, the launch of Ibrance in the US in February, and Xalkori and Inlyta globally.

Income before taxes increased 41% operationally mainly due to increased revenues with an associated improvement in gross margin, partially offset by a 19% operational increase in SI&A expenses due to investment in Prevnar 13 Adult indication, Nexium 24 Hour and Trumenba and Ibrance launches, and the 7% operational increase in R&D expenses due to increased investment in the Ibrance development program and the global immuno-oncology alliance with Merck KGaA in other oncology products.

In the First-Quarter Global Established Pharmaceutical revenues decreased 10% operationally mainly due to the loss of exclusivity and immediate multi-source generic competition for Celebrex in the US in December of 2014 and, to a lesser extent, from the loss of exclusivity of Lyrica in certain developed markets in Europe during the First-Quarter of 2015 and Zyvox IV in the US in January 2015, continued generic competition for Lipitor in developed markets, and the termination of the Spiriva copromotion agreement in most countries including the US in April of 2014. All of these were partially offset by strong operational growth of 10% in emerging markets driven by Lipitor, Viagra and Norvasc.

Income before taxes declined 14% operationally, due to the decrease in revenues and 1% operational increase for a 2.1 percentage point increase as a percentage of revenues and cost of sales due to an unfavorable change in product mix, flat R&D expenses primarily due to increased spending in our biosimilars development programs offset by lower clinical trial expenses, all of which were partially offset by a 9% operational decrease in SI&A expenses driven by cost reduction and productivity initiatives.

Now I'd like to walk you through the updated full-year 2015 guidance ranges for reported revenues, reported diluted EPS and adjusted diluted EPS relative to our 2014 actual results. I want to point out that there are no unfavorable changes to our operational outlook. We are only updating the 2015 guidance ranges for these elements solely due to the negative impact of recent changes in foreign exchange rates in relation to the US dollar from mid-January to mid-April, primarily driven by the weakening of the euro. This updated guidance assumes an FX rate for the euro of approximately $1.06.

As a result, we are lowering our reported revenue range by $500 million and now expect the range to be $44 billion to $46 billion. It's important to note that the actual negative impact of foreign exchange in our full-year 2015 revenues is actually greater than $500 million. However, the operational strength of our revenues is allowing us to absorb this. In addition, we are lowering our reported adjusted diluted EPS ranges by $0.05, and now expect reported diluted EPS to be in the range of $1.32 to $1.47 and adjusted diluted EPS to be in the range of $1.95 to $2.05.

Before moving on, I want to point out that actual rates in mid-April 2015 do not include the impact of a potential devaluation of the Venezuela bolivar. We are reaffirming the remaining elements of our 2015 financial guidance which we issued on January 27, 2015.

Moving on to key takeaways, we recorded solid financial performance in the First Quarter. While we have no unfavorable changes in our operational outlook for the remainder of 2015, we have updated our financial guidance solely to reflect the negative impact of recent changes in foreign exchange rates. We entered into an agreement to acquire Hospira for a total enterprise value of approximately $17 billion. Subject to the appropriate regulatory approvals, we continue to expect to complete the transaction in the second half of 2015.

We achieved several key R&D milestones so far in 2015, including receiving accelerated approval from the FDA for Ibrance with letrozole for first-line advanced breast cancer, our Phase 3 PALOMA-3 study for Ibrance with fulvestrant met its primary efficacy endpoint, the FDA lifting the partial clinical hold on our tanezumab development program, and we are preparing to resume Phase 3 activities with our partner Eli Lilly in the EC approving expanded indications for the use of Prevnar 13 Adults aged 18 years and older.

We continue to create shareholder value through prudent capital allocation. In the First Quarter of 2015, we've returned $7.8 billion to shareholders through dividends and share repurchases. It's important to note that after repurchasing $6 billion of our common stock in the First Quarter of 2015 including our $5 billion accelerated share repurchase, we have already met our 2015 share repurchase target and do not currently expect to repurchase additional shares this year.

