Pfizer (PFE) Earnings Report: Q2 2015 Conference Call Transcript

The following Pfizer conference call took place on July 28, 2015, 10:00 AM ET. This is a transcript of that earnings call:

Company Participants

- Chuck Triano; Pfizer Inc.; SVP of IR
- Ian Read; Pfizer Inc.; Chairman and CEO
- Frank DAmelio; Pfizer Inc.; CFO
- Mikael Dolsten; Pfizer Inc.; President of Worldwide R&D
- Geno Germano; Pfizer Inc.; President of Global Innovative Pharma
- Albert Bourla; Pfizer Inc.; President of Vaccines Oncology & Consumer
- John Young; Pfizer Inc.; President of Established Pharma

Other Participants

- Gregg Gilbert; Deutsche Bank; Analyst
- Marc Goodman; UBS; Analyst
- Tim Anderson; Bernstein; Analyst
- Jami Rubin; Goldman Sachs; Analyst
- Mark Schoenebaum; Evercore ISI; Analyst
- Andrew Baum; Citigroup; Analyst
- Colin Bristow; BofA Merrill Lynch; Analyst
- Vamil Divan; Credit Suisse; Analyst
- Chris Schott; JPMorgan; Analyst
- Alex Arfaei; BMO Capital Markets; Analyst
- John Boris; SunTrust Robinson Humphrey; Analyst
- Jeff Holford; Jefferies LLC; Analyst
- David Risinger; Morgan Stanley; Analyst
- Seamus Fernandez; Leerink Partners; Analyst

MANAGEMENT DISCUSSION SECTION

Operator:

Welcome to Pfizer's second-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 (SVP of IR):

Thank you, operator. Good morning, and thanks for joining us today to review Pfizer's second-quarter 2015 performance.

As usual, I'm joined today by our Chairman and CEO, Ian Read; Frank DAmelio, our CFO; Mikael Dolsten, President of Worldwide R&D, 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. The slides that will be presented on this call can be viewed on our homepage, Pfizer.com, by clicking on the link for Pfizer quarterly corporate performance second quarter 2015, 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 discussions during this conference call will include forward-looking statements, and actual results could differ materially from those projected in these statements. Factors that could cause actual results to differ are discussed in our 2014 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 our 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 (Chairman and CEO):

Thank you, Chuck, and thank you for joining our call this morning. During my remarks this morning I will briefly recap the highlights from the quarter, provide some comments on key areas of focus within the pipeline, and close with a few words about business development and the pending Hospira acquisition.

Starting with the quarter, it was another quarter of strong operational performance. For the third consecutive quarter we saw operational revenue growth, excluding the impact of foreign exchange, and despite LOE headwinds. We continue to see solid revenue growth from our newer products, as a result of investments we've been making in R&D and our commercial operations.

Specifically in the second quarter as compared to the same period last year, Eliquis alliance revenues nearly tripled on a global basis, and Xeljanz revenue nearly doubled. Prevnar 13 revenue in the US increased 87%, primarily due to continued strong uptake in Prevnar 13 in adults, with most of the growth in the overall Prevnar 13 franchise coming from the adult indication in this quarter. We have done an excellent job for the first half of this year of getting to patients and capturing the potential of Prevnar 13 adults in the US, as evidenced by the outstanding year-to-date performance, which has been primarily driven by the catch-up opportunity.

Over the next few years, we believe this catch-up opportunity in the US will be robust. However, we will likely need to expend more effort to reach these individuals, and the opportunity will moderate over time, as the catch-up opportunity becomes fully realized. And given current demographics and aging trends, approximately 4 million Americans will turn 65 each year, and a part of these adults will be part of our immunization effort.

As we move through the catch-up population and get to a more normalized adult immunization rate domestically, we'll be expanding our efforts to capture expected new growth outside the US. Given the aging demographic trends, we expect to obtain several pneumonia recommendations and reimbursements between 2016 and 2018 in many international markets.

Ibrance continues to be well-received by oncologists treating postmenopausal women with ER-positive HER2 negative advanced breast cancer, with approximately 3,000 healthcare practitioners already prescribing Ibrance. This is up from 800 at the end of the first quarter. Our current first line market share in this patient population was approximately 22% during the quarter, up from 10% during the first quarter.

We look forward to filing for approval in the EU later this year, and are working to add the data from the

PALOMA-3 study to our US label for women with HR-positive HER2-negative metastatic breast cancer, whose disease has progressed during or after endocrine therapy. I would note that all of these products I just mentioned are now meaningful contributors to our business. We also saw quarter-over-quarter operational growth from several of our in-line key products, including Lyrica, Sutent, Xalkori and Inlyta.

In our consumer business, we saw quarter-over-quarter operational growth from several brands including Centrum, Advil, Robitussin and [Immersion] CC. We are seeing strong performance from Nexium OTC, despite a decline this quarter, due to the non-recurrence of initial retailer stocking associated with the launch last May. Since its launch, Nexium has generated revenues of approximately $300 million, making it one of the largest and most successful Rx to OTC switches.

Regarding other Rx to OTC opportunities, we have received the top line results from the Lipitor actual use trial that was completed last December. The results show that co-primary endpoints were not achieved.

Based on our analysis of the data and recent feedback from the FDA on the overall program, we have decided to terminate the program. That said, we continue to evaluate other products for potential Rx to OTC switches. And within emerging markets, revenues increased 6% operationally compared to the year-ago quarter, driven by operational growth in Prevnar, Lyrica, and Lipitor.

This quarter was a favorable example of our track record of a solid operating performance. Given our strong execution across the businesses during the first half of the year, coupled with an improved operational outlook for the remainder of this year, we are raising the midpoints of our 2015 financial guidance for reported revenue by $500 million, and for reported diluted EPS by $0.03 per share and adjusted EPS by $0.04.

As we enter the second half of this year, our strategy, focus and priorities remain unchanged. Top line growth remains a priority. Over the last three quarters we have seen top line operational growth on a total Company basis.

Recent product launches in key in-line products have performed well, while the impact from the remaining LOEs has diminished. For example, the impact from the Celebrex LOE will be annualized after another two quarters, and Zyvox shortly after that. Once this happens, we'll have put the most significant LOEs behind us, and expect to return to a more measured cycle of product loss of exclusivity.

We remain steadfast in our efforts to deliver the next wave of potential new innovative therapies over the coming years. The areas where we see the largest potential to benefit patients, and where we're focusing our resources include building a strong immuno-oncology portfolio. Through our through our agreement with Merck KGaA, we believe we have one of the most comprehensive IO platforms in development in the pharma industry today. We have -- we expect to have five different IO drugs in the clinic this year, and up to 10 different drugs by 2016.

The key targets include avelumab, the anti-PD-L1, OX40, 4-1BB, our vaccine-based immunotherapy regime, CCR2, [IDA1], and several bifunctional antibodies. We believe that these combinations are the key to better patient outcomes in IO, and given the breadth of our assets, we think we are well-positioned to win here. We will be collaborating on up to 20 studies with Merck KGaA, and we plan to have up to six immunology Phase III trials ongoing by the end of the year across several tumor types, including non-small cell lung cancer, ovarian, renal, bladder, and gastric. Our second-line non-small cell lung cancer registration study is currently recruiting.

