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Pfizer's CEO Discusses Q2 2013 Results - Earnings Call Transcript

Executives

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Ian C. Read - Chairman and Chief Executive Officer

Frank A. D'Amelio - Executive Vice President-Business Operations and Chief Financial Officer

Geno Germano – President and General Manager-Specialty Care and Oncology

John Young – President and General Manager-Primary Care

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Chris T. Schott - JPMorgan Securities LLC

Gregg Gilbert - Bank of America-Merrill Lynch

Tim Anderson - Sanford C. Bernstein & Co. LLC

Jami Rubin - Goldman Sachs & Co.

Mark Schoenebaum - ISI Group

Alex Arfaei - BMO Capital Markets

Marc Goodman - UBS Securities LLC

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Pfizer Inc. (PFE) Q2 2013 Earnings Conference Call July 30, 2013 10:00 AM ET

Operator

Good day, everyone and welcome to Pfizer's Second Quarter 2013 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.

Charles E. Triano

Good morning and thank you for joining us today to review Pfizer's second quarter 2013 performance. Joined today as usual by our Chairman and CEO, Ian Read; Frank D'Amelio, our CFO; Olivier Brandicourt, President and General Manager of Emerging Markets and Established Products; Mikael Dolsten, President of Worldwide Research and Development; Geno Germano, President and General Manager of Specialty Care and Oncology; Amy Schulman, General Counsel and Business Unit Lead for our Consumer Business; and John Young, President and General Manager of Primary Care.

The slide 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 2013 which is located in the Investor Presentations section in the lower right hand corner of this page.

Before we start, I would like to remind you that our discussions 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 2012 Annual Report on Form 10-K, and in our reports on Forms 10-Q and 8-K. Discussions during this conference 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, July 30, 2013.

Also as we outlined in our earnings release, as a result of the full dispositions of Zoetis, the financial results of the Animal Health Business are now reported as a discontinued operation for the second quarter and year-to-date for both 2012 and 2013.

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

Ian C. Read

Thank you, Chuck. I will begin with some comments on the quarter. We saw solid operational revenue growth at a number of areas. Moving on Innovative business, oncology grew 28% driven by the uptick of new products, mostly Inlyta and Xalkori in several major markets and we saw strong performance from Lyrica in developed markets which grew 14% and Celebrex in U.S., which grew by 13%. The consumer business grew 5% operationally, primarily due to strong global growth from Centrum. And China had strong volume growth, most notably for Lipitor and Prevenar. Overall total China revenues grew 14% operationally or 22% excluding the impact of product transfers in connection with forming a partnership with Hisun.

We continually expect that the second half of this year will be stronger than the first half of emerging markets. Although on a full-year basis, we now expect to see operational revenue growth of mid single-digit rather than high single digits. It is mainly due to a slowdown in growth in Brazil and Russia and the impact of cost containment measures in Columbia, Polland, Thailand and Turkey.

We completed the full separation of Zoetis into a standalone public company. The transactions related to the disposition of Zoetis generated approximately \$17.2 billion of after-tax value for Pfizer's shareholders. And our board of directors authorized a new 10 billion share repurchase program to be utilized overtime. This new program is an addition to the 3.1 billion of authorization remaining under the company's current repurchase program.

Turning to our products and pipeline assets, the launches of both Eliquis and Xeljanz continued progress in various markets around the world. And we are gaining market approvals to both Xeljanz and Eliquis in additional countries. We are encouraged with the potential for both of these therapies over the time. For Eliquis, we're focused on gaining preferred formulary acceptance, continuing to obtain reimbursement and building physician knowledge and comfort about the drug in this profile.

With this unique profile in atrial fibrillation is the only product with superiority versus Warfarin in stroke prevention, major bleeding and a proven mortality benefit, we're confident we will continue to see steady growth that will build overtime.

For Xeljanz, we're seeing good opportunities with patients who are switching from their current biologic therapy, as well as patients who are initiating Xeljanz's therapy and as a second-line setting. That is following the tricks before a biologic DMARD. In fact, almost half of our recent prescriptions are in the second line setting, with the remainder being

patients who have been on one or more, biological DMARDs and not achieving satisfactory results.

In addition, we began our direct consumer campaign in the U.S. early in June and that's seen a subsequent uptick in prescription volume. Last month, we announced that the FDA had accepted for review our supplementary new drug application to include progression of structural damage in Xeljanz label and as of today, Xeljanz will be commercially available in Japan, where it'll be co-promoted by Pfizer and Takeda Pharmaceutical Company Limited.

Overall, we remain encouraged by what we're seeing what physicians and patients experienced so far. I would describe our progress as measured and steady and we recognize, it will continue to take time for rheumatologists to feel comfortable making a change. The launch is consistent with our expectations for new oral mechanism.

Turning to the status of Xeljanz in Europe, last week we announced The Committee for Medicinal Products for Human Use in the EU confirmed their prior opinions on marketing authorization applications for Xeljanz, although with a much closer vote. Given the novel mechanisms or action to Xeljanz, the CHMP wanted to see more data, particularly around safety to better understand the full profile of Xeljanz relative to other agents used in this patient population.

As a result of the reexamination process we addressed several of the questions and had more clarity on the remaining ones. We plan to work with European Medicines Agency to determine what additional data will be needed in order to resubmit a marketing authorization application and anticipate this will result in several years to lay.

Regarding the Xeljanz Phase III psoriasis program it continues to progress. However given the large size and complexity of this data set the analysis and reporting of the data have been more complicated than we anticipated. That said, there is no issue with the integrity of the data and this delay is purely due to operational issues. As a result, we now expect as the top line results from two of our four psoriasis ongoing studies by the end of the year.

One of the studies expected to read out this year evaluates maintenance of efficacy when patients are withdrawn from and then retreated with Xeljanz therapy. The second study compares the efficacy and safety of Xeljanz to Enbrel and placebo. We anticipate reporting the top line results from the two pivotal studies that will be part of our planned regulatory submission in the second guarter of next year.

For Prevnar sales this quarter were adversely impacted in the U.S. by the variability of CDC purchase patterns and a lower birth cohort in the U.S. as well as the end of a supplementary dose program in Asia. Regarding CAPiTA we continue to accumulate events and based on (indiscernible) spend rates we expect to complete the study this year. Given the size of the study, which is approximately 85,000 patients once the number of events is achieved it will still take several months to complete the necessary database validation and related activities prior to unblinding the results. Given where we are today we expect that we should see top line results in the first half of 2014.