We continue to expect to return approximately $13 billion to shareholders in 2015 through a combination of dividends and share repurchases. Finally, we remain committed to delivering our attractive shareholder returns in 2015 and beyond.

Now I'll turn it back to Chuck.

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

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Mark Schoenebaum, Evercore ISI.

Mark Schoenebaum - *Evercore ISI - Analyst*

I will use my question, please, to ask about use of capital, if I may. I know it's something you've discussed a lot but I think we are always interested in even subtle changes in how you answer these questions. But, Ian, I was just wondering, when you think about use of capital, are you at this point -- I think in the past you've remarked that if the numbers make sense you would be open to a large deal, similar to the AstraZeneca proposal last year. Just wanted to take your temperature on that.

And then also would you, in theory, be interested in buying a company, and adding small molecule and DA capabilities to the Established Products business? Or do you feel that the acquisition of Hospira filled the main gaps that that business may have had?

And then, finally, as you look across the landscape in biotech, do you have general thoughts on biotech valuations and opportunities there? Thank you.

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

Okay. One question became three. I think the organization is agnostic to the size of BD. It has to be BD that will move the needle. And I'm not concerned about doing a large transaction if the value is there for shareholders.

Vis-a-vis between adding to Innovative or adding to GEP or adding to Consumer, we are driven by value. Does it create value for shareholders? We have the capacity to add businesses in any one of those areas.

And the last part of the question was I think valuation? I think I said last quarter I thought that the valuation in biotech was buoyant. I still believe it remains there. So it means we are very careful as we evaluate deals.

There's probably no deal that actually occurs that we haven't looked at and evaluated. But we have a strong focus on creating shareholder value. And that's what guides us. Thank you for the question.

Operator

Jami Rubin, Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

Ian, in your prepared remarks you failed to mention tax inversions. I'm curious to know how much of a priority a tax inversion still is or unlocking the value of your overseas cash flows. And if you were to abide by the current IRS laws today, doesn't that mean that there are fewer large targets available to you than before? Can you confirm that and really just your appetite?

And then, secondly, you've said before that the earliest that you can break up the Company is in 2017. I'm assuming that's J1 2017 because we will at that point have three full years of financials. And if that's correct are you targeting a decision sometime next year? I would think that once you make the decision, it's going to take about a year or so before you actually execute on this split, or maybe it won't take quite that long. But are you targeting a decision next year? And if so what at this point are you waiting for to make that decision? Thanks very much.

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

Taking the last question first, I believe what we've said is that we would be in a position, if we so took the decision, to effectuate or start the split in 2017, which probably means we would have to take the decision in the latter part of 2016. We do need three years of financials. We will get those three years of financials by the end of 2016.

And what are we waiting for? As we've said before, Jami, I want to see how these two divisions are operating inside of Pfizer. Are they on their own, sustainable businesses? So I'm waiting to see our pipeline developed. I'm waiting to add, as we have done with Hospira, more attractive assets into Established Products.

And then I'm also looking to see how does the Street value the Pfizer as it is today. We've given you a lot of information on our segments, so is it sum of the parts different from the whole? And we will make that decision around the latter part of 2016.

So I think that answers that question. We are, as always, focused in our decision-making on creating shareholder value. And I think those three elements I laid out to you would describe how we would judge whether any such action would create shareholder value.

On the issue of lowering our tax rate, are we domiciling? Tax is one of our largest expenses. We, as any management should be, are focused on trying to prudently manage our expenses.

The new rules, or the new proposed rule change, does make it more difficult to immediately realize any benefits from being re-domiciled. But it really depends upon the target, the very complex issues of where the assets and where the cash and the tax position of the target. And so, really, it's very difficult to say what the universe of possible targets are. But rest assured that when we look at those type of BD deals, we're looking at the creation of value. Thank you.