And where possible, we will be looking to accelerate these studies. For example, we are planning to move quickly into a registration study with avelumab in combination with Inlyta in kidney cancer later this year.

We also continue to build our palbo franchise, moving our R&D efforts into early stages of the treatment paradigm, as well as in non-breast cancer indications. In cardiovascular, we have a comprehensive Phase III trial program for bococizumab, our investigational PCSK9 inhibitor, with potential to lower low-density lipoprotein cholesterol and improve cardiovascular outcomes. We anticipate our Lipitor-lowering trials will complete in 2016, and we estimate that our CV outcomes data will be available in the first half of 2018.

The outcome studies are time to event trials, so it is difficult to predict exact dates, but we anticipate this will be consistent with the timing of other industry outcome studies expected by our peers. Our ertugliflozin Phase III program is well underway, and given Januvia's recent positive CV outcomes clinical trials results, we remain enthusiastic about the demand potential for the ertugliflozin-Januvia combination, in an area of significant patient need.

In vaccines, we recently started a Phase IIb study for a staph aureus vaccine, and depending upon the results, it could serve as a registrational study. Also, this month, we initiated a Phase II study to evaluate the safety, tolerability, and immunogenicity of our investigational C difficile vaccine. Both of these vaccines could be key to stemming the spread of the leading causes of serious healthcare-associated infections.

In immunology, the FDA accepted our review for a supplementary new drug application for Xeljanz once-a-day modified release tablets. Our PDUFA date is February of next year. If approved, it would bring us one step closer to offering the first and only once-a-day oral JAK kinase inhibitor treatment for those living with moderate to severe RA, who have had an inadequate response or intolerance to methotrexate. We believe this will be an important product modification.

In rare diseases, we enrolled the first patients in Phase III clinical trials assessing the efficacy and safety of rivipansel, for the treatment of vaso-occlusive crisis in hospitalized individuals with sickle cell disease who are six years of age or older. And additional clinical studies are underway for prevention of sickle cell crisis disease. We believe this was built on our strength in researching and bringing to market therapies for hematological rare diseases, based on our deep history of hemophilia.

In biosimilars, we started a Phase III clinical trial of our potential biosimilar to adalimumab, making a total of five monoclonal biosimilars now in Phase III development. In sterile injectables, we're excited about the opportunity to combine Pfizer's branded portfolio in global commercial organization, with Hospira's demonstrated R&D capability, and manufacturing capacity of sterile injectable products, and this will occur upon the close of the acquisition.

Overall, as a result of the work we have done to focus our R&D efforts in the areas that we believe offer the greatest potential for therapeutic benefit and chance for commercial success, we are building a stronger portfolio on behalf of our patients that we believe will create value for our shareholders.

Turning now to a few words on business development. It remains enabler of our strategies, and as I've said before, is not a strategy on its own. While we are seeing strong performance from our recent product launches, over the next few years, we are looking at business development as a way to invest in generating sustained near-term and future growth. Knowing that the next wave of our potential major registrations or launches won't happen till 2017. In the interim, we have the financial capacity to actually seek out the right deals at the right price, that will create value for our shareholders.

We are optimistic that we can find these deals as we go through the period to 2017. In keeping with this philosophy, we have proactively evaluated virtually all of the deals announced this year, and have chosen to pursue only those that efficiently use capital to strengthen the business, drive growth, and accelerate value. For example, we have entered into several agreements year-to-date that have

bolstered our scientific integral capabilities, and provided us with the potential for new growth opportunities. Of particular note are the two most significant transactions with Merck KGaA in immuno-oncology, and the pending acquisition of Hospira .

Regarding Hospira we are proceeding on track and are awaiting regulatory approval from several jurisdictions. We continue to expect the transaction to close in the second half of the year.

In closing, I am pleased with our strong financial position, new and in-line product performance, pipeline advancements, and recent business development activity. We are performing well, and for the remainder of this year, we will focus on service, strengthening both our innovative and established businesses, to best position them for their long-term success. I'll now turn it over to Frank to take you through the financial details of the quarter.

Frank DAmelio (CFO):

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

Second-quarter 2015 reported revenues were approximately $11.9 billion, and reflect year-over-year operational growth of $125 million, or 1%, mainly driven by the strong performance of Prevnar 13 adult, Eliquis, Ibrance, and Xeljanz, all of which are early in their life cycles. The addition of vaccines acquired from Baxter in 2014, and operational growth of 6% in emerging markets, mainly due to Lipitor and Prevnar 13.

Reported revenues were unfavorably impacted by the loss of exclusivity of Celebrex and Zyvox in the US, and Lyrica in certain developed European markets. Adjusted diluted EPS was $0.56 versus $0.58 in the year-ago quarter. The decrease was primarily due to the $0.06 negative impact of foreign exchange, and partially offset by a lower effective tax rate, and fewer diluted weighted average shares outstanding, which declined by 201 million shares versus the year-ago quarter, due to our share repurchase program. Which includes the impact of our $5 billion accelerated share repurchase agreement executed in February of 2015, and completed in July.

I want to point out that excluding the unfavorable impact of foreign exchange, adjusted diluted EPS would have increased by approximately 6%. Reported diluted EPS was $0.42 compared with $0.45 in the year-ago quarter, due to the previously mentioned factors and the unfavorable impact of higher legal charges and acquisition-related costs associated with the pending acquisition of Hospira versus the year ago quarter, as well as charges incurred during the second quarter of 2015 for legal entity alignment activities. Partially offset by lower restructuring and other charges associated with cost reduction and productivity initiatives, lower purchase accounting adjustments, and a lower effective tax rate versus the year-ago quarter.

Foreign exchange negatively impacted second-quarter reported revenues by approximately $1 billion or 8%, and positively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate by $518 million or 7%. As a result, foreign exchange negatively impacted second-quarter adjusted diluted EPS by approximately $0.06 compared with the year-ago quarter.

Now moving on to the financial highlights of our business segments. In the second quarter, global innovative pharmaceutical revenues increased 8% operationally year-over-year, due to the strong performance of recently-launched products including Eliquis globally and Xeljanz in the US, and the continued strong performance of Viagra in the US and Lyrica in the US and Japan, which were partially offset by declines of Rapamune and BeneFIX in the US.

Income before taxes increased 9% operationally, due to the operational increase in revenues and the 2% operational decrease in cost of sales, partially offset by a 6% operational increase in SI&A

expenses, primarily due to additional promotional investment in certain in-line and recently launched products. And the 21% operational increase in R&D, reflecting incremental investments in our late-stage pipeline, primarily for bococizumab.

Second-quarter VOC revenues increased 29% operationally, due to the 52% operational revenue growth from our global vaccines business as a result of Prevnar 13, which grew 87% in the US, due to continued strong uptake in adults and 10% internationally, and the inclusion of Baxter's marketed vaccines in Europe. A 36% operational increase in oncology revenues, driven by the launch of Ibrance in the US in February, and to a lesser extent by Sutent, Inlyta, and Xalkori.

Income before taxes increased 51% operationally, mainly due to increased revenues and associated improvement in gross margin, and a 16% operational decrease in R&D expenses as a result of lower clinical spend for Trumenba, Prevnar 13 adult, and certain oncology products. Which were partially offset by a 15% operational increase in SI&A expenses, due to increased investment in both the Prevnar 13 and Ibrance launches. In the second quarter, global established products revenues decreased 14% operationally, mainly due to the loss of exclusivity, and immediate multi-source generic competition for Celebrex in the US.