As we announced yesterday, we are moving forward with formally internally separating our commercial and management structure into innovative and value business segments. And we will integrate emerging markets' fully into each of these segments.

One of the innovative business segments will be led by Geno Germano, who'll become Group President Innovative Products. This business segment will generally include products that have exclusivity beyond 2015 across multiple therapeutic areas consisting of immunology and inflammation including Enbrel, cardiovascular metabolic, neuroscience and pain, rare diseases and women's and men's health. XELJANZ and Eliquis, examples of products in this business.

The other innovative business segment will be led by Amy Schulman who will become Group President of Vaccines Oncology and Consumer Healthcare. Each of these businesses will operate in the separate global business. Each has a different operating model with the same specializations around science, talent and market approach.

The Value Product segment will be led by John Young. They will include the brands that have lost their exclusivity and generally a mature patent protected products are expected to lose exclusivity through 2015 in most markets. Some examples include Celebrex, Zyvox, Viagra outside of the U.S. and Lyrica in the EU.

The Value business will also include our biosimilars portfolio and current and future collaborations for broadening our off patent portfolio, such as our existing partnerships with Mylan in Japan, Hisun in China and Teuto in Brazil. While we have decided to integrate emerging markets into the innovative value businesses, these markets will continue to play an important role in Pfizer's long-term success.

We see the fastest-growing emerging markets becoming more aligned with the profile of developed markets. With these changing dynamics we believe this is the right strategic to move for us at this time. I've asked Olivier Brandicourt to lead the transition from the current emerging markets business into each of the three business segments.

And with Amy becoming the Group President of Vaccines, Oncology and Consumer Healthcare, we're appointing Doug Lankler currently our Chief Compliance and Risk Officer to be Pfizer's General Counsel. And additionally, Ray Johnson, Senior Vice President and Associate General Counsel will become the new Chief Compliance and Risk Officer.

All of the leadership changes are effective January 1, 2014. We will be moving towards operating in the new commercial structure at the start of 2014 while we continue to manage our business and report our financial results and the existing structure for the balance of 2013. All the current leaders will continue in their roles for the remainder of this year.

Starting with a release of our financial results for the first quarter of 2014, we will provide greater transparency into the financial profile of each of the three new business segments. Our plan is to provide 2014 baseline management view of profit and loss to each segment. We anticipate providing additional financial detail as we move forward within a new structure effective January 1, 2015.

In summary, I believe this new commercial structure will put us in a better position to assess the capabilities, progress and opportunities, our innovative core and provide our value business dedicated resources required to fully strengthen and grow and position it to be a market leader.

Now, I'll turn it over to Frank to take you through the details for the quarter.

Frank A. D'Amelio

Thanks Ian, good day everyone. As always, the charts I'm reviewing today are included in our webcast. Before I begin, I want to point out that as a result of the full disposition of Zoetis on June 24, 2013; the financial results of the Animal Health business are now reported as a discontinued operation, and the condensed consolidated statements of income for the second guarter and year-to-date for both 2012 and 2013.

Now let's move on to the financials. Second quarter 2013 revenues of approximately \$13 billion, decreased 7% year-over-year reflecting a 3% negative impact from foreign exchange and an operational decline of approximately 4% driven mainly by the loss of exclusivity of several key products in certain geographies, most notably Lipitor and developed Europe for the second quarter of 2012, and multi-source generic competition for Lipitor in U.S. beginning in late May 2012.

The decline in Pfizer's share of revenues for the terms of the co-promotion agreements for Spiriva, which are in the final year in the U.S., Australia, Canada and certain European countries. The timing of government purchases of Prevenar in various markets and the transfer of certain product rights to our joint venture in China with Hisun in first quarter.

Adjusted Diluted EPS of \$0.56 decreased 5%, primarily due to the previously mentioned decrease in revenues and the impact of foreign exchange, which were partially offset by a lower effective tax rate, and fewer diluted weighted average shares outstanding, primarily due to our ongoing share repurchase program.

Reported diluted EPS was \$1.98 compared with \$0.43 in the year-ago quarter. So, it's mainly driven by the pre-tax gain of \$10.5 billion associated with the full disposition of Zoetis and to a much lesser extent by the Protonix patent litigation settlement and lower legal charges, which were partially offset by the previously mentioned decrease in revenues and a 5.1 percentage point increase in the effective tax rate on reported income from continuing operations mainly attributable to the tax liability associated with the previously mentioned Protonix patent litigation settlement.

During the second quarter, biopharmaceutical revenues in the BRIC-MT markets declined 2% operationally, primarily due to the timing of government purchases of Enbrel in Brazil and Prevenar in Turkey and the transfer of certain product rights to the Pfizer-Hisun joint venture in the first quarter. These were partially offset by strong volume growth in China, especially for Lipitor and Prevnar.

In these BRIC-MT markets, volume growth of 1% was more than offset by price reductions of 3% versus the year-ago quarter. In addition, foreign exchange negatively impacted BRIC-MT revenue by 1% in the second quarter of 2013. Revenue from all emerging markets increased 4% operationally in the second quarter. If you exclude the portfolio of products whose rights would transfer to our joint venture in China with Hisun, we would have had operational revenue growth of 5% in our emerging markets business and 22% in China, and BRIC-MT operational revenue would have been flat compared with the year-ago quarter.

Operational, biopharmaceutical revenue growth from all emerging markets business is expected to accelerate in the second half of the year to a high single-digit percentage. However, we now expect full year operational revenue growth

and our emerging markets business to be in the mid single digit percentage due continued slowing growth in some markets as pricing pressures continue to build and governments take additional steps to contain rising healthcare expenditures.

As we previously stated, because of the continued volatility in emerging markets, we anticipate our performance in that business to fluctuate from quarter-to-quarter.

Foreign exchange negatively impacted second quarter revenues by 3% or \$392 million, and had a net positive impact of 3% or \$228 million on the aggregate of adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses. As a result, foreign exchange negatively impacted second quarter adjusted diluted EPS by approximately \$0.02 compared with the year-ago quarter.

