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PFE - Q4 2014 Pfizer Inc Earnings Call

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OVERVIEW:

PFE reported 4Q14 reported revenues of approx. \$13.1b and reported diluted EPS of \$0.19. Expects 2015 reported revenues to be \$44.5-46.5b and reported diluted EPS to be \$1.37-1.52.



CORPORATE PARTICIPANTS

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Fourth-Quarter 2014 Earnings conference call. Today's call is being recorded. At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

Chuck Triano - *Pfizer Inc - SVP of IR*

Thank you, operator. Good morning, and thanks for joining us today to review Pfizer's fourth-quarter 2014 performance.

Joined today, as usual, by our Chairman and CEO, Ian Read; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Albert Bourla, President of Vaccines, Oncology, and Consumer; Geno Germano, President of Global Innovative Pharma; John Young, President of Established Pharma; and Doug Lankler, our General Counsel. 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 2014, which is located in the Investor Presentations section in the lower right-hand corner of this page.



Before we start, I'd like to remind you that our discussion during this 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 2013 annual report on Form 10-K, and in our reports on Forms 10-Q and 8-K.

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

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

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Chuck, and good morning, everyone.

We finished 2014 with another quarter of good performance, and met or exceeded every element of our financial guidance for the year. Frank will take you through the numbers but before he does, I want to re-emphasize how our four key imperatives have guided the actions we have taken, and the decisions we have made and will continue to guide us going forward.

These imperatives are about the steps we are taking to create a sustainable high-value pipeline, effectively and in a disciplined way deploy our capital in ways to create shareholder value, create a culture where colleagues take appropriate risks and accept accountability for their actions, and earn the respect of society. My remarks today will primarily focus on two of these imperatives, the evolution of our pipeline and how we are creating shareholder value.

When we started this journey at the start of 2011, we said improving the performance of our innovative core will be a multi-year endeavor. Over this time, we have significantly changed the composition of our pipeline to have a clearer focus on the therapeutic areas that have strong commercial and scientific potential. We have improved productivity in the pipeline. Since undertaking this effort, we have received 16 approvals as of the end of last year, 10 of which were new molecular entities.

Today, we have a total of 86 programs in clinical development, with 29 programs in late stage development or registration.

We continue to grow in key areas, most notably in some of our recently launched new products. Eliquis is winning share amongst cardiologists, and moving towards the leading position in the new to brand share in several markets, including the US and Japan. We grew our Xeljanz market share, so it is now ranked number three in new to brand prescription share with rheumatologists, and we are seeing good uptake of our Prevnar 13 adult vaccine following the CDC's Advisory Committee on Immunization Practices recommendation.

This is good progress and over the course of the next four years, we expect to have more than 20 Phase 2 and 3 registration study starts and hope to have more than 15 potential approvals, many of them new molecular entities. These numbers do not include study starts and approvals as a result of our Merck KGaA partnership in immuno-oncology.

Many of the new molecular entities have the potential to be first-in-class assets that give us growth platforms. These include the CDK4/6 platform in oncology with Ibrance, or generic name palbociclib, and its potential for indications being studied in the broad spectrum of breast cancer as well as lung, prostate, head and neck, melanoma, ovarian, renal, and brain tumors in young children.

We expect to have a competitive immuno-oncology program. We believe we have a comprehensive program with all of the elements to be an industry leader.



Through our partnership with Merck KGaA and their anti-PD-L1, avelumab, we are able to accelerate our participation in the immuno-oncology space, enabling both companies to participate in the first wave of potential single agent monotherapy treatment regimens of several tumor types, some of which we expect to be first or second to market.

Additionally, through this partnership, we are positioned to be a potential leader in the next wave of I-O combination therapies. We expect to be amongst the first three companies in certain cancer indications with monotherapy and a leader with combinations of PD-L1 avelumab, with targeted agents; for example, Inlyta, Xalkori and our second-generation ALK; or dual I-O combinations, for example, 4-1BB, OX-40, ADCs, et cetera; and in various cancer indications.

This year, we'll be collaborating on up to 20 studies with Merck KGaA, with registrational intent on up to 6 of these studies. In addition, through the collaboration, we expect to have 5 different IO drugs in the clinic this year, and up to 10 by 2016. This strategy includes: checkpoint inhibitor mAbs, small molecule immuno-modulators, cancer vaccines, bi-functional antibodies, CAR-T cell-based therapy, and antibody drug conjugates.

Our partner expects to present data from their PD-L1 study at ASCO in June. To best of our knowledge, it is one of the most comprehensive I-O platforms in development in the pharma industry today.

We also have leading research on JAK biology with potential new indications for Xeljanz in Psoriasis and Psoriatic Arthritis with our oral product, Atopic Dermatitis with a topical formulation, new GI indications in Ulcerative Colitis and Crohn's Disease, and in Ankylosing Spondylitis.

We have what we believe is a differentiated approach within the PCSK9 area for hyperlipidemia. Our lead asset, bococizumab, has a differentiated clinical trial design which includes high risk patients and also assesses primary prevention for patients. In addition to this large molecule approach, we have both a small molecule and a vaccine in development nearing first in human.

We have made progress with tanezumab, and plan to submit preclinical data to the FDA this quarter in a Complete Response to potentially lift clinical hold on that program.

In the Rare Diseases area, we're seeing good progress with enrollment in our Cardiomyopathy Phase 3 program for tafamidis, and are advancing towards Phase 3 with Rivipansel, pending our discussion with the FDA on the final optimization of the formulation. We have just announced a collaboration with OPKO for a long-acting growth hormone product that we believe could also be first-in-class and further expand that market.

We have a broad biosimilars portfolio of complex monoclonals. Of the current pipeline of five assets, three are in ongoing or enrolling Phase 3 trials and include potential biosimilars to Herceptin, Rituxan, and Remicade. We have completed a Phase 1 trial for Avastin, and expect to initiate our Phase 3 study later this year, and we have an ongoing Phase 1 proof-of-concept for Humira. We believe we can become one of the world's preeminent biosimilar companies.

There are also several potential acceleration opportunities in the pipeline that include a next generation ALK/ROS-1 inhibitor that holds the potential to significantly extend the lives of patients who no longer respond to Xalkori. We expect to start a pivotal study this year.

As you know, our Staph Aureus vaccine is currently in Phase 2 clinical trials, and was granted Fast Track designation by the US Food and Drug Administration in February 2014. A Phase 2b study that could be registrational is scheduled to start during the middle of this year.

I am pleased with the progress we have made and in a relatively short period of time in terms of the quality of the assets in our pipeline, and the potential for delivering breakthrough products starting in late 2017 and 2018.