In December of 2014, generic competition for Zyvox in the US, and Lyrica in certain developed markets in Europe beginning in the first half of 2015. And to a lesser extent, from continued generic competition for Lipitor in developed markets, and the termination of the Spiriva co-promotion agreement in most countries, including the US in April of 2014. All of these were partially offset by operational growth of 2% in emerging markets, primarily driven by Lipitor.

Income before taxes declined 17% operationally, due to the decrease in revenues, a 1.5 percentage point operational increase in cost of sales as a percentage of revenues due to unfavorable change in product mix, a 3% operational increase in R&D expenses reflecting increased spending in our biosimilars and sterile injectables development programs, largely offset by lower post-marketing clinical trial expenses, all of which were partially offset by an 11% operational decrease in SI&A expenses, driven by cost reduction and productivity initiatives.

Because of our strong operational performance and improved operational outlook for the remainder of the year, we are raising the midpoint of our 2015 guidance ranges for reported revenues by $500 million, and the midpoint of our adjusted diluted EPS guidance by $0.04. We now expect reported revenues to be in the range of $45 billion to $46 billion, and adjusted diluted EPS to be in the range of $2.01 to $2.07.

We also now expect reported diluted EPS to be in the range of $1.38 to $1.47. In addition, based on our year-to-date results, we now expect cost of sales as a percentage of revenue to be in the range of 18% to 18.5% versus our previous expectation of 18.5% to 19.5%.

To reflect incremental expenses for ongoing Phase III programs, we now expect R&D expenses to be in the range of $7.3 billion to $7.6 billion versus $6.9 billion to $7.4 billion previously. It's important to note that any changes in foreign exchange rates since mid-April, which exclude the impact of potential devaluation of the Venezuelan Bolivar, did not materially impact our latest guidance.

I also want to point out that we are continuing to absorb an estimated $3.4 billion negative impact due to continuing product losses of exclusivity and declining alliance revenues, and an estimated $3.3 billion negative impact from unfavorable changes in essentially all foreign exchange rates relative to the US dollar, compared to foreign exchange rates in 2014.

Moving on to key takeaways, we achieved another quarter of solid financial performance, primarily driven by products that are in the early stages of their life cycles, Prevnar 13 adult, Eliquis, Ibrance and Xeljanz. Also I want to point out that this is the third consecutive quarter of operational revenue growth.

We have raised the midpoints of our 2015 reported revenue and EPS guidance ranges to reflect our strong operational performance and improved operational outlook for the remainder of 2015. We achieved several key R&D milestones since our first-quarter update, including FDA acceptance of our NDA for Xeljanz once-daily, the anticipated PDUFA date February of 2016, and the presentation of data for our immuno-oncology portfolio at ASCO, which included 10 abstracts on avelumab with our partner Merck KGaA, and results from our Phase I study of our anti-4-1BB antibody.

We continue to create shareholder value through prudent capital allocation. To date, in 2015, we've returned $9.6 billion to shareholders through dividends and share repurchases, and 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 attractive shareholder returns in 2015 and beyond. Now, I'll turn it back to Chuck.

Chuck Triano (SVP of IR):

Thank you, Frank and Ian, for the summary. With that, operator, can we please poll for questions?

QUESTIONS & ANSWERS

Operator:

(Operator Instructions)

Gregg Gilbert, Deutsche Bank.

Gregg Gilbert (Analyst - Deutsche Bank):

First, on the immuno-oncology franchise, while you're somewhat behind, Ian, can you comment on some of the aspects of your strategy in IO that might not be fully appreciated by the investment community? And my second question, perhaps for either of you, on the subject of what you call business and legal entity alignment activities, those costs are growing strongly. Can you offer any color as to when those activities might wrap up, or at least what some key mile markers are along the way on that process? Thanks.

Ian Read (Chairman and CEO):

Thank you, Gregg. We believe that we will be first in some tumor types with the PD-L1 from Merck . But we also feel it's very important to understand that we're just at the beginning of this immuno-oncology wave, and we have, as I have commented previously, a substantial number of assets that can be combined and added, both with immuno-oncology assets, and with the backbone targeted therapies or chemotherapy, or with Inlyta, or with Xalkori, with Ibrance potentially.

So we feel that as this market develops, what's going to be really important is the ability to have combination products, and the ability to have a more fuller control of the total value, or the total pricing of those combination products to the payers. So we believe that Pfizer will be very well-positioned, with multiple combinations of immuno-oncology assets, and combinations with its own in-line assets, to be very effective in those combinations. Frank, do you want to talk about the --

Frank DAmelio (CFO):

Sure. On the business and legal entity alignment, let me run the numbers first, and I'll answer the question. Which is for the quarter, we spent $63 million year-to-date, $164 million in business and legal entity alignment cost. I said previously, we forecasted a spend of approximately $400 million for the year,

we'll be give or taking that range of approximately $400 million. The spend will continue, obviously for the rest of 2015 through 2016, we've talked about a decision on alignment in the fourth quarter of 2016, by no later than the fourth quarter of 2016 so spending obviously would continue through then, at which point, we make a determination going forward based on the decision.

Chuck Triano (SVP of IR):

Thanks, Frank. Next question please, operator?

Operator:

Marc Goodman, UBS.

Marc Goodman (Analyst - UBS):

First question is, can you give us your latest thoughts on what's going on in China, as well as just the broader emerging markets? Second, in the press release, it talked about for Prevnar, the GAVI shipments and emerging markets had some special programs. Can you give us a sense of how much of that was one-timers versus what we should expect ongoing? And then I think you mentioned how much FX hit your expenses but can you carve out the gross margin specifically, and how much that had an impact? Thanks.

Ian Read (Chairman and CEO):

We remain, as we said, optimistic about the long-term in China and the emerging markets. We continue to see a secular movement to middle-class and wealth creation. I would ask John Young, who manages the majority of our business in the emerging markets, to make some comments specifically on China, and perhaps his view of the opportunities more broadly in emerging markets.

John Young (President of Established Pharma):

Thanks for the question, Marc. I think Ian said it head on in our view, in summary form. It's obviously a significant population, 1.3 billion people. We continue to see strong economic growth, albeit moderating economic growth, but we envisage that economic growth will continue.

And I think as Ian has already flagged, we see a continued commitment from the Chinese government to expand access to healthcare, to quality healthcare, to citizens. We don't see that trend halting in the short to medium, even the longer-term. And so we believe that actually for manufacturers such as ourselves, who are in positioned well in China with a strong existing base, a strong network of joint ventures, and a portfolio frankly that is well-suited to the needs of Chinese patients, ranging from our innovative portfolio with oncology medicines and vaccines in the future. As well as today's portfolio, such as Lipitor, which is obviously a leading treatment to help to manage cardiovascular disease, which is a growing concern for Chinese patients.

So when you sum all of that up, we knew that we will continue to see some pressures on our business in China and pricing. We factor that into our forward-looking views. But we continue to see China being a significant opportunity for future growth.

Ian Read (Chairman and CEO):

Okay. Similar story has played out in most of the emerging markets too in differing forms. Albert, do you want to talk about the GAVI shipments, and those items that were raised?