Operator

David Risinger, Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

With respect to the potential separation of the businesses, I'm guessing that you're not willing to disclose the relative cash flow of the two segments? But my assumption is that the cash flow of the Innovative business is an even smaller percentage of the total Company cash flow than the earnings that you disclosed from the Innovative business would suggest. Anyway, Frank, I was hoping you could speak to that and help us understand

whether that's accurate and whether the lack of cash flow in the Innovative business is something that could potentially constrain your ability to separate or monetize that business.

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

Yes. Couple of comments, Dave. Let me start by reminding everyone, this quarter, when we file our 10-Q, we'll be including balance sheet information for the segment. But we won't have debt or cash, for example, by segment. We'll have on the asset side accounts receivable, inventory, tax assets and other assets. And then on the liability side, we'll have accounts payable of accrued compensation and other liabilities. So we'll start providing balance sheet information but we won't be providing debt or cash by the various segments since those are really enterprise assets, enterprise liabilities at this point.

What I would say is this, that I don't see capital structure -- I'm going to raise it up a little bit -- you asked about cash but I'll answer the question by saying I don't see capital structure as somehow impeding our decision-making relative to whether or not to execute a split of the Company. I believe we can clearly manage our way through capital structure so that's not in any way, shape or form some sort of impeding factor relative to our decision-making.

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Just two here. First on Ibrance, can you just discuss a little bit more the launch in commercial plans from here for the asset? And as part of that can you give us a little bit of color on the importance of PALOMA-3 to the market opportunity and the ramp of the product? And how big of an opportunity does this open up for Pfizer?

My second question was, coming back to GEP, do you have the capacity to pursue another large deal here? Or are you primarily focused on the Hospira integration at this point, not so much financial capacity, but if you have the personnel in place if another big deal were available could you pursue it? Thanks very much.

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

Let me just talk about the deal. We've done several large integrations. We're working well with Hospira. We expect it to close in the second half of this year.

Should value be there? This organization has the capability of undertaking other deals independent of size of it was important for our shareholders. So, I'm not concerned about that. I would pass it over to Albert to talk about Ibrance.

Albert Bourla - *Pfizer Inc. - President of Vaccines, Oncology & Consumer Healthcare*

Great. Thanks for the question. Overall we are very pleased with the results. So far, Ibrance has been well-received by oncologists. We have over 800 healthcare practitioners prescribing. We have over 2,000 new patients in one quarter. And we had approximately 3,000 total scripts written so far.

First line market share is already approaching 10%. That's way ahead of previous analogs. And also we see stronger investments so far.

Now, expectation is that Ibrance will gradually grow to become a new standard of care, a first-line treatment of this group of patients. But over time, Ibrance momentum in this country will build beyond first line as other studies read out positive. For example, you mentioned the results of PALOMA-3 which will be presented at ASCO. But we plan to work with the FDA to expand the label to other lines of therapy based on these results.

And also, as a remainder, there are several other breast cancer studies running in early and recurrent settings. And needless to say also we also have many non-breast tumor studies including head and neck, lung, melanoma, et cetera.

Now, for your particular importance of PALOMA-3, as I said, so far there is limited medical use in second and third line given that the label is in first line. So, as I said, we will work with FDA to expand the label to other lines of therapy. But beyond label amendments, I think we should see the PALOMA-3 in the way that adds to the level of confidence in the mechanism of action. And of course is also confirmation of an additional effect of Ibrance combination, this time with Faslodex, before we had with letrozole.

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

Thank you, Albert. We are at Pfizer very focused on speed and maximizing the opportunity of Ibrance and getting this great product to patients as fast as possible. And I believe we will be filing in the EU in the second half of this year. Is that right?

Albert Bourla - *Pfizer Inc. - President of Vaccines, Oncology & Consumer Healthcare*

This is correct.

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

Thank you.

Operator

Tim Anderson, Bernstein.

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

A couple of questions. Enbrel was down 8% operationally in Europe. I'm wondering how much of this reflects the impact of biosimilar Remicade. And if you can talk about expeditions for that product going forward in Europe both in terms of volume growth and pricing.