Turning next to how the prudent deployment of capital has yielded significant returns to our shareholders. Over the last four years, we have maintained our operating margins and have taken approximately \$5.5 billion out of our operating expenses, during a period where we lost significant revenue to LOEs and co-promote expiries from several high margin products like Lipitor, Enbrel in Canada and the US, and the loss of Spiriva.

This year, and for the next couple of years, ongoing expense reductions will result from continuous improvement efforts. However, given that the largest opportunities have already been realized, the amount of potential reductions is more limited. Also, there are certain areas where we will continue to invest in such as R&D and new product launches.

Further, we have returned just over \$64 billion to shareholders through share repurchases and dividends over the last four years. As we have worked to transform Pfizer, Business Development has been an important enabler of our strategy. We have entered into a series of partnerships, in-licensing agreements and made some acquisitions that have bolstered our vaccines portfolio, enhanced our established products portfolio, strengthened our oncology pipeline, expanded our Consumer portfolio, and fortified the set of assets we have across our key therapeutic areas. Given the strength of our late and mid-stage pipeline, we will evaluate business development opportunities biased towards deals with the potential for creating value in the near term.

Beyond business development, here's what you can expect to see from us in terms of additional actions we plan to take in 2015 to create shareholder value.

We will continue to invest in the launch of new products. We are excited about the potential revenue and continued growth prospects primarily for Eliquis, Xeljanz, Prevnar 13 Adult, Trumenba, Inlyta, Xalkori and Nexium 24HR.

We expect these products, along with a few others [Vyndaquel, Bosulif, Duavee, and the vaccines acquired from Baxter] including Ibrance's pending approval will generate nearly \$2 billion in incremental operational revenue growth this year compared to last. So while we expect product launch costs will increase approximately 25% year-over-year, we are seeing good leverage from the investment we are making in these products.

In addition to new launch products, the Innovative business will be focused on growing market share in our major in-line brands like Lyrica, Enbrel outside the US, Viagra in the US, Chantix, and the Prevnar franchise. And our Consumer business will be focused on growing its core brands, Advil and Centrum, growing Nexium OTC market share and continuing to pursue Rx to OTC switch opportunities.

For our Established business, we will build on our success in 2014 in providing high-value, high-quality, low-cost treatments in emerging markets. We expect to see operational revenue growth of mid-to-high-single-digits in the emerging markets this year, by focusing on opportunities in key growth markets such as China, Brazil, India, Russia and Turkey.

In 2015, we will continue our efforts to establish the groundwork required to be in a position to operationalize a potential split of the Company. And we have made good progress on this work. For 2015, we anticipate the effort that will be required for this work will result in approximately \$400 million of one-time costs on a pretax basis.

Let me remind you, at this point in time, we have not yet made a decision to split the Company. We have said the final decision will depend upon how our businesses perform in their markets, having a high degree of confidence that the businesses will be successful as standalone entities; and how our shareholders value these businesses -- if the sum of the parts is greater than the whole.

And in 2015, we will again be in the position to reduce our adjusted effective tax rate. We expect it will decrease from 26.5% in 2014 to approximately 25% this year. We will continue to manage our tax line as we do any other expense line, and look to be as efficient as possible.

I would note that foreign exchange is one of those items that can either work for us or against us. Most importantly, it is not indicative of how the business is performing in a fundamental manner.

As always, all of our decisions will be rooted in how best to strike the right balance in terms of capital deployment, dividends, buybacks and business development. One of the reasons I'm confident that we can accomplish all of this is because we have an employee body that is motivated and engaged in the successful execution of the initiatives we have undertaken to drive results. Over the past four years, we have created a culture engrained in a strong ownership environment.

In summary, we will build on our performance over the past four years to create a sustainable, high value pipeline. To have market leading strong commercial businesses, to manage our cost structure, and continue to be disciplined in how we deploy our capital. Collectively, these elements of our strategy that will allow us to generate results and continue to create shareholder value, and it will enable us to bring patients innovative medicines that best meet their needs.

Now I'll turn it over to Frank for additional details on the quarter, the year, and our finance guidance for 2015. Thank you.

Frank D'Amelio - Pfizer Inc - CFO

Thanks, Ian, and good day, everyone. As always, the charts I'm reviewing today are included in our webcast. I want to remind everybody that as a result of the full disposition of Zoetis on June 24, 2013, the financial results of the Animal Health business and the gain associated with its full disposition are reported as a discontinued operation in the consolidated statements of income for the 12 months ended December 31, 2013.

Fourth-quarter 2014 reported revenues of approximately \$13.1 billion, which reflects a slight operational increase of \$9 million year over year, was mainly driven by the strong performance of Lyrica, Prevnar, and Eliquis in developed markets and Xeljanz which grew primarily in the US.

And 7% operational growth in emerging markets, driven by Lipitor mainly in China, as well as Prevnar and Enbrel, which were offset mainly by the unfavorable impact of foreign exchange of approximately \$449 million or 3%, the loss of exclusivity for Celebrex in the US, the expiration of the co-promotion term of the collaboration agreement for Enbrel in the US and Canada, and termination of the Spiriva collaboration in certain countries, and other product losses of exclusivity in certain markets.

Adjusted diluted EPS was \$0.54 versus \$0.56 in the year-ago quarter. The decrease was primarily due to a \$0.01 negative impact due to foreign exchange; the 4% aggregate operational increase of adjusted cost of sales; adjusted SI&A expenses and adjusted R&D expenses, driven by an unfavorable change in product mix; and increased R&D expenses, due to incremental expenses for the ongoing Phase 3 programs for bococizumab, palbociclib, ertugliflozin and certain other new drug candidates; as well as potential new indications for previously approved products, especially for Xeljanz.

Adjusted SI&A expenses, however, decreased by 2% operationally because of continued benefits for cost reduction and productivity initiatives. Partially offset by investment to support several recent product launches and other in-line brands. Adjusted diluted EPS was favorably impacted by a lower effective tax rate, and fewer diluted weighted average shares outstanding which declined by 159 million shares versus the year-ago quarter, due to ongoing share repurchases.

Reported diluted EPS was \$0.19 compared with \$0.39 in the year-ago quarter, due to the previously mentioned factors, and the unfavorable impact of a charge for the \$850 million upfront payment associated with the global strategic alliance formed with Merck KGaA in November of 2014 and an additional amount of approximately \$300 million, reflecting the fair value of certain co-promotional rights for Xalkori granted to Merck KGaA; higher charges related to certain legal matters, as well as the higher effective tax rate, all of which were partially offset by lower restructuring charges and purchase accounting adjustments in the fourth quarter of 2014, versus the prior-year quarter.