Albert Bourla (President of Vaccines Oncology & Consumer):

Yes. I wouldn't call them one-time. What is happening with the GAVI business is that there is volatility.

Volatility depends when CDC will place an order, when GAVI will place an order, or when NAP will occur, so this volatility will continue. This is the normal course of a vaccines business. But in general, the outlook is doing very well this quarter, with 5% overall growth.

Ian Read (Chairman and CEO):

Thank you. Frank, on the FX?

Frank DAmelio (CFO):

Sure. Marc, lots of moving parts, obviously, that impact gross margin. Favorable items would be things like our oncology and alliance revenue growth. An unfavorable item would be our US LOEs.

But maybe the easiest way to do this is macro level with numbers. Q2 last year, our cost of sales as a percentage of revenue, 18.9%. This quarter, 17.9%. If we remove foreign exchange from this quarter, which reduced cost of sales by $255 million, that 17.9% becomes 18.4%, so roughly flat year-over-year. If you go year-to-date, last year, year-to-date 17.9%, this year, year-to-date, 17.3%. If we remove foreign-exchange, that 17.3% becomes 18.2%. Once again, relatively flat year-over-year, with a lot of moving parts impacting the number.

Chuck Triano (SVP of IR):

Thank you, Frank. Operator, next question, please?

Operator:

Tim Anderson, Bernstein.

Tim Anderson (Analyst - Bernstein):

Thanks. If I could go back to the topic of M&A, and I know you made some comments earlier. Watching the Big Pharma industry for almost 20 years, seems like Big Pharma companies have very often not participated in biotech M&A, because there's been this long-standing sense that the valuations are too high. And if I listen to what several companies say, now at the current point in time, several Big Pharma companies again, raise that concern. If I look at what Pfizer has bought over the years, it's generally been either Big Pharma companies or other types of targets, like Hospira .

So my question to you is, how do you currently view valuations in the biotech space, and have you loosened up at all on your valuation framework, such that you think you can find value in the biotech landscape at the current levels of valuation? And then the second question is on Enbrel, and whether you expect to see any pressure caused by biosimilar Remicade now being available in Europe, whether you expect pressure in your 2016 or 2017, or maybe even in the current year?

Ian Read (Chairman and CEO):

Okay. I'll make some comments on the M&A, and then I'll ask Geno to comment on Enbrel in Europe. Tim, I believe that the marketplace is extremely efficient, and that the valuations in biotech are in many ways, priced to perfection. But of the deals that have been done, we have looked at them. The deals work for some companies because of their portfolio, because of their ability to achieve synergies in ways that we couldn't.

We do remain disciplined on our cost of capital. We think long-term that's important, that people invest in Pfizer expect their return -- risk-adjusted return on the cost of capital. That means that we don't expect to find value in the marketplace. There are always opportunities. We stand ready. We have the cash, we have the capability, we have the management team. We are continually looking for those opportunities.

As I say, I'm optimistic that we'll be able to deploy our capital in a way that will increment value to shareholders. I would say, further, that if you look at the established products business and the innovative business, if there were two projects and both of them were risk-adjusted equal, our inclination would be to do, for portfolio reasons something in innovative space rather than the established space, given that we've done the Hospira acquisition for established. So once again, I'm very well aware that there is an active market of business development. We think we've done the ones that are prudent. We evaluate all our opportunities, and we're optimistic that we're going to find and have sufficient courage to find those opportunities that come into the marketplace. So with that, I'll pass it over to Geno to look at Enbrel.

Geno Germano (President of Global Innovative Pharma):

Sure, Tim. Enbrel continues to do well. We had good 2% operational growth this quarter outside the United States, on a very large base, so the business continues to deliver for us. With regard to Remicade biosimilars, we're not seeing a significant impact on the Enbrel business. Given the different administration routes, Remicade being infusion, and Enbrel and Humira and others being self-injected therapies, we don't see a lot of overlap but there. There's a lot of experimentation going on country by country, so there's always a possibility that we'll see some new things happening, but overall, we're not seeing are expecting a major shift in the Enbrel business related to the Remicade biosimilar.

Chuck Triano (SVP of IR):

Thank you, Geno. Operator, can we move to the next question, please?

Operator:

Jami Rubin, Goldman Sachs .

Jami Rubin (Analyst - Goldman Sachs):

Ian, in your prepared remarks, you signaled M&A activity focused on top line growth bridging the gap to 2017 filings. Two questions related to that. Are you backing off from breaking up the Company of strategy you outlined -- or certainly outlined the optionality for a couple years ago? Where are you on that?

And number two how big would you consider going? Can you throw out some parameters there in terms of size? Is it all about top line growth? Is synergies a big consideration, and also, you had talked before about tax inversions being an important part of that equation too, so if you can put that in perspective? And then my last question relates to Lipitor OTC. Now that product doesn't appear to be going forward, would you consider putting your consumer business up for sale? Thanks.

Ian Read (Chairman and CEO):

Jami, as always three big questions. On the break-up, we have not changed our views on wanting to have the optionality of the breakup. We continue to spend considerable amounts of money preparing and putting ourselves in a place to trigger that optionality if we take that decision. And as I said, we've laid out the criteria for that, which includes our business is doing well. Do we think they could do well on their own? Is there trap value and is there after-tax value that could be achieved? And we will make that decision, by the latest, fourth-quarter of 2016 on whether to trigger that optionality.

On your question about big, small, growth opportunities, look, we look at it from the point of view of as a pharmaceutical company, we want to buy, the ideal of course is to buy a pipeline and also products that are growing. These products and opportunities you have to have a belief in the future, often the future potential of the products you're buying. There's a lot involved in an acquisition this large. It's a

combination of what you think the portfolio will do, what you believe the synergies will come through on the operational side, and of course, tax and tax planning plays a role in that.

So to a certain extent, the discussions that are going on in Washington right now about a potential international tax reform does affect the way we look at the different opportunities we have in the marketplace. You'd expect us to be looking at that very carefully. Certainly, any acquisition we do make will have a bias on the near-term revenue opportunities and on accretion.

OTC, look, the consumer business is a tremendous business, a tremendous store of value. We talked Nexium OTC, and it has been an incredible success. We continue to invest in the consumer business. We always look at our businesses, all of them, on a regular basis and our strategic plan vis-a-vis what part they play in the total value of Pfizer shareholders. We are always reviewing that. At this moment, I think the consumer business is a very valuable and growing asset for Pfizer .

Chuck Triano (SVP of IR):

Thanks, Jami. Our next question please, operator?

Operator:

Mark Schoenebaum, Evercore ISI.

Mark Schoenebaum (Analyst - Evercore ISI):

Thank you for a very clear opening statement. All of you, it's always very helpful. I want to go back and build on some of the questions that have already been asked, but the first one is, Ian, and I know you get asked this every quarter, and I'm sure Chuck tells you get asked this every quarter, but this quarter, I think it's become a little bit more of a focus for investors.

The widespread Wall Street rumors that you might be interested in something like an Allergan . I understand you wouldn't comment on that, but can you comment in general on your interest in inverting at this point? What the thresholds would need to be versus what the official thresholds right now to make you comfortable that such inversion could be completed? Is inversion still a priority for Pfizer ?