And then going back to this topic of splitting up, looking to see if you could give us odds of the possibility that Pfizer chooses not to split up? You consistently leave that open as a possibility for the last several years that we've talked about this topic. And as I'm sure you're aware, most investors want you to do something beyond just buying more targets and getting bigger, so it would be helpful to know with the odds of that not being delivered on is it less than 10%? Less than 20%? Less than 50%? Or what exactly?

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

Okay. Let me try and deal with the split before we ask Geno to deal with Enbrel. What I would say, Tim, is that I think this management team has established a reputation of focusing its actions on shareholder value. So, I don't really think it's useful to give odds. Where I think it's useful is to say we will do what's best for shareholders in creating value for them.

And some of our transactions, when we were looking at previous ones last year, at times we talked about getting bigger to get smaller. By getting bigger we could add and strengthen the independent businesses and then get smaller if it made sense. So, frankly, we are focused on creating value for shareholders. And if a split or getting bigger and then splitting makes sense, we will execute that, because the prime driver of this management team is to create shareholder value.

With that, I'll pass it over to Geno to talk about Enbrel in Europe.

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

Okay. Tim, the situation in Europe with Enbrel was that we implemented a new distribution model in the UK. We started at the end of last year where we moved away from the retail channel into just the hospital channel and direct to patient. What we saw in the First Quarter this year was some inventory workdown in the First Quarter and that affected our sales in the UK.

We had good, strong sales in Italy and France and Spain. We really didn't see anything more widespread than the distribution change.

In terms of effect of biosimilar Remicade on the Enbrel business, we really haven't seen an impact there either. We are expecting to see continued modest growth. It's a very large base of business, it's a very well-accepted product throughout Europe and the rest of the world. And we anticipate continuation of modest growth for the brand outside of the US.

Operator

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

First, Frank, just mechanistically how would a very large transaction, if you did one, affect the timing of a potential split? Clearly the Hospira deal did not affect your timeline but I imagine certain deals could.

And, secondly, for John, it's good to see another strong quarter from Hospira. Is it fair to say that the addition of Hospira, in your mind, takes GEP from flat to declining in sales in the out years to pretty squarely into growth territory? Thanks.

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

Just to reiterate what I said before and then I'll answer the question specifically, we are doing all the things we need to do, in particular the three years of prospective audited financials so that we'd be in a position to exercise our option in 2017 if we chose to do so. And as I've said before, the Hospira acquisition does not impact that timeline.

But then, Gregg, specific to your question, if we were to do a large transaction, and as Ian said before, we are agnostic to size, it's really all about we believe we can create shareholder value for our shareholders it could -- it clearly could impact our timeline. If we were to do a transaction and if it were to impact our timeline, please know we would proactively tell you all that as soon as we knew.

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

Gregg, it's John here. Thanks for the question. First of all, just to reiterate, as you know we obviously don't provide guidance by individual business. But obviously we're very pleased to see the continued positive strong momentum for the Hospira business.

This quarter, the GEP business has been subject to some LOEs, which I think Ian mentioned in his script and as we've flagged. We knew that in the short term that will therefore impact the revenue trajectory of the base GEP business over the next year or two.

But overall, the transaction certainly represents an immediate incremental source of revenue growth with products that can be expanded into additional markets, given Pfizer's global reach. And I the excitement that I think we've seen in the financial community, that certainly we share, really is around the transaction bringing together two excellent businesses that will deliver not only near-term profitable revenue growth, but also provide a platform for future growth that can be enhanced through Pfizer's global reach and infrastructure. So, we remain very positive about the combination of the two businesses.

Operator

John Boris, SunTrust.

John Boris - *SunTrust Robinson Humphrey - Analyst*

Congrats on the results. The first one just has to do with the Hospira transaction. Can you give any clarity on when you might anticipate HSR clearance? Most notably, one thing that we noticed was that on medium- and broad-spectrum antibiotics and betalactins that there's some overlap, and then certainly the overlap in the biosimilars. So any commentary on product divestitures would be helpful.