Now, moving on to our 2013 financial guidance, we are reaffirming all components of our full year 2013 adjusted financial guidance that we updated on June 24 to solely reflect the impact of the Zoetis exchange offer. I want to remind everyone that the weighted average shares outstanding used in the calculation of adjusted and reported diluted EPS reflects the net reduction of 405.1 million shares of Pfizer's outstanding common stock as a result of the exchange offer. Because the exchange offer was completed on June 24, we will recognize only a partial year benefit to our full year 2013 adjusted and reported diluted EPS.

As an additional reminder, when we completed the full disposition of Zoetis in June we announced that the expected impact of the removal of the full year 2013 financial contribution of Zoetis and the impact of the partial year benefit from the net reduction in shares of our outstanding common stock due to the exchange offer would result in a \$0.04 decrease to the upper and lower ends of our projected range for 2013, adjusted diluted EPS.

Today, we've also updated our 2013 reported diluted EPS guidance range of \$3.07 to \$3.22 to reflect the gain associated with the full disposition of Zoetis, and income from the previously mentioned litigation settlement.

Now moving on to key takeaways. Second quarter results reflect the loss of exclusivity of certain products in various geographies as well as the continued volatility in emerging markets.

As I previously mentioned, we expect high single-digit operational revenue growth in emerging markets during the second half of 2013, and now expect mid single-digit growth for the full year.

We continue to mitigate the earnings impact of product LOEs with both expense discipline and share repurchases. We completed the full disposition of Zoletis during the second quarter, and we accepted 405.1 million shares of Pfizer common stock in exchange for our remaining interest in Zoetis.

We continue to expect the transaction to be accretive to reported and adjusted diluted EPS on a full year basis in 2014. We are reaffirming all components of our 2013 adjusted financial guidance, we remain excited about the potential of our new product launches in mid-to-late stage pipeline. We've announced our intention to implement the new commercial structure beginning in fiscal 2014, which we except will better position Pfizer in long term success, and we continue to create shareholder value through prudent capital allocation.

In the second quarter, we repurchased approximately \$3.3 billion of our common stock. To date in 2013, we have repurchased approximately 8.7 billion or approximately 309 million shares and have \$13.1 billion remaining under our current authorization. And we continue to expect the repurchase in the mid teens of billions of dollars of our common stock this year, despite the blackout period for share repurchases during and for 10 business days after the Zoetis exchange offer period. Finally, we remain committed to delivering attractive shareholder returns in 2013 and beyond.

Now, I'll turn it back to Chuck.

Charles E. Triano

Thanks Frank and Ian for the update. Operator, can we please now pull for questions.

Question-and-Answer Session

Operator

Your first question comes from the line of Chris Schott from JPMorgan.

Chris T. Schott - JPMorgan Securities LLC

Thanks very much for the questions. The first one was on the corporate structure. Can you just elaborate a little bit on why three divisions here as compared to simply the innovative and value core franchises you've discussed in the past. I guess is there – I know you're talked about the – is there a scenario where Pfizer could break itself into three companies at some point in the future.

And then my second question was – and just so I am clear can you elaborate a little bit more on what type of P&L granularity we should be anticipating in 2014 and then maybe even looking forward to 2015 for this three operating divisions? Thank you.

Ian C. Read

Thank you, Chris. So, why the three rather than two. Well, I think it basically is very strong operational reasons that the innovative business under Geno has a collection of large disease areas that cut across both the primary care and specialty and they have challenges both capital allocation and of the go-to-market model as we look to be more efficient in how we deliver the message and how we get to see primary care physicians. Whereas the oncology business and the vaccine business have a very distinct culture, they're smaller businesses that I wanted to make sure that you can get, didn't get assumed into a large primary care business. They have specific customers, they have dedicated search facilities and research focus and I thought it was very important for those business to maintain their unique focus and extend it globally. So, that was the primary reason for maintaining or claim a structure where we had two innovative businesses.

On the details, I'll turn it over to Frank.

Frank A. D'Amelio

Yeah. So, Chris, on the P&L granularity for '14 and then as about beyond 2014. For 2014 fiscal year, we will show revenue for each of the three businesses. We'll show direct cost and we'll show direct expenses and then what we'll do is on expenses that we don't allocate today that we don't allocate to come fiscal 2014, we'll provide some qualitative directional statement. So, that you will be able to model some good full stream P&Ls. Come fiscal 2015, we'll provide that same information and then we'll provide some additional balance sheet information as well. So, that's kind of the rhythm of how we're thinking about this.

Charles E. Triano

Thanks Frank. Next question please.

Operator

Your next question comes from Gregg Gilbert from Bank of America-Merrill Lynch.

Gregg Gilbert - Bank of America-Merrill Lynch

Sure. On the separation, was curious, as you internally separate these businesses, are you considering any changes that could affect the overall tax structure at Pfizer? Then on Palbo, I've a couple of questions. By when will you know that you might not have data in time for San Antonio? I assume it's some time before the actual start of that conference. So, let us know if there's a key date there. And Lilly has a program that's much earlier in that class, but they talk about the ability of their product to be dosed continuously. Any comments on that subject of continuous dosing versus otherwise? Thanks.

Ian C. Read

Great, thank you. I will ask Frank to comment on the tax issue.

Frank A. D'Amelio

So in terms of the tax structure, the creation of these three businesses in and up themselves does not impact in any material way the tax structure, but we are always doing tax planning to see what we can do to be more efficient from a tax perspective.

Ian C. Read

And if, Geno could you respond to the guestions on Palbo?

Geno Germano

Yeah, I mean, with regard to the timing on Palbo, we're continuing to accumulate events, and based on the rate of accumulation that we're seeing at this point, we think it's unlikely that we'll be presenting data at San Antonio. So, I don't have a specific date to give you, but I think our best view at this point is, it's unlikely that we'll present at San Antonio. We still expect to accumulate the required events around the end of the year, but unlikely we'll meet the San Antonio date. And then with regard to continuous dosing, I'm really not sure and familiar with the Lilly program. So, I can't really comment on that.

Charles E. Triano

Thanks, Geno. Next guestion please?

Operator: Your next question comes from Tim Anderson from Sanford Bernstein.