Second question was for Frank. Maybe you've disclosed this, I'm not sure, so it's a shame on me if you have, but I've heard from little birdies that money that you've already spent preparing for separation, this might have been embedded to an earlier answer, it wasn't clear to me, but the money that you've already spent preparing for separation of Pfizer is on the order of $1 billion. I'd just like to know if that number, if you are willing publicly to talk about whether or not that number is realistic.

And then the final question is, and this is a tougher one, I don't know if you'll be able to answer it, but some of us have been now thinking about, if and when Pfizer splits, perhaps instead of floating one or more of these companies, they might be strategic acquirer for one or more of these companies. And I think we're all trying to get a sense of what the cost basis is for these companies, so that we could understand if it's realistic that someone could buy them, or would the tax burden on such a transaction would be prohibitive? I don't know if there's any finger in the wind, words of wisdom you can give us, Frank. Thank you.

Ian Read (Chairman and CEO):

Mark, on the inversion question, the reason you do any deal is, as we said before, and it sounds like motherhood and apple pie, but it is because you believe it's going to create value for shareholders long-term. And so we can remain interested in the potential of an inversion, because it would facilitate and enable wealth creation for shareholders. It would certainly also position Pfizer under current tax laws to

be -- it would liberate our balance sheet, and would position us to be far more active in the M&A space, and competitive, which is why there is all this push to have tax reform, because at the moment, the American companies are not as competitive as European companies, given the different tax rate.

So the inversion is attractive both because it creates a major value and it enables you to meet the premiums to acquire the Company. And it's attractive because it will liberate your balance sheet for future activity and spending and cash flow. And that, in its turn, informs you as to what level of inversion you would find acceptable, whether you want an inversion that is between 60 and 80 or below 60. So it's a complex issue, and we're not focused totally on inversions.

It's only a component of the business development strategy, and only comes in when you believe you need that value that's created by the inversion, to get to the premium to buy the Company. But it's not just -- inversions is not our one track business development strategy. With that, I'll pass it over to Frank to answer the other two difficult questions.

Frank DAmelio (CFO):

The little birdie questions. Mark, year-to-date cumulatively to date, because that's what you asked, not year-to-date, cumulatively to date, we spent, give or take, approximately $300 million, when I include the $164 million year-to-date this year. The thing to remember about these kinds of optionality projects, think about carve-outs as a sense, there's a massive amount of work that needs to be done. And when you're looking at -- I'll call it the total cost structure, these kinds of projects, they do run into the low billions of dollars. That's the nature of what they do.

But here's what you've got to remember. In that number, there's tax leakage. You do everything you can to minimize tax leakage, but you've got to create multiple legal entities. Anytime you're creating multiple legal entities, or more than one in the country, you create tax exposure, tax leakage. There's potential leakage regarding debt and decision-making you make around whether or not you're going to repurchase debt. And then there's all the, I'll call it blocking and tackling, that needs to be done in areas like systems. Legal entity and tax planning, regulatory work, supply chain. It's a massive amount of work.

And think about the visual. This is a Company that's been restructuring for a decade. Integrating, putting things together, and now you want to do something where you're taking a major piece of the Company and you're going to carve it out in a sense, undo much of the work that you've done previously. Requires a lot of effort, it costs a bunch of money. But year-to-date, which is what you asked me, cumulatively to date, it's been about $300 million.

Ian Read (Chairman and CEO):

That being said, we do see the logic of, because there are two different businesses, and we do feel that the amounts we will need to spend to put ourselves in the position to complete optionality, has been money well spent for shareholders, given the potential upside of what optionality could produce.

Frank DAmelio (CFO):

It's essentially the cost of having the option, is really what it translates to, Mark. It's the cost of having the option. And then the last piece about tax basis, obviously, it's premature to get into tax basis of the businesses, but what I would say is, to just punctuate what Ian said, the fourth criteria is being able to unlock that trapped value, assuming there is some, in a tax efficient way. So obviously anything we would do would have extensive tax planning, and would minimize obviously -- or maximize the after-tax returns to our shareholders.

Chuck Triano (SVP of IR):

Thanks, Ian and Frank. Next question, please, operator?

Operator:

Andrew Baum, Citigroup .

Andrew Baum (Analyst - Citigroup):

Three questions, please. Firstly, just revisiting the tax question, could you give us some sense over the next three, five years where your effective tax rate is going, as the business currently stands, giving the change in mix of business, particularly the increasing US contribution? And second, on the tax, via the ongoing debates in Washington, or the probability you feel of any meaningful change, may improve the effective tax rate that you pay?

Second, could you comment how the recent Teva Allergan deal impacts the M&A landscape from the Pfizer perspective? And finally you obviously reported a very strong quarter for Prevnar 13. To what extent should we expect an inventory destock in the following quarter? IE, how much of this is industry stocking, given, I imagine, that most of the vaccinations are going to happen in adolescents. But please correct me if I'm wrong.

Ian Read (Chairman and CEO):

Thank you, Andrew. On the tax question, we don't project our tax rate. There are just too many variables in there including business development, including where we make our earnings, including potential changes in US tax law, and we give guidance on a yearly basis on our tax rate. Frank, you want to add anything?

Frank DAmelio (CFO):

Just that year-to-date, our tax rate's 25%. Our guidance for the year is 25% so for 2015, we're running pretty much right according to our guidance. And then just to punctuate what Ian said, there's just too many moving parts to try to project our tax rates beyond the current year, but we'll obviously include the 2016 rate when we provide our 2016 guidance.

Ian Read (Chairman and CEO):

Thank you. On DC, it's too difficult to speculate on what would happen on tax legislation. I do think I am heartened by the conversations that are occurring, and the acknowledgment in Washington, that something has to be done to allow global US corporations to become competitive, given the nature of the US tax system. And hopefully they will take action earlier rather than later to allow us to be competitive, and I think we will see that unfold in the next five months, as to whether Washington will take any action on that or not.

On the Teva Allergan , does it change landscape for us? I don't think it changes the landscape for Pfizer in any material way. We continue to have our own strategies and pursue our own BD objectives and this doesn't impact impinge upon that. Frank, want to talk about anything else? And then it's Albert on Prevnar 13?

Albert Bourla (President of Vaccines Oncology & Consumer):

Yes, Andrew. I'm monitoring the inventories, and there was no significant inventory build in the quarter, so inventories didn't materially affect the adult performance at all.

Ian Read (Chairman and CEO):

So I think Andrew, what you need to do on Prevnar -- what we need on Prevnar 13 adult, is you have three influences, or four influences going on. One, you have the underlying rate of US citizens becoming 65, which is about 4 million a year. You have then in the US, the bolus of catch-up which is significant, and we believe will last certainly this year and next, and maybe into the third year. And then you have you have the progress in the G6 countries as we get and have had for our registration and labeling changes, to enable adult vaccine to be sold to the 65 and above.

And there, of course, you have a huge cohort, probably substantially larger than the US, probably twice the size of the US. And that's going to take market development. We're going to have to work on that country by country, but we see there also, the movement of the population to over 65, plus the catch-up opportunity. So overall, when you look at those waves of opportunities, I feel that we feel that the adult vaccine is an interesting ongoing large franchise for Pfizer .

Chuck Triano (SVP of IR):

Thank you. Next question, please?

Operator:

Colin Bristow, Bank of America .