Foreign exchange negatively impacted fourth-quarter adjusted revenues by \$453 million or 3% and positively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate by \$351 million or 4%. As a result, foreign exchange negatively impacted fourth-quarter adjusted diluted EPS by approximately \$0.01, compared with the year-ago quarter.

Now moving on to the financial highlights of our business segments. In the fourth quarter, Global Innovative Pharmaceutical revenues increased 6% 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. All of which was somewhat offset by the previously mentioned expiration of the co-promotion term for Enbrel in the US and Canada.

Income before taxes declined 5% operationally due to a 5% operational increase in cost of sales; a 25% operational increase in SI&A expenses, due to increased investment in new products, such as Eliquis and Xeljanz and certain in-line brands; and a 25% operational increase in R&D expenses, due to incremental investment in late stage pipeline products; mainly bococizumab, ertugliflozin, and additional Xeljanz indications.

Fourth-quarter VOC revenues increased 14% operationally due primarily to the strong performance of Prevnar 13 Adult in the US and Xalkori globally; Inlyta in most markets; and Sutent in emerging markets; as well as Nexium 24HR in the US.

Income before taxes increased 13% operationally, mainly due to increased revenues which were partially offset by a 12% operational increase in cost of sales, driven by increased sales volumes. As a percentage of revenue, the cost of sales decreased by 30 basis points due to a favorable change in product mix.

A 13% operational increase in SI&A expenses, due to investment in Prevnar Adult; as well as launch and pre-launch expenses for Trumenba and Ibrance; and a 17% operational increase in R&D expenses, due to increased investment in the Ibrance and Trumenba development programs; and the global alliance with Merck KGaA.

In the fourth quarter, Global Established Pharmaceutical revenues decreased 7% operationally year over year, due to the loss of exclusivity of Celebrex in the US, Detrol LA in the US, and Aricept in Canada; as well as the termination of the co-promotion agreement for Spiriva in most countries including the US. All of these were partially offset by 7% operational growth in emerging markets and the strong performance of Lyrica in Europe.

Income before taxes declined operationally 9%, due to the decrease in revenues; a 5% operational increase; or a 2.3 percentage point increase as a percentage of revenues in cost of sales, due to LOEs and unfavorable changes in product mix; and a 5% operational increase in R&D expenses, primarily due to our biosimilars development program, partially offset by lower clinical trial expenses.

All of which were partially offset by a 17% operational decrease in SI&A expenses driven by cost reduction and productivity initiatives. As you can see, in 2014, we met or exceeded all components of our annual financial guidance. Now I'd like to walk you through the 2015 guidance ranges for reported revenues, reported diluted EPS and adjusted diluted EPS relative to our 2014 actual results.

First, it's important to note that the 2015 reported revenues incorporate an anticipated \$3.5 billion negative impact due to continuing product losses of exclusivity and declining alliance revenues, which will be partially offset by expected operational growth of certain other products.

In addition, we expect foreign exchange to have an additional \$2.8 billion negative impact on reported revenues. Consequently, we expect 2015 reported revenues to be in the range of \$44.5 billion to \$46.5 billion. Before moving on, I want to point out that the actual mid-January 2015 rates used to determine our 2015 guidance do not include the impact of a potential devaluation of the Venezuelan bolivar or any other currency.

Reported diluted EPS and adjusted diluted EPS also include the negative impact from product losses of exclusivity, a \$0.17 negative impact from foreign exchange rates, and a negative \$0.03 impact from the pending transaction with OPKO. As a result, we expect reported diluted EPS to be in the range of \$1.37 to \$1.52, and adjusted diluted EPS to be in the range of \$2.00 to \$2.10.

In addition, I want to remind everyone that guidance ranges for both reported and adjusted diluted EPS incorporate \$6 billion of anticipated share repurchases in 2015, including \$715 million of our shares repurchased to date. These repurchases will more than offset the potential dilution related to employee compensation programs.

In summary, if you exclude the anticipated FX impacts and the impact of the pending OPKO transaction, our FY15 adjusted diluted EPS guidance midpoint is in line with full year 2014 actual results, despite the \$3.5 billion negative impact from expected product LOEs and declining alliance revenues.

Now I'll review the remaining elements of our 2015 financial guidance. We expect cost of sales as a percentage of revenue to be in the range of 18.5% to 19.5%. We expect adjusted SI&A expenses to be in the range of \$12.8 billion to \$13.8 billion. We expect adjusted R&D expenses to be in the range of \$6.9 billion to \$7.4 billion, which includes a planned upfront payment of \$295 million to OPKO, expected in the first quarter of 2015.

upon completion of the transaction announced in December of 2014. We also expect adjusted other income to be approximately \$500 million, and we expect our tax rate on adjusted income to be approximately 25%.

Moving on to key take-aways. We achieved or exceeded all elements of our full-year 2014 financial guidance in an environment that continues to be challenging. We advanced our strategy through pipeline advancement and business development. The FDA approved Trumenba, our meningitis B vaccine, and we announced that we are in labeling discussions with the FDA for Ibrance. We entered into a collaboration with Merck KGaA which positions us well to potentially compete in the first wave of immuno-oncology therapies, and be a leader in the second wave of combination therapies.

Our full year 2015 reported revenue guidance range includes the anticipated negative impact of \$3.5 billion due to product loss of exclusivity, and \$2.8 billion due to adverse changes in foreign exchange, partially offset by nearly \$2 billion of anticipated operational revenue growth in certain products. The adjusted diluted EPS guidance range includes a \$0.17 negative impact from foreign exchange, and a \$0.03 negative impact from the planned upfront payment to OPKO.

We continue to create shareholder value through prudent capital allocation. Overall in 2014, we returned nearly \$12 billion to shareholders through dividends and share repurchases. From 2011 through 2014, we returned more than \$64 billion to shareholders through dividends and share repurchases.

In addition in 2015, we anticipate returning approximately \$13 billion to shareholders through dividends and share repurchases. Finally, we remain committed to delivering attractive shareholder returns in 2015 and beyond.

Now I'll turn it back to Chuck.

Chuck Triano - Pfizer Inc - SVP of IR

Thank you, Frank. Operator, can we please poll for questions. Thanks.

QUESTIONS AND ANSWERS

Operator

Thank you.

(Operator Instructions)

Your first question comes from Jami Rubin from Goldman Sachs.

Jami Rubin - Goldman Sachs - Analyst

Thank you very much. Ian, just a question for you, sort of high level. Based on all the press reports that we're all reading every day, it sounds like you are intensely focused on landing a large target and these articles are all saying most companies are rebuffing you.

I think this is a great opportunity for you to sort of remind us what are your strategic objectives? Do you have to make a large transaction?