Tim Anderson - Sanford C. Bernstein & Co. LLC

Thank you. A couple of questions on the split up. Can you give us a very rough preliminary idea of how operating margins might compare across those different businesses, could establish products had the highest margins because those products seem to kick off a lot of cash and don't require a lot of support even directional guidance on this sort of thing would very helpful because that's what folks, I think, are going to be interested in as we head into 2014?

And then separately you've talked about meeting three-years of audited financials before you could potentially truly split up the Company if that's what you're ultimately destined to do. There's been some speculation that perhaps you could use historic data for this three-year requirement, which means you wouldn't have to wait until 2017 or so until we really carve it up. Is this a possibility, should we really think of 2017 as being the earliest you could really split things up?

Ian C. Read

Well, I'll ask Frank to answer the margin issue the best he can and also your hypothetical question on data needed to split.

Frank A. D'Amelio

Sure. So, let me answer the second question first, which is on data requirements. If we were ever to decide to do something external to the Company, obviously we haven't decided anything yet, and which is, it requires three-years of audited financials and our current thinking is those would be prospective. And the thought of trying to retrospectively create those, when we look at everything that we need to be done is, would be extremely difficult. So, the current thinking is clearly that those will be prospective in terms of the three-years of audited financials. So, that's how I'd answer the second question.

On the first question on operating margins, the way I think about this is we're going to provide 2014 guidance. We're going to stop providing more granularity relative to these three businesses. So, Tim for the time being I really don't want to start projecting the margins on those businesses until we start showing them from 2014 and that will give lots more clarity when that time comes.

Ian C. Read

Thanks Frank.

Charles E. Triano

Next question please, operator.

Operator

The next question comes from Jami Rubin from Goldman Sachs.

Jami Rubin - Goldman Sachs & Co.

Thank you. Just to follow-up on that last question. Frank is there a difference in SEC requirements for a spin versus a split. And then a question for you Ian on M&A, you've done an amazing job returning cash to shareholders, which

we've all strongly applauded. But you also say that with respect to M&A that you would always use share buybacks as the case to be, but with your stock at a 12 to 13 multiple there really is no case to beat relative to a share buyback. So I am wondering, how you are thinking about M&A going forward especially as it relates to the potential to split the Company into multiple parts that might require more growth drivers or M&A activity? Thanks.

Frank A. D'Amelio

Thank you. So, on the BD issues we look at BD not as a strategy but as a way of creating shareholder value and strengthening cost of our franchises or portfolio. We always try to analyze it sort of in the light of new capabilities or strengthening capabilities we already had. We've tended to talk in terms of bolt-ons and you'd have to think that bolt-ons would be you'd easily consider single-digit in billions of bolt-ons for this company. And we've also said, we'll look at any type of acquisition, never say never to larger acquisitions that made sense.

Regarding when would we consider our share price to be at a level that BD would be more effective. Well, you know, it depends on what deal we are looking at in BD, how it's priced and where our expectations are of our multiple is going in the next two to three years. So, I don't know I can answer that in a hypothetical way, but more in a look at each case by case. We look at each deal. We're active in looking at deals. We can pair to what we think the value of buybacks are and we take the decisions on a deal by deal basis. Do you want to add anything to that, Frank?

Frank A. D'Amelio

Yeah, let me just add quickly to that and then I'll answer the question about split versus spin which, and Jamie when we look at deals remember in terms of the case to [BP] in buybacks, it's also over what timeframe. So, is it year one, is it year two and then, well, how do we feel about the certainty of being able to achieve those EPS projections based on assumptions on synergies and the like. So, in my mind to Ian's point, it's deal by deal situational and then over what timeframe do we see that being, I'll call it, accretive relative to the buybacks. And then the terms of the split versus the spin question and is there any difference in required financials, the answer is no. Both scenarios require three years of audited financials.

Jami Rubin - Goldman Sachs & Co.

Thanks, Frank.

Charles E. Triano

Operator, can we move to the next question please?

Operator

Your next question comes from Mark Schoenebaum from ISI Group.

Mark Schoenebaum - ISI Group

Hey guys. Excuse me. Thank you very much for taking the questions. Maybe I can build on Jamie's question around use of cash, I think in the past I've heard you say things like your priorities for cancer vaccines and also general practitioner drugs, I wondered if you could clarify or confirm that and when you say, you never say never do a larger deal, maybe you could just expand on that, is that just a theoretical statement or is that something that we should be thinking about as possible move for Pfizer? And then, under the new structure, have you decided will BD be centralized or each unit have independent BD M&A functions within them? And then, maybe just quick R&D if I can, do you expect the NGF antibody to return to clinical development? Thank you

Ian C. Read

Okay, so, you asked about BD by segment. Clearly, BD that builds on a capability, it allows you to synergize your expense space, is how easy they get done than BD when you're going to a totally new space.

So, while we look at any good intellectual property that we could bring to patients and use our capabilities to bring to patients, they're easy to get done, if you've got some inherent synergies. On a big deal, all I would say is, look we're focused on creating value for shareholders and you do the analysis and you look at the risk and you look at the uncertainties and you make your decisions as you go forward. We've been up-till-date primarily focused on bolt-ons.

Frank, do you want to talk about the BD? Certainly, I would say, part of the rationale for creating these goal

businesses is that, I now feel I can have management teams tasked on creating both organic and inorganic growth, and they're obviously going to have close ties and working with our BD organization. Frank, do you want to add to that?

Frank A. D'Amelio

Sure. On the BD org structure question, the way we approach this is, the BD resources are centralized, however there's matrix from a client support perspective. So, when you look at any of the businesses, they'll have folks that are dedicated to them, that literally from a business perspective are on their team. Who they report to, from my perspective, is irrelevant. We matrix, this in such a way that their reporting is transparent. They're living with those folks. They're collocated with those folks. They're working with those folks on a dedicated day-to-day basis. That's how we do it, quite frankly for just about all of our enabling functions.

Ian C. Read

John you want to add something?

John Young

Yeah, thanks for the question about tanezumab, which is our NGF antibody. Just sort of a quick update on that, on the 19 of July this year, we actually received notification from the FDA that the partial clinical hold for tanezumab has been lifted. You may know that the partial clinical hold have been placed on the development of all the NGF inhibitors back in December 2012 based on observation and some animal tox studies conducting in NGF inhibitors in development through other manufacturers.