Colin Bristow (Analyst - BofA Merrill Lynch):

Couple of quick ones. On your Avastin biosimilar, you started the Phase III trial with a primary endpoint of objective response rate. Can you talk about the discussions you've had with regulators, and whether you anticipate objective response rate will be an approval endpoint? And then two on the IO pipeline. Can you walk us through the key readouts we should be paying attention to over the next 12 months? Thanks.

Ian Read (Chairman and CEO):

Okay. Technical question there, Colin, on that. I don't know if Mikael, you want to address that.

Mikael Dolsten (President of Worldwide R&D):

All of our five biosimilars have been evolved in their development strategies in close consultations with the major regulatory agencies, and particularly FDA. So that will reflect the input and robustness in trial design, and what should be predicted the best choice of endpoint for approval opportunity.

Ian Read (Chairman and CEO):

So I think we feel satisfied that we have an agreement with the major agencies and the endpoints will be the ones necessary to get approval. IO pipeline, Mikael, do you want to run through that or what you think of the significant things going forward? And when we are likely to be issuing results?

Mikael Dolsten (President of Worldwide R&D):

So I'm really excited about our IO pipeline. And starting with anchor drug, avelumab, we have now more than 1,000 patients that have been on avelumab, and we feel that we see a consistent good response rate, substantial clinical durability, and responses, and robust safety profile. And we report that some studies at ASCO, and now we have positive readouts in line, gastric, ovarian, and bladder, you're aware, and Ian alluded to that we've started a second line lung cancer trial. We expect in a relatively near-term opportunity to move to first line in that setting. Our experience in cost various indications will lead this year too numerous announcements of Phase III, up to six pivotal studies that include several in line gastric, ovarian, bladder, and renal.

We also at ASCO communicated favorable date on 4-1BB, already seen in the Phase I in follicular lymphoma showing good tolerability, and together with rituximab, favorable responses. We are expanding that study. 4-1BB, which is a unique molecule, one of the few I think in this industry this advanced, is also in studies with Keytruda, as well as the soon-to-be extensive program with avelumab. We also have recently entered clinical studies with OX40 as another positive event for our immuno-oncology pipeline, and we have communicated favorable data with CCR2 in pancreatic cancer.

And later this year, we expect vaccine to start dosing for prostate cancer. And we have numerous compounds and means that will also enter next year. So you see really us evolving a very comprehensive monotherapy and a combination therapy. We will, over time, share more data. There is an ESMO conference that will give you an update on avelumab and will include particular lung cancer, ovarian, and also some bladder, we expect. And we will continue to inform you about the progress of 4-1BB.

Chuck Triano (SVP of IR):

Thank you, Mikael. Next question, please?

Operator:

Vamil Divan, Credit Suisse.

Vamil Divan (Analyst - Credit Suisse):

Two if I could. One building a little bit on what you talked about earlier around the amount of cost around planning for a potential split. Do you have a sense of what the dissynergies would be to actually execute a split of the Company at this point, if you're trying to split into two parts? I think you may have some sense of that by now. And as more of us can undo on a Pfizer on a self-enforced basis it will be helpful to have a how you think the dissynergies would be.

And then the second question I had was on the vaccine side, starting with the VOC business, a lot of focus on oncology obviously, but can you talk a little more generally about your strategy in vaccines? You're obviously making good progress with Prevnar in adults. Staph is moving along, that obviously looks promising. Maybe a little bit more broadly, where you see other potential areas for value there. You have obviously made some deals, you have maternal vaccines, you talked about C diff. What you think people might be underappreciating with your vaccines business as opposed to how you see it internally right now? Thanks.

Ian Read (Chairman and CEO):

Okay. Well, cost of dissynergies, Frank, want to make a comment on that?

Frank DAmelio (CFO):

Just from my perspective, we've obviously been looking at this, we've been analyzing the detail. I think I'd summarize it by saying we don't see it as being a material dissynergy relative to optionality, based on our current analysis.

Ian Read (Chairman and CEO):

No. So your question on the vaccines I'll try and do a summarized answer, and then I'll ask Albert if he wants to add anything on to it. I think you are seeing us continue to drive and maximize the Prevnar 13 opportunity, both in infants and adults. We believe that the opportunity in adults is broad and deep and durable, so we're confident in that. We continue to work on Prevnar, on the Prevnar family, to look at server enhancements.

We believe there's a real opportunity to accelerate the -- as long as the Phase II trial on the back surgery performs as we expect, we think there's an opportunity to accelerate the staph aureus vaccine. We are in Phase II with what we believe is a very good vaccine with C. difficile, and then we've made acquisitions of other vaccines like the Baxter acquisition, to add some critical mass to our what our field force carries. We have Trumenba, which we think will develop over time as an important vaccine, and then we've done acquisitions and licensing of -- for vaccines for infants. So you want to add some more detail to that, Albert?

Albert Bourla (President of Vaccines Oncology & Consumer):

Very few things to add, Ian. I think in vaccines, we have substantial scientific capabilities, and significant substrate, research substrate, that allows us to see optimistically the future. And to have very good track record of delivery. With staph, we have already initiated, as Ian said, the Phase IIb study, and that's in 2,600 patients. If the Phase IIb data show considerable efficacy, we will consider requesting an accelerated approval from this product, and the study that we're running now could potentially serve to support registration.

Ian Read (Chairman and CEO):

They have breakthrough status, right?

Albert Bourla (President of Vaccines Oncology & Consumer):

And breakthrough status. Same as with C. difficile. That has breakthrough status, but also, as you recall, we had outed recruitment and vaccinations in a previously initiated Phase IIb study, as a result of some cases of redness that we observed at the injection site. Now, we have already recently received approval from the FDA to initiate a new Phase II program with a different formulation, so we are moving full speed in materializing that as well.

Chuck Triano (SVP of IR):

Thanks. The next question, please?

Operator:

Chris Schott, JPMorgan .

Chris Schott (Analyst - JPMorgan):

First one was just a little bit more color on Prevnar 13 adult. I appreciate the earlier comments, but can you give us a little bit more color? When you think about the US catch up bolus, how large is that bolus, and how far through are you at this point? Do you have numbers in that front, would be pretty helpful.

Second, on your PD-L1, I know you've highlighted in the past a high disease control rate that we have seen with some of the studies. When can we see more survival data that could help us assess that disease control rate, versus maybe some higher overall response rates we're seeing from other products, as we think about this as a combinable agent longer-term?

And the final one was coming back to business development, does seem like we're seeing a significant consolidation in the industry at the same time we're seeing an uptick in innovation. I know Pfizer has priorities in terms of what it needs to do, given its product cycle, but can you elaborate a little bit more how this rapidly-changing environment is impacting your business development priorities, either in terms of further sense of urgency, willingness to broaden the scope of what you're looking at? I'm trying to understand how the backdrop of the sector effects how you're pursuing deals. Thanks very much.

Ian Read (Chairman and CEO):

Prevnar 13, Albert?

Albert Bourla (President of Vaccines Oncology & Consumer):

Again I will express how my excitement about the success that they're of having so far with Prevnar in the US. And basically we are able to make pneumonia vaccination for adults an age-based event so people who get vaccinated when they come to age of 65, rather than a seasonal event. But of course, we were very successful in catching up a lot of previously vaccinated.