And if so, is it -- it would seem to me that it's the GEP business that would need the biggest growth drivers, or is it the other areas of the business? If you could just prioritize for us which of the areas of the business make most sense for you for a large transaction, if indeed that's what you believe you need?

And then just a second question, maybe this is for Frank. On the GEP business, is it permissible for you guys to buy a foreign Company and use it as a new address when you potentially go to spin out, if you decide to do so, your GEP business? Is that actually an option? Thanks very much.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Jami, for the question. Rumors are rumors. We don't comment on rumors or speculation or what they write in the press.

I would go back to my comment that BD is an enabler of strategies. Our strategy is to deploy our capital in a way that is shareholder friendly. We've been doing that through dividends and buybacks.

And we have been doing BD. I would look at BD as a potential always to accelerate incremental value to shareholders. That's the purpose of deploying that capital, strengthening our businesses.

And we look at all opportunities to do that, but we do that in a disciplined manner. We did not push beyond what we thought was reasonable to do the AZ deal.

I don't feel that we need to do a large deal. I do believe, though, that we can deploy capital in a way that it can improve return to shareholders.

Frank D'Amelio - Pfizer Inc - CFO

And then Jami, on the second question where you were specific to the GEP business. And I think the question was buying a foreign company and potentially changing the address. Now, my answer is, it's kind of one of those things that's almost impossible to speculate upon.

It's very situational, depends on lots of things, valuations, markets and the like. Tax reform is an ongoing area where I think that it's still subject to change. So I don't want to speculate on what may or may not happen as a result of some hypothetical acquisition.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Frank. Operator, can we move to the next question, please.

Operator

Your next question comes from Chris Schott from JPMorgan.

Chris Schott - JPMorgan - Analyst

Great. Thanks very much. Just a couple questions here.

First for Ian. I believe you mentioned that your business development is now focused on creating value in the near term, given the late-stage pipeline. I guess just first of all, is there a shift from prior focus or what we were thinking about in 2014?

And then the second question on business development. When you look at valuations resetting kind of across the biopharma space, is that reducing the opportunity set as you look at these targets, given the valuation discipline you've highlighted for Pfizer?



Ian Read - Pfizer Inc - Chairman & CEO

Well, I think if we'd have been concerned about the state of our research and if we hadn't strengthened our research, which we did with the deal with Merck on the immuno-oncology asset. Then we may have felt we needed to do more business development in acquiring assets in our research.

But I feel our research pipeline, middle stage to late stage, is strong. And I would rather take our capital right now and direct it to opportunities to accelerate EPS growth as I think we've got the right balance of capital allocation in the medium to long term on the innovative side. So it's just really a balance of where you're deploying your capital and where you think you have areas you want to strengthen.

That being said, if there was a piece of intellectual property that added huge value and we thought we could develop it, we would not be shy in acquiring that intellectual property. I do think that the values are high at the moment in their many sectors.

We are disciplined. But when we find an appropriate deal that will meet our strategies of strengthening our businesses and accelerating shareholder value, we feel very comfortable that we have the ability to do those deals.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Ian. Operator, next question, please.

Operator

Your next question comes from Mark Schoenebaum from Evercore ISI.

Mark Schoenebaum - Evercore ISI - Analyst

Thank you very much for taking the question. First of all, great -- congrats to Frank, great P&L management this quarter, and also for the guidance. If I may ask some R&D questions.

On the PCSK9 program, could you just update us if you would be willing to do so on the time lines and the enrollment status for the outcomes trial on the PCSK9 program?

Number two, I was intrigued by your comments during the prepared remarks, Ian, on immuno-oncology where I think you mentioned that you thought you'd be among the first three companies to launch in several or a few tumor types. Wondering if you'd be willing to tell us what tumor types you think that could be?

And then finally, on palbo, and I suppose this is more of a commercial question. But just as we all contemplate a near term launch as a clear possibility, can you help us frame the initial market opportunity? Do you expect this to be a very rapid cancer launch or something that's a little bit more tempered since these women have a standard of care today? Thank you.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Mark. Good questions. Perhaps Geno can you address the PCSK9 status, and then I'd ask that we'll then move to answer your questions on palbo and which products we think we could be first or second in from Albert. Geno?



Geno Germano - Pfizer Inc - President Global Innovative Pharma

Sure, Thanks, Mark. Regarding the PCSK9 program, our outcomes trials, we're in the process of ramping up site initiation and enrollment. This is something that we monitor frankly on a daily and weekly basis.

So we're making good progress there. We expect to be competitive with the other programs from Amgen and Sanofi in terms of timing for completion of those outcomes trials, which we currently see occurring in the late 2017, early 2018 time frame.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Geno. Albert?

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

Yes. On the question on the initial Ibrance launch uptake. We are very excited about this initial launch for two main reasons. First, we have not seen an approval of a new therapy in first-line advanced [breast] cancer in over 10 years. So there is a great unmet need.

And secondly, Ibrance has demonstrated not only a statistical significant improvement, but more importantly a clinically meaningful benefit to patients because that would be a first, and added 10 months to the standard of care. As a result, we expect the uptake to be robust.

Having said that, as with all launches, there will be some oncologists that will be early adopters, while others will wait for additional data or more experience in the field. But for this group, we already have four Phase 3 trials ongoing, two of which are expected to complete this year.

Let me say that we are working to build a broad franchise around breast cancer. We are starting with first-line metastatic breast cancer. And then we are moving fast to recurrent advanced and then to early breast cancer. And I'd like to remind everyone, that we are currently running Phase 3 pivotal registration enabling studies for all of these indications.

Now, to your question on immuno-oncology. As Ian said, this deal is transformational for our immuno-oncology program for two reasons. And the first is that it will enable us to quickly move into the first wave of potential monotherapy treatments. You asked for some examples of that; examples would be ovarian or gastric for example. And this is where we are going to see to put our emphasis rather than on indications that are more crowded as melanoma, for example.

But don't forget the second also benefit, which is enable us to accelerate our combinations program by more than two-and-a-half years. This acceleration in conjunction with our broad range of combination therapies with, Xalkori, Inlyta, Ibrance, ALK/ROS inhibitor, OX40, 4-1BB, will enable us to be the leading player in the second wave where we see also a much greater portion of the [inaudible].

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Albert.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Albert. Operator, next question, please.

Operator

Your next question comes from Gregg Gilbert from Deutsche Bank.



Gregg Gilbert - *Deutsche Bank - Analyst*

Thanks, good morning. A couple unrelated questions.

First, Ian to slice the M&A question a different way, it's clear you have a sense of urgency to find deals that could be -- if they're shareholder enhancing. Would you care to comment on the sense of urgency to supplement the Innovative versus the Established Products? You've made it clear that you'd rather have near term accretion or value accretion versus long-term, but I want to make sure we understand that you're still committed to both or is one taking precedent?