So, there partial clinical hold was lifted on a commitment by Pfizer to submit non-clinical data before initiating dosing in clinical trials and thereafter limiting dosing duration until the additional non-clinical data has been submitted and reviewed by the FDA. So, those record at non-clinical data studies have already been started and with the lifting of the partial clinical hold and on the assumption of a positive review of the non-clinical data by the FDA, we're preparing for resumption of Phase III clinical studies in 2014.

Charles E. Triano

Thanks John. Next question please.

Operator

Your next question comes from Alex Arfaei from BMO Capital Markets.

Alex Arfaei - BMO Capital Markets

Good morning and thank you for taking the questions. First on the R&D and perhaps M&A's front, either for Ian or Geno. Could you comment on the extent to which cancer immunotherapy is a priority for you? And then, for Frank, you've obviously returned a lot of cash to shareholders in terms of buybacks, but any thoughts on the dividend increase, given your relatively low payout ratio? Thank you.

Ian C. Read

Mike, do you want to take the R&D question?

Mikael Dolsten

So, we have a broad effort in quality in immunology and we certainly have interest also in the cancer immunology area. On one hand we some vaccines in the cancer immunology area that are starting to move into pre-clinical development, but we also have some monoclonal antibodies. Let me mention the 4-1BB or CD137 checkpoint activating antibody that we now have in Phase 1 study in hematological and solid tumors and are following with quite some interest that are antibody and other assets.

Ian C. Read

Thank you, Mikael. Frank, do you want to ...?

Frank A. D'Amelio

Dividend?

Ian C. Read

Dividend.

Frank A. D'Amelio

Sure. So let me just run the numbers on the dividend and then I'll answer the question which is when we announced the Wyeth acquisition back in 2009, we cut the dividend in half, from \$1.28 to \$0.64. Since then we've increased the dividend 2009 to 2010, 2010 to 2011, 2011 to 2012, 2012 to 2013 from \$0.64 to \$0.72 to \$0.80 to \$0.88 to \$0.96. 12.5%, 11%, 10% and 9% dividend increases over the last four years.

Our cadence is always at our December Board meeting. We typically – Ian and I make a recommendation to the Board relative to what we expect or what we want the dividend to be for the following year. Once the Board approves that we come out with a release to let everyone know what the new dividend will be. That's what we are expecting to do this year.

And then in terms of just absolute dollar amounts, at the current dividend level we'll be paying more than \$6 billion in cash to our shareholders this year.

So big number and you mentioned the payout ratio, if you use the mid-point of our guidance and then use the \$0.96 you get about 45% which is roughly in line with the industry, maybe a couple of points below. But we've been closing that gap over the last couple of years with our increases.

Ian C. Read

Thank you, Frank.

Charles E. Triano

Our next question please.

Operator

Your next question comes from Marc Goodman from UBS.

Marc Goodman - UBS Securities LLC

First is PCSK9 the subcu I think we are supposed to hear about that in mid-year, just wondering an update there. Second on Xeljanz I know you are working on a once daily version I was curious if you could update us there. And then there were a couple of products in the U.S. that were very strong, Lyrica and Celebrex, were their stocking that drove out or can you help us there? Thanks.

Ian C. Read

Okay, Mikael do you want to talk about PCSK9 results and then Geno will talk about Xeljanz and John on Lyrica and Celebrex.

Mikael Dolsten

Yeah, so, thank you for the interest in PCSK9. We do believe there will be a limited number of entrants in this new drug class. We think it has potential to be a very important drug class with substantial, clinical and commercial potential. Key here will be to over time demonstrate important to see the outcome value for the patients, physicians and payors.

Our own antibody is now fully enrolled in Phase IIb and we'll soon complete that study. We have seen interim results showing potent antibody with a competitive profile, and we will assemble all the data from the Phase IIb and look at opportunity for subcutaneous delivery at various time intervals and make a decision at end of this year about the next step forward.

Geno Germano

Thank you Mikael. With regard to the XELJANZ once-a-day program, we do have a delayed release formulation that we're moving forward with. We've had dialogue with the FDA on the development plan and we have determined that the registration package will be comprised primarily of pharmacokinetic data, PK data without a requirement for a clinical Phase 3 trial, which will accelerate the development of that program. So, we expect to be filing by early 2015.

John Young

Mark, with regard to your question about the operational performance of Lyrica and Celebrex, essentially both products have seen strong operational growth in the quarter and year-to-date. We haven't seen any effect of stocking or changes in inventory levels in the marketplace. In fact, those have been very steady, and really the performance that you're seeing is really just a reflection of the combination of both price and volume in the U.S. and a value proposition that continues to resonate very well with physicians.

Charles E. Triano

Thanks, John. Next question please?

Operator

Your next question comes from David Risinger from Morgan Stanley.

David Risinger - Morgan Stanley & Co. LLC

Yes, thanks very much. I have three questions on the new business structure and then a pipeline question. So, first, is it dilutive to create three business units and build the matrix, and enabling functions? Second, could you discuss breaking up the sales forces in emerging markets and implying them to the new segments? And then third, regarding the three years of audited financials, I'm assuming that's to affect tax free exits, but would you consider divesting one of the units, for example, established products before you have three years of audited financials or is that just not realistic given the necessity to ensure tax-free transactions. And then for Mikael, could you just tell us what the key pipeline disclosures are to watch through year-end including whether you're going to provide any updates on your Breakthrough Therapy discussions with the FDA on Palbociclib. Thank you.

Ian C. Read

So, we don't believe this new structure will be dilutive to our present structure. In fact, we assume that there will be some modest savings, as we go to that structure. You have to remember, we already have in the developed markets, we already have a primary care, a specialty care vaccines and oncology business and then we have an emerging markets business in the rest of the world and we are effectively collapsing most of the primary care and specialty business into one BU. So, we do not believe that those standing up to those BUs are going to be dilutive.

On the field force in the emerging markets, it really depends country by country, but if you take a country like China, the vast majority of the field force will fit in the value business and we will have internal service agreements to provide field force support for the innovative products. I do not see that at all as an operational issue it's something we've been doing for quite some time is sharing field forces between BUs.

I'd ask Frank to talk about the three-years and the possibility of divestiture prior

to that and then we'll go to Mikael.