To give you a sense of the numbers in the US, as Ian said, approximately 4 million people are turning 65 every year. In 2014, when we started with Prevnar, there was a large cohort of approximately 27 million people that were previously vaccinated. With an old technology vaccine, and there was also another cohort of 18 million people that had never received a vaccine. So in total, 45 million people. Usually, there is 2.6 million deaths also, that are happening per year in that cohort.

So main, we don't have exact split of how much is catch-up and how much is normal business in the US, but given the massive number of vaccinations that are occurring, a big part is coming from catch-up, and this is a lot, as we said. That's why we said that this year will continue growing, and will be very big. Next year also will be substantial, very big, might not grow versus 2015, but will be very big.

And then we move international. Internationally, the aging demographics are more compelling than in US, because the percentage of people that are living above 65 is much higher. Countries like Japan for example is almost double than in US in terms of percentage, 14% approximately in the US to 26% 27% 28% in Japan, and this is where we expect in 2017 to start getting a wave of recommendations, now that we've got approval in Europe for pneumonia. That as long as we get recommendation, then reinvestment comes, and then we start commercially penetrating very aggressively, as we did in the US.

Ian Read (Chairman and CEO):

Thank you, Albert. I believe that cohort in the G6 countries are around 94 million?

Albert Bourla (President of Vaccines Oncology & Consumer):

That's correct. Double the US.

Ian Read (Chairman and CEO):

Okay. PD-L1 data? That we are in partnership with Merck KGaA?

Albert Bourla (President of Vaccines Oncology & Consumer):

So at a more higher level, we can say when we carefully go through data from lung, ovarian, gastric and bladder, where we have extensive number of patients followed for six months or more, we see response rates that are very comparable to other PD-L1 agents. Of course, it depends on how you cut your data. We have generally looked at response rates, including all patients, and not solely PD-L1 positive, and that's part of our long-term strategy, that it seems that patients that even have low expression of PD-L1 will benefit, particularly when you later develop combination therapies, so we accumulate experiences across all PD-L1 spectrum, but will of course, in various endpoints, look at PD-L1 positive.

That was the strategy in our second line lung cancer, which is all-inclusive for lung cancer patients in second line, but the primary endpoint is on PD-L1 positive. Disease control rates are very high in our studies. In general, 50% or higher across several indications. And when we again compared to others, where do we look at disease control rates, six months progression-free survival et cetera, we're very

pleased with avelumab, both for efficacy and tolerability. And you will get further data update at ESMO oncology conference.

Ian Read (Chairman and CEO):

Thank you. Going back to BD, we look at BD probably in two large ways at Pfizer . One is when we're looking at individual needs of the business units, which can be like a smaller tuck-in or can be an acquisition of an individual product. When we look at individual products, it tends to have a -- normally, because, very often you're buying a product at the beginning of it's -- either before it's approved or after it's approved, but we're looking at it opportunities to expand indications, and so we look at the risk-adjusted return, and we make a decision whether to participate in that franchise. And that can be influenced by the ability to combine it with our existing therapeutic areas, if we can get also additional synergies through operational savings. So that's one way we're looking at BD, which is more opportunistic product related.

The second type of BD is trying to buy technology, like perhaps gene therapy, or select us when we're going to CAR-T technology, and those tend to be longer-term investments. And the third type of BD is what you would say is a more traditional BD, where we look at total companies, and there the driver of value often is existing pipeline, existing products, potential pipeline products, opportunities for synergies, and potentially tax savings and future liberation of the balance sheet, because you're no longer constrained by the US tax situation. So I think what you've been seeing in the marketplace is foreign companies with significant tax advantages taking advantage of acquisitions in the US, and building up their organization.

You've seen a refocusing by some companies, and you have seen, as with the Allergan Teva transaction, where one Company is to strengthen its portfolio and focus by acquiring the generic of the other company. So look, we are actively monitoring this process. I don't think we've lost out to any opportunities that would have made sense to our shareholders. We're determined if an opportunity is there, that we will not lose out. We have the will, we have the capability, we have the capital we have the management team. So I feel that frankly, our BD strategy and philosophy and approach is appropriate for this point in time, in the value cycles.

Chuck Triano (SVP of IR):

Thank you, Ian. Next question, please?

Operator:

Alex Arfaei, BMO Capital Markets.

Alex Arfaei (Analyst - BMO Capital Markets):

Congratulations on a strong quarter. First on biosimilars, you have five antibodies in development. You are obviously making a significant investment there. Can you update us on your updated views of the potential size of the biosimilar market, in light of what we're seeing in Europe, and how we should think about the opportunity for Pfizer ?

Follow-up on that, given these investments, how should we think about some of the overlapping assets that you're getting from Hospira ? And then finally, could you comment on the recent PCSK9 approval and potential implications for your bococizumab? Thank you very much.

Ian Read (Chairman and CEO):

Thanks for the question, Alex. First of all, in terms of your question about the size of the market, we

continue to see around about $100 billion of currently patented biologic medicines that will lose patent protection over the next five to 10 years. That's a significant market opportunity for companies that have the technology platform capability, and current biosimilar portfolio to be able to capitalize on that opportunity. So we continue to think that we are very well-placed. And in relation to your question about Hospira , we continue to see that our portfolio and Hospira's are highly complementary. And we're very excited about the opportunity that presents post close.

On the PCSK9 approval by Europe from Amgen and the US, by Sanofi, Regeneron, I think we expect it on LDL lowering. I don't see substantial -- I see modest use of these products until the outcomes data comes through. We don't think we would be that far behind on outcomes data. I think the size of the market is difficult to predict at this time.

It really depends on how the CTEP development comes through. If the CTEPs, which are oral, come through, I could see a market that is segmented three ways, IE statin use so you can get to goals, statin plus a CTEP or CTEP alone if you're statin intolerant, and then potentially PCSK9 being held in reserve, if the CTEP can't get to the goals of the statin. So it's very, very difficult to predict how this market will shake out in value. And I think it's interesting to see what will happen in 2016, if the CTEPs are improved and what type label, what type of pricing they come to the market with, and what type of pricing we see develop on the PCSK9s as negotiations occur with managed care.

Chuck Triano (SVP of IR):

Thank you, Ian. Next question please, operator?

Operator:

John Boris, SunTrust.

John Boris (Analyst - SunTrust Robinson Humphrey):

Congratulations on the quarter. Just back to Prevnar 13, can you quantify the shipments that you made into GAVI and the vaccine alliance, and also provide some additional color on which national immunization programs included Prevnar 13 into their program? And then secondly, on your Xeljanz filing in the EU, can you remind us what led to the rejection, and what remedies that you've made to the filing? I believe you mentioned you're on track to file before the end of the year in the EU. That would help enhance the ability to secure approval on Xeljanz in Europe. Thanks.

Ian Read (Chairman and CEO):

Geno can deal with the Xeljanz question, and then I'll see if Albert has any data at hand. That's pretty specific on your question, John or if we will just have to answer to generalities right now. But let's get to Geno first.

Geno Germano (President of Global Innovative Pharma):

Thanks, John. I think the questions from the CHMP revolved a lot around the immune system effects of Xeljanz, understanding the safety profile, primarily. So we have done some additional pharmacology studies. We've done a study with herpes zoster vaccine to demonstrate a lack of interference with the immunogenicity of the vaccine, and of course, collected longer-term follow-up data from our long-term extension files and our post-marketing surveillance trial. So it will be a combination of these data points that will comprise the resubmission that we're planning on for later this year.