And then second question, on your oncology business if you look at Xalkori, you have number one, number two competitors in oncology launching ALK-positive compounds globally. Inlyta, in light of I-O data that potentially is becoming available. Can you maybe discuss the OS benefit Inlyta has potentially to being able to compete with I-O? And then on Ibrance just potentially competitive threats since competitors are indicating they could have data in 2016 to Ibrance, just your thoughts on your competitive positioning of that franchise going forward here.

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

Okay, John. Thank you. Some very optimistic questions there. Why don't we deal, first of all, with Hospira. Doug, can you do that?

Doug Lankler - *Pfizer Inc. - General Counsel*

Sure. We're looking at all the aspects relative beyond, obviously, biosimilars, as well. We are working closely regulators and we are very pleased with the progress that we're making. We continue to expect to close the transaction during the second half of 2015.

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

And on the oncology issues, would you like to comment upon what we expect the competition launching and then our second generation or third generation ALK ROS? And then perhaps Mikael may want to comment on some of the competitive dynamics.

Albert Bourla - *Pfizer Inc. - President of Vaccines, Oncology & Consumer Healthcare*

Absolutely. Thanks, John, for the question. In Ibrance, I spoke a little bit before and right now, we're really the only company that has randomized data there so we can make any comparisons. We have the most advanced and the most broad program in CDK 4/6.

I say more advanced because we are the only ones that have registration to start with and we have already announced positive results of a second the study in a different population. And of course we are having already initiated right now we have in this year running already four Phase 3 studies

on the breast cancer. And we are running beyond breast cancer over 30 studies in multiple tumor indications. I have a lot of respect for competitors, but I think in that one we really are way ahead.

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

I think one competitor just announced that they may be finishing their Phase 3 in 2017. Is that right?

Albert Bourla - *Pfizer Inc. - President of Vaccines, Oncology & Consumer Healthcare*

In 2016. Yes. We have already registration. And for the same type, we expect the confirmatory study to come to completion at the last quarter of this year, in our case. And as Ian said before, also we have discussions with EU authorities. And we plan to file for Ibrance in the second half of this year, as well.

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

Mikael, any comments?

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

Yes. I wanted just to briefly comment on your discussion about our ALK franchise. I think we should look upon it as an ALK franchise where Xalkori is the most experienced drug with a very much recognized stable profile.

We shared at recent conferences, including presentations at AACR, our third generation ALK inhibitor with 3922 number name. And it's deemed really unique compound that hits all known ALK mutations including the GE 1202R. And to the best of my knowledge, it's the only compound so far that has shown strong effect for [sole] mutations independent whether the patient has experienced several of the currently available ALK inhibitors.

Moreover, several responses also against brain metastases have been reported for this drug. So I think the combined ALK franchise from Pfizer will over time be very strong. Inlyta can nicely also be combined with immuno-oncology product as per our strategy. We shouldn't see Inlyta as alone facing other entrants but we and Merck Serono are exploring immuno-oncology of avelumab, Inlyta and other agents. So I think you will see us building a strong position in renal cell carcinoma.

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

Thank you. And, John, I see the competition coming in and extending the survival time of patients with the ALK mutation as very positive for our third generation when it comes to market, as you'll have all patients have gone through our first line Xalkori, and treating second line on products of competitors and creating a more substantial patient base for our third generation ALK. Thank you for the questions.

Operator

Vamil Divan, Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

I've got two quick ones on the product side and one on the expense side. Just on the products just if you can give us a sense of your optimism on tanezumab at this point. I know you're talking about Phase 3 now but just given the safety issues that have been raised before, do you see that as potentially a blockbuster type product deal or is it a more of a niche product just given some of the safety questions?

On Lipitor, a quick question on the real world study there. I know it's completed, it's been completed for some time. Any update on when we might see the data there?

And then just last one on the expense side, if I read the release correctly, you had quite a bit of expenses allocated to the other bucket as opposed to being allocated to one of the three specific business units. Now that we are five quarters into the company operating as three separate units how should we think about that in terms of your ability to actually split into two entities if you want to without having a significant amount of dissynergies, given that there seems to still be a lot of overlap in how the expenses are being spent?