Frank A. D'Amelio

So, on the tax-free question that you asked, Dave, way I've been, I think about this is tax is aside, we'll need to follow – if we would ever do anything externally, we haven't decided, we would need to follow registration statement, those registration statements require three years of audited financials, so that's the way I think about that.

In terms of something prior to three-years of audited financials, now our current thinking is this is all about getting these three businesses to hum internally, top rates with excellence inside the Company and our current thinking is all around three-years of prospective financials that would be auditable.

Mikael Dolsten

So, David thank you for your interest in our pipeline and I'm very excited about the pipeline both short-term and over

the next couple of years. With the focus on this year, we already touched upon our phase 2b PCSK9 that will get data readout in – during this second half of the year.

Fairly as Ian has touched upon the two trials that we'll have a read out this year that will give us some first insights, how Xeljanz is performing this new indication. We also have I would like to say in psoriasis a topical study that now is running which I think is a very interesting further exploration of Tofacitinib. You heard about Prevnar in adult that we are expecting to complete during the later part of this year.

Within the vaccines franchise we are also now in the finalization of our reports from staphylococcus aureus PUC trials that we will share during the latter part of this year. I'm very encouraged by the profile I have seen so far, when it comes to this unique technology that we are deploying for a very broad immune response to stop aureus. In oncology, we have the two dacomitinib trials for second third line and third line or fourth line that we expect to have data this year that we'll be probably shared early next year. And you have heard earlier Geno's comment on Palbociclib that we expect to have the final pieces of the data coming together this year, and we have previously had very good dialogs with FDA on the breakthrough designation. So, we expect to continue a very close dialog and our guidance how to best use those data to the benefit of patients. And on top of that in Phase II, let me just point to couple of intriguing areas.

We have a best-in-class IL6 antibody and very long-acting antibody with a good potency and we expect read outs this fall in Lupus and late next year in Crohn's. We have a read out in COPD related to a piece of data inhibitor. We have our second biosimilar that have a readout this year Rituximab. We have earlier communicated positive data from our first biosimilar product Herceptin. And then, we're broadening our inflammation efforts to also involve the intersection of cardiovascular disease with a readout from a novel PDE5 inhibitor in chronic kidney disease. So, I do look forward to share with you the output from all of these studies in the next years to come.

Ian C. Read

Excellent. Thank you, Mikael. Good comment, our next question please?

Operator

Your next question comes from Tony Butler from Barclays Capital.

Tony Butler - Barclays Capital, Inc.

Thank you very much. Some brief questions on the new structure if I may, if we could back to the notion of business development, and if we use an example say in established products with your partnership with the Brazilian company Teuto, I believe there is an option to actually buy the entire company. So, the question is, is that a decision by John Young and his Group. They make a recommendation to you, Ian and Frank and the Board, how does that capital actually get allocated if that were to occur?

The second question is around R&D to the structures is 100 – this may seem silly, but is the 100% of the R&D allocated to these three structures and I say this because I might, if they were split apart one could argue if all are should go in one of the innovative areas versus one of the others or not at all could be less then?

And then, similarly in the established products group with respect to R&D allocation, I could actually argue under the Pfizer umbrella there is very little R&The, but yet I suspect they were standalone if you look at Teva and Mylan as examples, 6% of total, 6.8% of total revenue is actually R&D. So, I'm just trying to understand when we see this in January, Frank, how does it actually look, if you could provide some additional granularity? Thanks again.

Ian C. Read

On Teuto, what the global business units will do is they will be champions of projects and BD, but we need to maximize the use of BD across the Pfizer portfolio. So, the decision is taken at the corporate level and the BU leaders have to champion the deals.

On the R&D, clearly there are parts of R&D that are specific to the BUs and parts that are general infrastructure underneath it and I think we'll work through that as we go. I'll ask Frank to comment on that.

Frank A. D'Amelio

So Tony, let me provide a little more granularity and see if this is helpful, which is - so, before, when I talked about direct expenses to the new businesses, clearly the post-POC expenses that are in the business units today, would

continue to be in the business units tomorrow. Then, if you look at, I'll call it the pre-POC spend that we have, that resides in Mikael's organization today, and what we call WRD, Worldwide Research and Development, that doesn't get allocated to the business units today.

We're looking at how best to guide you all relative to that spend, and that's the stuff that we're working our way through, and we'll work our way through that through the year and obviously give you guys updates as we go, but we are looking at how best to basically, how best to communicate that to you all, so that you can model this appropriately, kind of point one.

Then, you mentioned DP, and if I could give you a little bit more direction, the answer is, of course I can. If you look at the overall R&D spend, the value of business as a percentage of revenue will have a lower spend, and innovative cobusinesses as a percentage of revenue and once again, and how we best direct and guide you all for next year is some of the sub-ledger detail that we're working our way through.

Ian C. Read

And Tony, this is part of the, one of the benefits, I expect to get out of having global businesses with Presidents who are champions, so the R&D today that would probably go to establish a smaller type of R&D that is safety, registration, regulatory some of biosimilars, and then some work around special formulations and that type of work. John's role will be to look at that and as you say compare it to what he needs to do it to drive growth and look at competitors in our Q4 capital allocation is appropriate into his R&D and this is what the benefit you get out of this type of focus on businesses.

Charles E. Triano

Thanks Ian. Next question please?

Operator

Your next question comes from Steve Scala from Cowen.

Steve M. Scala - Cowen & Co. LLC

Thank you. First on Xeljanz, the CHMP is seeking longer term safety data or is there a potentially rare and/or serious issue that they are requiring clarification upon? Secondly, is CAPiTA's delay due to a lower than expected event rate or is it due to some other reason? And then thirdly on emerging markets, may we anticipate high-single digit growth will return in 2014 and beyond or is this a business where mid-single digit growth is more likely? Thank you.

Ian C. Read

Geno?

Geno Germano

Yeah, Steve, so, with regard to CHMP and XELJANZ, obviously we're somewhat disappointed at the outcome following what was really a positive scientific advisory group meeting and a positive view from the rapporteurs this time around. Ultimately CHMP members, at least some of the CHMP members, a small majority wanted to see additional safety data and in particular wanted to understand kind of the full profile of Tofacitinib with a new mechanism of action relative to other agents that are used in this patient population. So it's not entirely clear whether we're looking for longer term data or a larger database.