Secondly, can you comment on Lyrica CR? Obviously, a large product that gets almost no focus. Are you planning to attempt a filing there to protect at least some of that franchise longer term?

And lastly, Albert, can you comment on Prevnar Adult versus pediatric and the progress there? And maybe share some color around the split between those two important buckets. Thank you.

Ian Read - *Pfizer Inc - Chairman & CEO*

Geno, do you want to talk about Lyrica first, and then Albert can talk about the vaccine, and I'll come back on our BD preferences or priorities.

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

So, Gregg, on the Lyrica program, we continue to advance the CR program for Lyrica. We have completed several trials, and seen positive outcomes. So we're continuing to move towards a registration, and we expect to see a registration potentially ahead of the expiration of the exclusivity in the United States.

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

Yes, Gregg, on the Adult, although early, we are very pleased with the launch. And we believe it is potentially a very large and durable opportunity, given current demographics and aging trends. The Adult sales in the US were around \$250 million, which was driven by higher penetration during the high flu season and of course also some inventory stocking with new customers.

Our market share jumped almost four times to 45% from 12% originally. Growth moving forward, we still expect to be strong throughout the year. Of course, keep in mind that this quarter was influenced by seasonality and some inventory build, and that can vary quarter by quarter.

On the pediatric that you asked, pediatric in fact was down this quarter due to the timing of a CDC purchases, which last year occurred in fourth quarter, and this year in third quarter.

Ian Read - *Pfizer Inc - Chairman & CEO*

Thank you. On the urgency to do business development, let me stress, the urgency I have is to create shareholder value. And if business development can do that then we will move on business development with urgency.

I don't really have a preference between strengthening either of the businesses. I think we can use business development to improve and strengthen both of them, and we will look at deals and if the deals make sense we will attempt to execute them. Thanks for the question.

Chuck Triano - Pfizer Inc - SVP of IR

Thank you. Operator, next question, please.

Operator

Your next question comes from Tim Anderson from Bernstein.

Tim Anderson - Sanford C. Bernstein & Company, Inc. - Analyst

Hello. I'm sorry, it's the same line of questioning but on inversion. So is that, in your view, pretty much off the table at this point for Pfizer or is that still something that you think you can pursue?

And then also on inversion, any visibility on when or whether Treasury might come out with a second round of regulations? Then on the pipeline, apart from palbo, if you had to pick two compounds that excite you the most, what would those be?

Ian Read - Pfizer Inc - Chairman & CEO

Okay. So on the inversion, Tim, inversions have not been stopped. What the potential rules of the government have done is delayed the value or potentially delayed the value realization of the inversion. So, inversions I think are being tempered by the ability to pay the target's price, given the slower realization of the inversion values.

I think it's an area that will remain fertile, while there's no change in the US tax laws. I think it's -- we're in a very uncompetitive situation with our tax code, and inversions will continue to be important as an instrument of increasing shareholder value just depending on the price you need to pay to affect the inversion. And the exact conditions of the inversion, which are very technical, depending on how you can manage your subsequent cash flows. So it's a very -- it's not an easy, general answer to what type of inversion you would want to do.

Apart from palbo, I think we have a lot of exciting products. I would probably talk about the ability to bring the Staph Aureus vaccine to market as quickly as possible.

I think bococizumab clearly has a huge potential. I think we're well placed with the clinical trial design. Ertugliflozin is well positioned. Adult vaccine, which we've just launched, has a huge potential.

So I find it difficult to really pick just two assets. I think we have a lot of assets that we can create value from, and especially the total life cycle of palbociclib.

So our new Treasury regulations, I don't know. I'm not in Washington. I can't comment. They have published a rule. They haven't finalized the rule. And clearly, there's an intent to do that. There's an intent to make it somewhat more problematic for people to plan inversions, and we'll just have to work around that. Thank you.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Ian. Operator, moving on, please.

Operator

Your next question comes from Vamil Divan from Credit Suisse.



Vamil Divan - *Credit Suisse - Analyst*

Thanks for taking my questions. I have two.

One I guess, the first one is more for Ian, obviously a lot of discussion around the M&A and what you guys are looking to do. I guess just strategically, some comments earlier about valuations and people you're approaching, maybe not wanting to go ahead with a deal.

I'm thinking strategically, isn't it tougher for you to consummate a deal when you're being so public talking about the need to do something? And the near term focus that you're mentioning now, doesn't that make it tougher to get a deal done and doesn't it just raise the prices higher?

And then, the second one is more on the pipeline. If you could talk about I-O, appreciate the comments you gave earlier and thanks for all that. Can you talk a little bit about, on the biomarker side if there's anything you can share how you're planning to incorporate biomarkers at least into this first wave of studies that you've outlined here for this year? Thanks.

Ian Read - *Pfizer Inc - Chairman & CEO*

Vamil, I'm intrigued by your comments. I don't think I've ever said we have to do a deal. I think you're reading the press rather than what I've been saying.

If I felt there was a pressure to do a deal, we would have done the deal we were trying to do last year. We are very disciplined. We don't feel we need to do a big deal.

I do feel that we have the ability and we have the balance sheet that we can use if business development can further our base of strategies, which is to strengthen either one of our businesses or to acquire in an area like immuno-oncology, which we did to strengthen where we see we can create synergy and value. So I'm a little mystified about your comment about that Pfizer needs to do a deal.

I think there's a lot of rumors running around. We, as like any management team, look at opportunities. We have the capital and the wherewithal to do the deal, should we so decide.

I don't think it's a matter of is there value, and if there's value we can get the deal done. So I'm a little -- I hope that puts in perspective for all of you where we sit on business development deals. Good to do if they create shareholder value, disciplined. If they don't, we're not doing them. Biomarkers.

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

So that's a great question on how you bring immuno-oncology to the next level. First, as you know, we have considerable experience in selecting and developing biomarkers from Xalkori, where we've obviously linked that to the drug's efficacy, and we have also learned how to drive uptake of that diagnostic to very high rates in the marketplace.

Specifically for immuno-oncology, so in our partnership on avelumab, we certainly are looking at PD-L1, high versus low tumors. And the data we see really correlates, as expected, with high response in the PD-L1 high, but we also see responses in the PD-L1 low.

We have a second wave, as you heard from Albert, on the 4-1BB and OX-40 for combination. We think that the 4-1BB is unique in amplifying cytotoxic cells, CD8 cells. So we certainly will look for expression of those cells in the tumor. Similarly for OX-40, we think it's more on the CD4 side, so that will be another marker to monitor.