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

Geno, tanezumab?

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

Yes. Tanezumab, we see this as a real innovation, one of the first real breakthroughs in pain management in many years and a significant unmet need, overuse of opioids being a big problem. And a substantial number of patients with the conditions that we're pursuing osteoarthritis, chronic low back pain and cancer pain. So, we see that this drug has significant potential.

We know a lot about this medicine. We've completed quite a number of studies and we're anxious to see it advance through this next phase of development and enter the market.

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

Thank you. Albert, real world, real life study, Lipitor?

Albert Bourla - *Pfizer Inc. - President of Vaccines, Oncology & Consumer Healthcare*

Yes. Thank you. The actual use trial was completed in December. The results are expected this quarter. The results of the study will inform next steps and timelines for potential NDA filing. And we will continue to update you as we have more news on that.

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

Okay. Frank, on expenses?

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

Yes. The major items in that other bucket are WRD, so Michael's organization and I'll call it corporate. Think about corporate as what we call the enabling functions. So, it's IT, finance, legal, HR, facilities, public relations, all those functions basically are what are in our corporate bucket there.

Last year, in the Q we gave you all percentage of how to allocate those various items to the segments. The key there is, in terms of the basis, so what's underpinning those percentages we give you, is really three buckets of allocation. There's, I'll call it, specific assignments, regional allocations and general allocations.

The specific assignments are about 40%, the regional allocations are about 20%, the general allocations are about 40%. We provide all that detail so that you can basically drive at the segment. And what that tells you is much of it is specific assignments in the regional allocation is very specific to an individual segment.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - *Leerink Partners - Analyst*

Just a few quick questions, a couple on the pipeline and then one for Ian. On the pipeline, maybe just to start off, maybe we could talk a little bit about when we might see data with your 4-1BB and what combinations we may see. Interestingly, we'd love to hear your thoughts on AstraZeneca's deal with Celgene and their comments on the challenges of getting into heme tumors.

The second question, just given the broad success of Opdivo in second-line lung cancer, when and how do you see your recently announced study recruiting in the US or perhaps even in Europe over the next 12 months as approvals are likely received?

And then lastly for Ian, when you say that you're agnostic to the creation of shareholder value, I think everybody has asked the question of the possibility that you go out and buy more assets. However, I do think that there certainly is a possibility of lowering your tax rate with a willingness to perhaps merge with an overseas entity, with that entity being the controlling entity. How agnostic are you truly to that kind of an outcome? Thanks so much.

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

Why don't I ask Mikael to comment on the 4-1BB? I don't really think it's appropriate for us to comment on AZ's strategy and how they go about financing their pipeline. And then on the lung cancer, perhaps Mikael or Albert can deal with that. And then I'll come back to you on how agnostic I feel.

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

Yes. Thank you. As you know, we believe that the field of I-O combinations is going to increasingly be prominent. And we have invested in a broad number of I-O combinations. We'll have up to five I-O drugs in the clinic this year and expect every year probably two new entering.

Specifically for 4-1BB, we will share additional data at ASCO. We have growing experience with 4-1BB in lymphoma on rituximab background that suggests stable activity and good tolerability profile. And I think suggests that this class of combining checkpoint activators with checkpoint inhibitors may be the route to go, as we have learned combining multiple checkpoint inhibitors acetyl 4 and PD-L1 may lead to a decreasing therapeutic window, while 4-1BB we are very encouraged that the therapeutic window will be launched. And the drug is an interesting part of this new I-O combination.

I also wanted to make a pitch that we actually are now entering the clinic with our OX40 antibody that also will be planned to be explored as monotherapy and later in combination with avelumab.

Briefly, just on second-line lung cancer, as we now start avelumab into several solid tumor indications, we expect over the years of 2017, 2018, 2019, and 2020 to see multiple pivotal trials with that and opportunities for drug registrations for several of the solid tumors including lung cancer.