As you know, we continue to collect safety data. We have long term extension trials. We have registries. We have a post-marketing study that we are kicking off from the U.S. registration. So we have multiple ways and then of course we have psoriasis and psoriatic arthritis programs. We have a number of mechanisms to generate additional safety data and we'll obviously continue to do that. It's not entirely clear at that moment what we'll need to do achieve a registration. We do anticipate we'll need to do some additional clinical work, and as Ian mentioned before, we think this could require several years of delay in Europe. So that's the best way I can kind of characterize the situation there with the CHMP.

With regard to CAPiTA, it's difficult to predict what the event rate is going to be. It is going to depend on various dynamics like the severity of the flu seasons, the efficacy of the vaccine. So if it's a highly effective vaccine then the only cases that you're accumulating are cases in the placebo growth. So it's difficult to predict and we becoming very

close to the target number of events and hope to be able to present more clarity in the very near future.

And On EM, we've always said that EM will be volatile. And we'll see swings in quarter-on-quarter and even year-to-year. I mean we'd all agree that secularly that's where we are seeing the vast majority of volume growth that's coming from in the foreseeable future as these economies continue to spend more on health care and the growth rate is going to fluctuate depending on how the volume is doing and what pricing pressures you are getting in the quarter. And so I would say it's really too early to tell or to reset expectations for where we think long-term growth in the emerging markets are going to go and we'll look at in our 2014 guidance. But overall we continue to be very bullish on the underlying demand for healthcare in emerging markets.

Charles E. Triano

Thanks Jim. Next question please, operator.

Operator

Your next question comes from Andrew Baum from Citi.

Andrew Baum - Citi

Yeah good afternoon. Couple of questions, first on the immunotherapy assays, you mentioned Mikael the CD137, when do we get the first read out in NHL is that next year? And then, same topic, before you divested Tremelimumab to Astra you obtained some rights, perhaps you could outline what invitation you have retained?

And then separately for Ian, one of your competitors is having very visible issues in China, to what extent do you think that the ongoing investigations over fraud are going to impact pricing or demand in that market?

Ian C. Read

Okav. Mikael.

Mikael Dolsten

We're now running the Phase Ib studies here with our 4-1BB. We think we'll have a real interest in antibody and we have seen some encouraging early signs of activity here. I would expect as we finalized the Phase I studies here we will use conventional on-quality conferences to report outcome. We also have behind it a couple of other antibodies, such as OX40 and [Gitter].

So you should see it as second wave of checkpoint inhibitors trying to benefit from the early anti-cells around the PD-1 space but building on that and bringing the field further on.

Tremelimumab, we did retain particularly rights to use it for vaccines, and I shared with you some anti-cells about our cancer vaccine platform, and I can inform you that it do include Tremelimumab as one of the options for adjuvant effect on cancer vaccine. So, that was a really good way for us to plan, when we did that retention.

Ian C. Read

Thank you. And on China, I can't really comment on individual cases. I would say what we've seen in China is that clearly as government, focusses in spending more on healthcare. They clearly want to be good buyers of value of pharmaceuticals, so we'd expect to continue to have robust conversations and debates with them as we go forward, as to the value of the innovation we bring. I think you'll continue to see as they've been doing, they do price reviews of segments of the market and they reset prices and normally, volume responds to different price points. So I think that will continue in China, as we go forward.

Charles E. Triano

Thanks you Ian. Moving on, next question please.

Operator

Your next question comes from Seamus Fernandez from Leerink.

Seamus Fernandez - Leerink Swann, LLC

Thanks very much. Just a couple of questions here. First, can you talk a little bit about how you are going to be thinking about cost of goods and some of the overlapping dynamics there, is this a situation where Pfizer might consider a co-bottling or [Lonza] type structure over time, should the units be split out or how is that going to operate as we think about it?

Separately, can you also talk a little bit about Europe and infrastructure there, relative to the overall industry's profitability, one of your competitors commented on that and I think that might be particularly relevant as perhaps particularly relevant for Geno's business unit?

And then finally, as it relates to the emerging markets, Ian you mentioned specifically that you see the emerging markets – some of the larger emerging markets starting to operate more similarly to the developed markets. Can you just give us a little bit of a better sense in what regard that is, is it on distribution, reimbursement what is it specifically and are we talking about more similar to the U.S. or more similar to Europe?

Ian C. Read

Thank you. So on the cost of goods, about in terms of absorption, 50% of our plans are absorbed through the value business and 50% are absorbed through the innovative business. There are a limited number of plans that are specific to one business or the other. So I would expect that internally simply a cross supply issue between the plans and if there was anything ever externally done, I think this is easily handled by supply agreements. Today Pfizer purchases about 30% of its requirements from external suppliers. So, this is easily handled in the ordinary course of business.

The next question was Europe and infrastructure, look the pricing squeeze that Europe has applied to the industry over the last few years, which has accelerated from low-single digits to mid-single digits is, of course, pushing companies to look at what their infrastructure is, how they deliver the educational messages decisions and their investment in general, part of our restructuring into the innovative one, innovative two and the value business, a response of that in the set we effectively are merging our primary care and our specialty BU into one. So, I expect in Europe, you'll continue to see pharmaceutical companies look for more cost efficient ways to deliver their message, to physicians.

And on the EM issue, I think if you look at Turkey, you can see Turkey has gone to a full reimbursement model, more like Europe, this out of pocket has now become less important in Turkey. The government is more influential, so they tend to be more dominant in the way they make acquisitions of pharmaceuticals and their pricing requests.

In sophistication, I talk really about the way the markets have been regulated in terms of compliance, in terms of the rules that are similar in Europe and the U.S., so I just see these markets evolving and also you're beginning to see more commonality and the requirements, they ask for registration, and that's really the sense of my comment about their evolving to looking more like mature markets.

Charles E. Triano

Thanks, Ian. And Operator, if we could please take our last question?

Operator

Your final question comes from Damien Conover from Morningstar.

Damien Conover - Morningstar Research

Great. Thanks for taking the question. Just had a question on the restructuring. Wanted to see how products would flow from the innovative pieces to the value piece post-2014, and whether or not there'd be any precedent set up for any sort of transfer of value that could be used if the entity is actually fully separated. And then second question on the break up was just a question on the consumer health business, and if I remember correctly, one of the driving reasons to have that business within the Pfizer umbrella is to help with any sort of RX to OTC switches and given that it's going in the vaccine and oncology bucket, I still wanted to know if that RX to OTC switch was still a major driving force behind that business underneath the Pfizer umbrella? Thank you.