But we also have programs coming on-board for key regulatory cells that may limit the overall immuno-oncology response and tumor suppressing macrophages. And we have assets coming within the next year or so on each of those particular subsets of immuno-oncology, and of course our

ADC portfolio is very much supported by diagnostic. We have now two ADC's in Phase 1 that show interesting responses, and we stocked enriched by diagnostic for those.

So I hope you get the sense that we go from standard diagnostic to more next-generation diagnostic, and we'll also do the kind of future diagnostic looking at circulating tumor cells to make it even more easy to integrate in medical practice. So we really see us being a driver of this change and a pioneer in this area. Thank you.

Chuck Triano - *Pfizer Inc - SVP of IR*

Thanks for the background, Mikael. Next question, please.

Operator

Your next question comes from John Boris from SunTrust.

John Boris - *SunTrust Robinson Humphrey - Analyst*

Thanks for taking the questions. First question, just going back to business development as an enabling strategy, Ian. I think you had indicated that one of the primary reasons for the AstraZeneca transaction was the tax considerations obviously around the inversion, and being able to unleash the value of the cash that you have trapped offshore.

If you go back and look at the last transaction, your tax rate around that time was around 22%. It's gone as high as 27%, not enabling you to bring that cash back. How much consideration is there that when you do a transaction, how much impact on the tax rate are you willing to absorb if it is a US asset that you're looking to you acquire?

Second question for Frank. You've disclosed what the impact of foreign exchange is. Can you articulate or quantify what the impact is on volume and price on growth in 2014?

And then last question on R&D and Xeljanz in EU. Any update on your ability to file Xeljanz in Europe? And then the implications for the Enbrel field force over there, especially in light of Samsung filing their SB4 and anticipating to be commercializing it, at least Biogen Idec commercializing Enbrel in the back half and how you're going to be adjusting for that resource if you don't have Xeljanz there. Thanks.

Ian Read - *Pfizer Inc - Chairman & CEO*

John, thank you. As always, good questions. Why don't you, Geno, deal with the whole issue of Xeljanz in Europe. And then Frank can look at the volume question, and then I'll come back to your rather complicated question on inversions and tax rates and perhaps Frank will also help me out there a bit.

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

So, John, regarding Xeljanz and the Enbrel inflammation business in Europe, we remain committed to resubmitting for approval in RA for Xeljanz in Europe. We have had recent interactions with regulators there, and a discussion on our plans for resubmission.

We were encouraged by those discussions. We continue to collect additional clinical data to support that resubmission, and our expectations are that we will resubmit by the end of the year in 2015.



Regarding Enbrel and potential competition, we see the introduction of biosimilars into the marketplace in Europe as something that's more evolutionary than transitional. And we expect to continue to support Enbrel through the near term, and realize continued support from that franchise. So I don't see a disruption at this point with the timing that we're anticipating and the impact that we see projected for biosimilars.

Ian Read - Pfizer Inc - Chairman & CEO

And of course, that market in Europe is very under-penetrated given their reluctance. So there's a lot of volume there that can be accessed via biosimilars as well as the original. Frank?

Frank D'Amelio - Pfizer Inc - CFO

John, for the quarter, this is Company-wide. So price was plus 1%. Volume was minus 1%. Foreign exchange was minus 3%.

FX drove the minus 3% for the quarter. And as I mentioned on my comments, we're actually up operationally by \$9 million, excluding foreign exchange for the quarter. For the full year, price was plus 2%, the volume was minus 4%, FX was minus 2%. If you put that together, you get the minus 4% that we reported for the year.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you. And on the BD, I think my comments on AZ have always been that we looked at three components of value. One was their pipeline, two was the amount of operational synergies that could be achieved, and third was the financial synergies. And we were disciplined in our approach because the financial synergies were the most risky part of the equation, and in fact were made eventually more difficult to achieve by the proposed rules.

I think the net-net answer to your question about tax rates is, it all goes into the value. What is the value of the acquisition we're trying to achieve, what's the value we create for shareholders? And the tax rate, just like the synergies, just like expenses, just like everything else, is part of that value equation.

If it works, the value works, we'll do the deal. If the value doesn't work, we won't do the deal.

But of course, undeniably, the foreign companies as you've seen for most of the acquisitions that have occurred in the last year, foreign companies do have an advantage given their tax rate. And this is something that should be of concern to the US economy.

Frank D'Amelio - Pfizer Inc - CFO

I think the only thing I'd add, Ian, is, John, in your question you mentioned before we announced Wyeth, it was 22% and we took it up to 27%. We actually took it up to 30%.

When we announced Wyeth, that we took the tax rate from 22% to 30%, and we've been I think in an effective way been able to step it down through a combination of changes in jurisdictional mix and tax planning. We've gone from 30%, to 29%, to 28%. This past year, we had said approximately 27%, we printed 26.5% on adjusted results, and now we've guided for 2015 to approximately 25%.

Chuck Triano - Pfizer Inc - SVP of IR

Thank you. The next question, please, operator.

Operator

Your next question comes from David Risinger from Morgan Stanley.

David Risinger - *Morgan Stanley - Analyst*

Thanks very much. I have two questions. Frank, in the context of a potential split up in the future, you've obviously set up the financials. But could you please discuss the dis-synergies and the risk of pro forma total costs being higher due to step-up costs if a separation were pursued in the future?

And then second, for Michael, could you please discuss the top three or four pipeline read-outs to watch in 2015? So specifically, what clinical trial read-outs are most important to focus on? Thank you.

Ian Read - *Pfizer Inc - Chairman & CEO*

Please, Frank.

Frank D'Amelio - *Pfizer Inc - CFO*

So, Dave, the way I think about the split question you asked me is in my mind they'll be basically three key determinants to obviously whether or not we would separate the Company. One is the performance of the businesses. The second one would be our confidence level in those businesses continuing to perform successfully on a standalone basis. And then three would be how the market values those businesses, and quite frankly, is there an opportunity to create a tax efficient way incremental value.

Is the sum of the parts greater than the whole? Is there an ability to unlock that value?

That value part of the answer, in my mind, would factor in the items you raised like dis-synergies. That's all part of the value equation that we'd have to factor in to get to a net-net positive, along with the aforementioned standalone performance.

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

Let me mention a couple of read-outs. So obviously from palbociclib or Ibrance, we are excited to also get read-outs from our recurrent study, combining with fulvestrant that Albert spoke about.

Avelumab, our partnership with Merck-Serono around ASCO will be the first time we start to share updated data sets. And I think there will be opportunity also later to hear how combinations are progressing, and possibly late in the year that we'll also share some data on 4-1BB, our own trial that we're running in lymphoma. We also have read-outs in ulcerative colitis, middle of the year or so.