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

Thanks, Mikael. Seamus, I think you mention, I think you perhaps misquoted me there. I'm not agnostic on value. I'm agnostic on size and I'm totally focused on value. And I think you're alluding your questions about whether you're 80/20 or 60/40 to maximize your benefits. And, once again, I am open to any set of combinations that when we look at it produces clear value for our shareholders. Thank you.

Operator

Steve Scala, Cowen.

Steve Scala - *Cowen and Company - Analyst*

I have a couple. First for Frank -- isn't the full-year share count guidance, 6.2 billion shares versus Q1's nearly 6.3 billion, that difference is $3.2 billion in share repurchase. And related to that, I'm surprised the share count was not much lower in Q1 versus Q4 given the $150 million share repurchase. I guess the answer might be that you weren't expecting the stock to be so strong but maybe you can clarify.

And then, secondly, how much of the $300 million in Prevnar sales in adults in Q1 would you consider catch-up versus the cohort of people that just turned 65 and are receptive to vaccination? Thank you.

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

On the share repurchase, Steve, our projections for the end of the year is a little bit higher than the number you quoted. And we obviously factored that into our guidance.

And then in terms of the shares, from Q4 to Q1, remember, on that accelerated share repurchase we got a partial quarter benefit to that in the number because we didn't put that in place until February. So, think about it as a mid-quarter impact. But if you go to the full year we are a little bit higher than the 6.2 billion. And what's really been driving that, and it's a good issue, is stock price is higher than we thought it was going to be from a share repurchase assumption perspective, only in terms of what we assumed in our planning. It's higher than what we had planned for. But net-net, it's all factored into our guidance.

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

Okay. Albert, if you'd like to try and dissect this interesting market for adult vaccines in the US and potentially internationally.

Albert Bourla - *Pfizer Inc. - President of Vaccines, Oncology & Consumer Healthcare*

Thank you, Ian. Thanks, Steve, for the question. I don't have specific data yet as to how much is catch-up or not, but the $300 million is an indication of the significant potential of this market.

Let me run some numbers for you. Every year, 4 million adults in the US alone are turning 65. There are 27 million adults that have been previously vaccinated with PPV23 and additional 20 million adults that have never been vaccinated. That's a pool of 47 million adults in US. Both of these cohorts are now recommended and reimbursed to receive Prevnar vaccine.

And the same comes with Europe. In Europe, we have already received in the label the prevention of pneumonia for adults 18 and older. We're working country by country to ensure recommendations and thus reimbursement, which will take some time but typically is happening.

And in general we are very pleased with the First Quarter, the results. They were driven, of course, by the broad recommendation. We had the severe flu season that also played a role. And also our commercial efforts were very successful.

Going forward, in the spring months we expect revenues to moderate given the seasonality of the business, but we expect strong revenue growth will resume in the fall. And overall we expect very strong growth for the year.

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

Thank you.

Operator

Andrew Baum, Citi.

Andrew Baum - *Citigroup - Analyst*

A question on your immuno-oncology portfolio. Do you have any evidence to date to conclude that the ADC-enabled properties of your PD-L1 are positively significantly differentiated versus the other non factor-enabled PD-L1s that [aren't clinical] approved?

Second, is it still the case that you haven't shown any solid tumor responses with your anti-CD-137 or has that changed?

And then, lastly, perhaps you could comment on the strategic outlook of your Consumer Health business given it's a very active market out there with numerous potential buyers who I'm sure would be interested in your assets. Thank you.

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

Thank you, Andrew. Mikael, could you take us through the immuno-oncology questions?

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

Yes. I think you asked briefly about ADCs and then mainly around differentiation for our immuno-oncology assets. Maybe I'll say a few words on ADCs. We have built up seven ADCs in the clinic. You heard recently about our calicheamicin ADC, inotuzumab, showing positive and good data for the first of two primary endpoints, hematological remissions.