Ian Read (Chairman and CEO):

Okay. Albert?

Albert Bourla (President of Vaccines Oncology & Consumer):

I don't have handy the numbers. I'll have to come back to you, but generally in emerging markets the growth was 18% for pediatric, approximately for the quarter. And this volatility will continue to exist.

Ian Read (Chairman and CEO):

Depends on the timing of NIP, timing of GAVI. Not something that we are particularly focused on. We have a full-year forecast which takes into account all these fluctuations, and we've built that into the change in our guide.

Frank DAmelio (CFO):

That's all part of our revenue guidance.

Chuck Triano (SVP of IR):

Okay. Thank you. Our next question, please?

Operator:

Jeff Holford, Jefferies.

Jeff Holford (Analyst - Jefferies LLC):

First one, just around business development, if you follow on here, do you have a bias towards OUS domiciled companies, when you're looking at opportunities to help grow the GIP business, given where your cash is held? Second, because of your focus on doing BD in a few years to bridge to 2017, does that mean we should expect much less cash to be diverted towards share repurchases? And then lastly, just around the BD, given your want or desire to help boost the business prior to 2017, doesn't that mean, given time for antitrust review or any other reviews of the transaction, that should we should be expecting you to complete, announce additional deals during the second half of this year for them to come into that timeframe? And then last question, just on a separate area, can you maybe outline for us just a couple of the biggest OTC switch opportunities that you see the business potentially in the next two to three years? Thank you.

Ian Read (Chairman and CEO):

On the OTC switch, I don't want to get into that because it's confidential and helps competitors prepare along with us in the marketplace. So I think you can look at our portfolio and make assumptions on your own as to which products are more likely to be switched or not.

On the BD, I have no bias towards a US or foreign Company. I have a bias to the value creation. I have no bias towards, well, I have a bias on our portfolio. If valuations are equal and opportunities are equal, I prefer to do a BD deal that strengthens our innovative business, as I think we've done quite a bit to strengthen the established business.

On the less cash depending on an acquisition, I think it depends on the type of acquisition, how it's structured, and I think it's too early to say, but of course any deal we do what we do we'll be looking at total shareholder returns, and we would factor that into the type of deal with restructuring. I think that's the most we can say at this time, frankly with that.

And then on timing, when I talk about 2017, I'm talking about -- frankly I use that as a mark, given

conversations I have with our owners, about the fact that great, you've got great in-line momentum, you've got these new products, you've got Eliquis, and you've got Ibrance and adult vaccine, and all the other in-lines that are moving well. I'm just looking at ways of increasing our revenues as we develop our pipeline, and we start to see that pipeline come to fruition in 2017 and launch in 2018, and we'll see those launches 2017 through 2018 through 2019.

So I think it's important to get any BD we do right, and I don't feel pressurized to get it right by 2017. What's important is to get it right to create value for our shareholders. And I don't think, frankly, there's a timing pressure on us to do BD.

We're going to look at it. We want to do BD. We're going to be opportunistic, but we're also going to make sure that we make the right decisions for Pfizer shareholders.

Chuck Triano (SVP of IR):

All right. Thank you, Ian. Next question, please?

Operator:

David Risinger, Morgan Stanley .

David Risinger (Analyst - Morgan Stanley):

I have two questions. First, could you remind us about the ex-US Enbrel exclusivity loss timing? And expectations for timing of biosimilar competitor launches? And then with respect to Ibrance, could you please discuss potential indications outside of breast cancer and what key trials we should be watching on that front? Thank you.

Ian Read (Chairman and CEO):

Thank you. Geno, could you do the Enbrel?

Geno Germano (President of Global Innovative Pharma):

Enbrel exclusivity expires near the end of this year so we expect to see biosimilar penetration beginning next year in Europe.

Ian Read (Chairman and CEO):

Okay. Ibrance indications outside of breast cancer?

Albert Bourla (President of Vaccines Oncology & Consumer):

We're very excited about the potential of Ibrance. And I think we have a real unique proprietary knowledge in understanding how to use science around Ibrance, combination new indications. So we have an extensive collaborative research clinical programs that you may be aware of, but in addition to that, I'm pleased to say that we are starting a number of Pfizer -sponsored new studies. And very soon, we'll start one study in head and neck cancer, HPV-negative patients that are recurrent metastatic, combining Ibrance with Erbitux, with prior experience of that combination in a collaborative study, and now launching a Pfizer -sponsored, which could have a very interesting path forward, if data is strong.

In addition to that, we have generated very compelling pre-clinical data on human tumors for pancreatic cancer, where particularly the combination of Ibrance with paclitaxel or Abraxane was very promising, and we are soon starting a Phase II study preceded by safety lead-in with Ibrance and Abraxane in pancreatic advanced cancer. We also have significant effort in understanding patients that progress on

Ibrance after having had long significant benefit in best cancer. And you learn more about Pfizer's program in double and triple combination, that also can further expand our stronghold and leadership in Ibrance.

Chuck Triano (SVP of IR):

Thank you. If we could take our last question, please, operator?

Operator:

Seamus Fernandez, Leerink.

Seamus Fernandez (Analyst - Leerink Partners):

Frank, maybe could you remind us the threshold for completing an inversion? And I ask the question particularly since some smaller deals appear to have gotten as low as 20% after the treasury update. So it would be helpful to know what your thoughts are on the threshold for inversion, because I think previously you had said it was really 40%. And then separately as part of your optionality calculus, with the split, do you also consider Pfizer as a potential target in that calculus, since this would appear to be a value-add option for shareholders? Thanks.

Frank DAmelio (CFO):

Are you saying Pfizer or the split of Pfizer ?

Ian Read (Chairman and CEO):

Seamus can't reply. Okay. Probably the split, we think that in the optionality, both companies would be robust and strong, and would have the ability to be successful companies on their own. And we really can't comment on whether there would be BD activity to try and buy those companies. They would be companies that would be independent, and continue to try and progress their own business strategies. On the inversion?

Frank DAmelio (CFO):

Prior to, I'll call it the September 22 proposed rule changes by the IRS, the hurdle was less than 80%, so our shareholders had to own less than 80% of the newly-formed Company that we acquired, to get the full benefits of an inversion. That hurdle was lowered to less than 60%, which means we'd have to do a larger acquisition to get the full benefits. So less than 80% to less than 60%.

Ian Read (Chairman and CEO):

The issue with this, Seamus is that the full benefit or non-full benefit is very idiosyncratic, depending on the Company you're doing the inversion on, and the complexity of the tax rule. So it may be that if you are in below 80 but not below 60, you still have substantial benefits from an inversion, and therefore despite the proposed rule changes, or it may be on different targets you need to be at below the 60 threshold. So the universe is not constricted or reduced to only 60-40. It's very dependent upon the type of assets, the structure, where the cash is, et cetera et cetera.

Frank DAmelio (CFO):

Very company-specific.

Ian Read (Chairman and CEO):

Very company specific. Thank you very much.

Chuck Triano (SVP of IR):

Thank you, and thank you all for your attention today.

Operator:

Ladies and gentlemen, this concludes Pfizer's second quarter 2015 earnings conference call.