We have top line results from induction study with Xeljanz. And please remember, in Phase 2, Xeljanz had very strong induction data, among the best that has been really presented in this field. And at the JPMorgan, I also shared very robust and really interesting data from our MAdCAM antibody in UC.

So you could really look up on UC as a space where we have multiple interesting data sets. More near term, you also have an opportunity to look at inotuzumab in ALL, which we'll have analysis for complete response or complete response with incomplete hematological recovery.

Chuck Triano - Pfizer Inc - SVP of IR

Next question, please, operator.

Operator

Your next question comes from Seamus Fernandez from Leerink.

Seamus Fernandez - Leerink Partners - Analyst

Thanks very much for the questions. First off, maybe, Frank, can you just walk us through -- we have an increase spending coming in -- well maybe not increased spending, but good cost controls overall. But is there more to achieve or be taken out of the business from here where you can be opportunistic as we head towards the potential loss of Lyrica and some incremental pressures? Or are we off an overall growth trajectory on the business, including the expense base as we think about 2015 plus?

And then separately, as we think about the PCSK9 opportunity, I think there's been a real emphasis on the outcomes from Pfizer. But Pfizer has also demonstrated an ability to succeed in the statin space without outcomes.

Just wondering, despite being third to market, how you would anticipate competing before perhaps outcomes are available? And could you be, as a third to market product, how would you expect to compete without outcomes versus other competitors who likely won't have outcomes data either? Thanks.

Ian Read - Pfizer Inc - Chairman & CEO

Okay, Frank, on spending.

Frank D'Amelio - Pfizer Inc - CFO

So on spending, Seamus, I've said this before. Clearly, we're in the late innings in terms of cost reduction. There's still opportunity. So I think there's always opportunities.

I think there continues to be opportunities in G&A, for example, continues to be opportunities with our portfolio as the portfolio ebbs and flows. So there's clearly opportunities related to the portfolio. And that said, it's hard. Ian mentioned in his comments that we've taken out \$5.5 billion in expenses and operating expenses over the last four years.

There's not another \$5.5 billion, for example, to take. So it's getting harder. If you look at our results for 2014, I'll give you the full year numbers operationally.

COGS was up 2%, SI&A was down 2%, R&D was up 9%. Clearly, that upward pressure on R&D we printed \$7.2 billion in 2014, as an actual number we guided to \$6.9 billion to \$7.4 billion for 2015. That includes the \$300 million upfront for OPKO, but I think R&D, OPKO aside is going to be in the low \$7 billions going forward.

So that's good upward pressure in my mind in terms of the late stage portfolio progressing in a good way. So I think that's probably more than you need. But I think the short answer is, there's always opportunities, but we don't have the same opportunities that we had several years ago because the base -- we've done a much better job I think in managing the base.



Ian Read - Pfizer Inc - Chairman & CEO

I'd just add to Frank's comments. That what we're looking at is a transition from dealing with some \$26 billion of LOEs from 2010 through 2015, and the need to rationalize our cost base to one of being investing in the future growth. Which I think is basically the most desirable state to be in, to have top line growth, and we're investing in our Phase 3 pipeline and our innovative products.

But this management team is very good at managing our P&L and our investment and where we invest. And are prepared to do what's necessary if business circumstances change on our expense base. With that, the other question was for Geno on PCSK9?

Geno Germano - Pfizer Inc - President Global Innovative Pharma

So, Seamus, just to respond, clearly Pfizer has a long history and heritage in the cardiovascular space. And I think that we can leverage that knowledge and obviously the data from our clinical trials to determine the best approach to the marketplace. Frankly, we really expect the PCSK9 market to emerge as a large and attractive market with the occurrence of the outcomes data and we're most focused on that.

We've obviously put our best thinking forward in our protocol designs. And should we have stronger data than the other companies in the cholesterol management arm, then we'll leverage that. But at this point, we'll have to wait and see how the data turns out, and again, our focus is mainly on the outcomes trials.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Geno. Next question, please.

Operator

Your next question comes from Steve Scala from Cowen.

Steve Scala - Cowen and Company - Analyst

Thank you. I have two questions. First for Frank.

Is the \$400 million in spend for a potential Company split in non-GAAP guidance, and what happens to this number in 2016? Is it the same? Is it higher or is it lower?

And then the second question is on palbociclib. Has the FDA taken a look or do you expect it to take a look prior to April 13th at the Phase 3 trial which is under way? Thank you.

Ian Read - Pfizer Inc - Chairman & CEO

Frank, do you want to talk about --

Frank D'Amelio - Pfizer Inc - CFO

Sure. So on the \$400 million, Steve, it's in GAAP, it's not in adjusted. We actually called that out in the release. It's in that bridge we give you all, that bridge is from adjusted EPS to GAAP EPS.

I think the bridge shows -- starts at the top, shows \$2 to \$2.10, and then we have three take aways from that. There's purchase accounting adjustments of \$0.41. There's restructuring and implementation costs that has a range of \$0.13 to \$0.18, and then there's a business and legal entity alignment cost which is the \$400 million you allude to which is \$0.04.

So that's the bridge from \$2.10 to \$2.20 to \$1.37 to \$1.52. So in GAAP, not in adjusted. And we give you a bridge that breaks out how we get from point A to point B.

In terms of 2016, quite frankly as we get towards the end of the year, early next year, we'll call that number out to you. Because a lot of that depends on how we progress through the year, how the businesses perform. So that's something that we'll call out obviously later in this year or early in 2016.

Ian Read - Pfizer Inc - Chairman & CEO

Albert, on palbociclib, Ibrance.

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

For Ibrance, I don't want to speculate what the FDA would like to do. But from a timing perspective, we don't expect to have the results of even an interim review of Phase 3 before the PDUFA date. And as you know, we are already in late stage discussions for the label.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Albert. Next question, please, operator.

Operator

Your next question comes from Jeff Holford from Jefferies.

Jeff Holford - Jefferies & Company - Analyst

Hello. Thanks very much for taking my question. First one is for Ian. Which is just really, what do you think about business development where you use OUS cash on OUS targets as non-inversion just straight M&A type deals as a potential pragmatic way to deal with the tax situation on those overseas cash assets? Do you see potential opportunities to do that?

And then, just a few financial questions. As you want to be able to allow investors to see the value in the two separate pieces, what do you think about giving midterm guidance on the two potential separate pieces for investors to help them reach that decision and how you reached that decision?

Do you think it's reasonable to assume that this is now the floor, 2015 is now the floor in Pfizer revenues and EPS going forward? And then lastly, are you happy that we just extrapolate this year's tax rate going forward, or are there any other factors that we should consider? Thank you.