We have a next wave in Phase 1/2 studies. I can in particular mention one, if not four, that you think you should keep an eye on that we also believe will continue to establish ADCs as an important modality. And we are indeed quite encouraged by the idea of combining the selectivity of ADCs with immuno-oncology, so I think your question was really good by asking about those modalities.

Our PD-L1, as you know, our view is that data available today suggests that it will have a similar profile to that of other advanced PD-1 and PD-L1 antibodies that presented data in unselected patients. And as you continue to explore enrichment of patients, such as increased level of PD-L1, it is expected that response rate will further increase as well as with drug combination.

There's been some suggestion from a reported [ASR] that avelumab may also, on the positive end, pick up some ADCCs NK cells. It remains to be proven in what tumor types this could potentially be a differentiation, but so far we have said that avelumab has a competitive profile similar to the other PD-1, PD-L1. And we are very excited to advance the molecule and we'll share an update at ASCO.

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

Thank you. And on the Consumer business, it actually had a very good quarter, very good growth. So, it's a business that we like to be in. I think it's a strategically important business for us. And we will continue to develop it. And if we have opportunities to do acquisitions to grow it, we'll also look at those. So, it's a good business to be in. Thank you.

Operator

Colin Bristow, Bank of America.

Colin Bristow - *BofA Merrill Lynch - Analyst*

A couple of quick questions. On the biosimilar Avastin, what's your view with regards to what agencies will require for approval? Do you think response rates will be sufficient or do you anticipate needing survival data?

And also, do you foresee any issues with recruitment here given the questionable incentives to trial the biosimilar versus the innovator?

And then just last question on Xeljanz, we see you're filing both the 5- and 10-milligram doses in plaque psoriasis. Is there potential for this data set to assist in the approval for 10-milligram dose in RA? Thanks.

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

Thank you. Biosimilar Avastin, Mikael? Comments on that?

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

Yes. I would say that for each of the biosimilars, we negotiate endpoints with the regulatory agencies. And we expect that data that indicate you have equivalent analytical on the drug pharmacokinetics and clinical profile, in general will lead to a registration across multiple indications.

I can't specifically speculate on what will be required for Avastin, but I will in general be optimistic that readouts such as response rates or PFS will be likely to confirm bioequivalence if you do have also strong robust data on the other aspects of bioequivalence. We have now five antibodies working closely with GEP in the pipeline and we are very pleased so far with all of those. Four are in Phase 3 studies.

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

Thank you. Geno, on psoriasis?

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

Colin, on the 10-milligram data in psoriasis, as you know, the psoriasis patient population is a much different patient population than RA. However, as we accumulate more and more data on the 10-milligram both in RA post-marketing surveillance studies and the additional indications including

psoriasis and ulcerative colitis and other indications, the database continues to grow. And that will serve as our support for continuing to evaluate the 10-milligram across all of the indications as time goes by.

Operator

Alex Arfaei, BMO Capital Markets.

Alex Arfaei - *BMO Capital Markets - Analyst*

A follow-up on biosimilars on your outlook -- could you comment on some of the intellectual property barriers that you might face in bringing biosimilars to the market. And specifically I'm wondering about the Humira biosimilar that you have in development. What do you expect the timeline for that product given some of the IP that AbbVie keeps referring to?

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

Thank you, Alex. John, please?

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

I think what we would say is obviously we look at full range of considerations. When we develop our portfolio of biosimilars, as Mikael just said in answer to the previous question, we engage very strongly with the regulators to make sure that we have an appropriate clinical program. And clearly we are very mindful of the IP landscape, which frankly varies by asset, is very complex ranging from base patterns to a range of other patterns.

We work very closely with our legal team to assess the likely time of entry to the marketplace for all of our biosimilars. And we take that into full consideration when we are constructing our development program and making our forecasts for the long range.

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

Thanks, John. And thank you, everybody, for your attention this morning.

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

Thank you. Have a good day.

Operator

Ladies and gentlemen, this does conclude today's Pfizer First-Quarter 2015 earnings conference call. You may now disconnect.