Ian Read - Pfizer Inc - Chairman & CEO

Okay. I'll let Frank answer your modeling questions. On the BD and using offshore cash for offshore deals, once again, it comes down to value, it comes down to the offshore deals often price in the fact that there's offshore cash. So you have to look at the price tag on the deals and see if they make sense.



But certainly, conceptually, you have a point. But it just comes down to the quality of the asset and the deals you're trying to do. Frank, on the other question.

Frank D'Amelio - Pfizer Inc - CFO

So let me hit the -- Jeff, let me hit the extrapolation of the tax rate first. I think the way I'll answer your question is we stepped it down this year to approximately 25%. That's down from 26.5% in 2014. So a nice decrease.

And please note that when we reduce a rate like we're doing for 2015, our intent is that that rate's sustainable for the foreseeable future. So that's how I'd answer your question.

And in terms of trying to provide guidance beyond 2015 for tax rates, given all the uncertainty in the tax environment, I think that just wouldn't be a prudent thing to do. In terms of your question on BUs and providing midterm type of guidance, we continue -- I think we're getting more and more transparent I think relative to our business units. This year, we started providing very detailed income statement information.

Come 2015, we're going to start to provide -- we'll start to provide some balance sheet information. So we're providing more and more information that I think enables a lot of good extrapolation work.

In terms of taking our guidance and peeling it down to another level, I think it's hard enough to provide annual guidance for the total Company. You then taking it and slicing by sub-ledger detail I think, it creates a level of complexity that I don't think we're inclined to do.

Chuck Triano - Pfizer Inc - SVP of IR

Thank you. Next question, please, operator.

Operator

Next question comes from Marc Goodman from UBS.

Marc Goodman - UBS - Analyst

Good morning. First of all, can you give us an update on China? How did it perform in the quarter, and how you're expecting it to perform in 2015? Give us some trends there. Second, just update us on palbo overseas and what the timing is there.

And then on the MAdCAM, you did provide some data. And I was curious if you could comment on the dose response, and on why it will take so long to move into Phase 3? I think you said you're going to move into Phase 3 in 2016, and then I think the Phase 2s were done. So I was curious about that.

And then lastly, just on Lipitor over the counter, I know there was one study that remains before you can go back and talk to FDA. I was curious where we stand on that, and when you think you'll be talking to FDA again? Thanks.

Ian Read - Pfizer Inc - Chairman & CEO

Okay, let's try and put it together. So if Albert can answer the palbo and the Lipitor question.



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

We have had discussions with the European regulatory authorities on the clinical data. And it is our intention to file in the EU this year. The anticipated filing packets will build off of what was submitted to the FDA, but it's too early to provide more details on that.

Coming to Lipitor, you're right, the actual use trial was completed in December of 2014, and the results are expected in second quarter. So once we receive the results, then we will define our next steps in our efforts to bring an OTC version of Lipitor.

Ian Read - Pfizer Inc - Chairman & CEO

Okay. John, China.

John Young - Pfizer Inc - President Established Pharma

So thanks for the question, Mark. So we continue to perform strongly in China. I'll comment on the GEP segment, which is the largest segment of our business in China.

Overall for the quarter, we had growth of 13%. Overall for the year, we saw growth of around about 18%.

We continue to see as we always do in emerging markets quarter to quarter fluctuation, but we continue to be very satisfied by our performance in China. Segments that are strong for us are particularly our cardiovascular franchise, with Lipitor and Norvasc performing strongly. And also a very strong performance from our anti-infectives business.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you. MAdCAM.

Mikael Dolsten - Pfizer Inc - President Worldwide Research & Development

Yes. So thank you for noticing the very interesting dose response that we shared with you. We do think it represents possibly through human biology that at the mid-doses, 22 to 75 milligrams, in that range, we possibly inhibit the autoimmune cells causing disease while at the higher doses, you may also start to interfere with regular T-cells that have a protective effect.

So it is very important to have done a very thorough dose response that can allow you to select the optimal dose. And we think this may distinguish our opportunity, MAdCAM versus other endocrine antibodies that may not have been able to do such a thorough dose response and pick the sweet spot. And actually if you look at our remission data, they really perform well versus other published comparisons, although it's historical comparisons.

Concerning the time lines, so we'll certainly see if we can accelerate this, but that relates to production of clinical trial manufacturing for a potential registration study, and also to really understand how to design a study where you could best develop a drug that has this really unique tolerability profile, both for induction and maintenance therapy and how it could play as an anchor drug across many IBD-like conditions. So that's why we gave a little bit of extended time period, and we may be able to shorten that as we go forward.

Chuck Triano - Pfizer Inc - SVP of IR

Thank you, Mikael. Operator, if we could take our last question, please.

Operator

Your final question comes from Alex Arfaei from BMO Capital.

Alex Arfaei - BMO Capital Markets - Analyst

Good morning. And I apologize if I ask redundant questions. I got disconnected briefly.

Ian, from your perspective, could you comment on the M&A landscape in general? Based on your conversations with management teams, are you finding willing sellers out there and is it just a matter of price?

The follow-up for Frank, and just following up on your earlier comments, how should we think about your margins for the next couple years? You're losing some high margin products.

You said most of the cost cutting is done, and you're investing in launches. So is it fair to expect somewhat stable or perhaps slightly declining margins going forward? Thank you.

Ian Read - Pfizer Inc - Chairman & CEO

Alex, on the price, willing sellers, price always determines whether you have a willing seller or not, normally. It's just a matter of what value you want to transfer. What I would say is I think the starting point of the prices are somewhat buoyant, shall we say, given where the marketplace is.

So that does give you some concern when you look at paying the type of prices there are premiums you need of what we see as high valuations to begin with. So we are being disciplined in how we look at that. And then would you like to answer the margin question?

Frank D'Amelio - Pfizer Inc - CFO

So, Alex, I think a very good question in terms of I'll call it the rhythm of the margins. There is some, I'll call it, some downward pressure on our operating margins. So we've got \$3.5 billion in LOEs next year [in 2015], some high margin products clearly putting some downward pressure on the operating margins.

We've given guidance where you can obviously go through the line items and compute the numbers. That said, all of that's factored into our EPS guidance. And I want to reiterate what I said before.

If you exclude foreign exchange in the OPKO transaction, the midpoint of our guidance for next year is roughly what we printed in 2014, despite that \$3.5 billion in LOEs. So we'll continue to manage our cost structure, obviously the opportunities aren't what they used to be, but there is some slight downward pressure on our operating margins. That is what it is.

Chuck Triano - Pfizer Inc - SVP of IR

Thank you, Frank. And thank you everybody for your attention this morning on the call.

Operator

Ladies and gentlemen, thank you for participating in today's fourth-quarter 2014 earnings conference call. This concludes the conference. You may now disconnect.



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