Ian C. Read

Thank you, Damien. So, I think the movement of products between the businesses will continue as they have been in the last three years as products that are innovative one, [go whether] we will move them over to the value business

and they'll be managed that way. Any hypothetical situation where there was – the two businesses weren't in the same corporate shell, then you would make your decisions based on what's the best way to continue to commercialize those products at a later date, but that's really very early to speculate on. And then, Amy, would you like to take the consumer.

Amy W. Schulman

With respect to the Type 1 that we have for RX to OTC switches, we continue to see feel very comfortable with the pipeline. It's robust and assuming regulatory approval we'll proceed with the [DEXIN] launch in 2014 and then we have a number of other promising molecules in the pipeline, some of which we talked about previously.

Damien Conover

Great. Thank you.

Ian C. Read

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

Charles E. Triano

Thank you.

Operator

Ladies and gentlemen, this does conclude the Pfizer's second quarter 2013 earnings conference call. Thank you for participating. You may now disconnect.

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Executives

Charles E. Triano – Senior Vice President-Investor Relations

Ian C. Read – Chairman and Chief Executive Officer

Frank A. D'Amelio – Executive Vice President-Business Operations and Chief Financial Officer

Geno Germano - President and General Manager-Specialty Care and Oncology

John Young - President and General Manager-Primary Care

Mikael Dolsten – President-Worldwide Research and Development

Analysts

Chris T. Schott – JPMorgan Securities LLC

Gregg Gilbert - Bank of America-Merrill Lynch

Tim Anderson - Sanford C. Bernstein & Co. LLC

Jami Rubin – Goldman Sachs & Co.

Mark Schoenebaum - ISI Group

Alex Arfaei – BMO Capital Markets

Marc Goodman - UBS Securities LLC

David Risinger - Morgan Stanley & Co. LLC

Tony Butler - Barclays Capital, Inc.

Steve M. Scala - Cowen & Co. LLC

Andrew Baum - Citi

Seamus Fernandez – Leerink Swann, LLC

Damien Conover – Morningstar Research

Pfizer Inc. (PFE) Q2 2013 Earnings Conference Call July 30, 2013 10:00 AM ET

Operator

Good day, everyone and welcome to Pfizer's Second Quarter 2013 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.

Charles E. Triano

Good morning and thank you for joining us today to review Pfizer's second quarter 2013 performance. Joined today as usual by our Chairman and CEO, Ian Read; Frank D'Amelio, our CFO; Olivier Brandicourt, President and General Manager of Emerging Markets and Established Products; Mikael Dolsten, President of Worldwide Research and Development; Geno Germano, President and General Manager of Specialty Care and Oncology; Amy Schulman, General Counsel and Business Unit Lead for our Consumer Business; and John Young, President and General Manager of Primary Care.

The slide 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 2013 which is located in the Investor Presentations section in the lower right hand corner of this page.

Before we start, I would like to remind you that our discussions 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 2012 Annual Report on Form 10-K, and in our reports on Forms 10-Q and 8-K. Discussions during this conference 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, July 30, 2013.

Also as we outlined in our earnings release, as a result of the full dispositions of Zoetis, the financial results of the Animal Health Business are now reported as a discontinued operation for the second quarter and year-to-date for both 2012 and 2013.

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

Ian C. Read

Thank you, Chuck. I will begin with some comments on the quarter. We saw solid operational revenue growth at a number of areas. Moving on Innovative business, oncology grew 28% driven by the uptick of new products, mostly Inlyta and Xalkori in several major markets and we saw strong performance from Lyrica in developed markets which grew 14% and Celebrex in U.S., which grew by 13%. The consumer business grew 5% operationally, primarily due to strong global growth from Centrum. And China had strong volume growth, most notably for Lipitor and Prevenar. Overall total China revenues grew 14% operationally or 22% excluding the impact of product transfers in connection with forming a partnership with Hisun.

We continually expect that the second half of this year will be stronger than the first half of emerging markets. Although on a full-year basis, we now expect to see operational revenue growth of mid single-digit rather than high single digits. It is mainly due to a slowdown in growth in Brazil and Russia and the impact of cost containment measures in Columbia, Polland, Thailand and Turkey.

We completed the full separation of Zoetis into a standalone public company. The transactions related to the disposition of Zoetis generated approximately \$17.2 billion of after-tax value for Pfizer's shareholders. And our board of directors authorized a new 10 billion share repurchase program to be utilized overtime. This new program is an addition to the 3.1 billion of authorization remaining under the company's current repurchase program.

Turning to our products and pipeline assets, the launches of both Eliquis and Xeljanz continued progress in various markets around the world. And we are gaining market approvals to both Xeljanz and Eliquis in additional countries. We are encouraged with the potential for both of these therapies over the time. For Eliquis, we're focused on gaining preferred formulary acceptance, continuing to obtain reimbursement and building physician knowledge and comfort about the drug in this profile.

With this unique profile in atrial fibrillation is the only product with superiority versus Warfarin in stroke prevention, major bleeding and a proven mortality benefit, we're confident we will continue to see steady growth that will build overtime.

For Xeljanz, we're seeing good opportunities with patients who are switching from their current biologic therapy, as well as patients who are initiating Xeljanz's therapy and as a second-line setting. That is following the tricks before a biologic DMARD. In fact, almost half of our recent prescriptions are in the second line setting, with the remainder being patients who have been on one or more, biological DMARDs and not achieving satisfactory results.

In addition, we began our direct consumer campaign in the U.S. early in June and that's seen a subsequent uptick in prescription volume. Last month, we announced that the FDA had accepted for review our supplementary new drug application to include progression of structural damage in Xeljanz label and as of today, Xeljanz will be commercially available in Japan, where it'll be co-promoted by Pfizer and Takeda Pharmaceutical Company Limited.

Overall, we remain encouraged by what we're seeing what physicians and patients experienced so far. I would describe our progress as measured and steady and we recognize, it will continue to take time for rheumatologists to feel comfortable making a change. The launch is consistent with our expectations for new oral mechanism.

Turning to the status of Xeljanz in Europe, last week we announced The Committee for Medicinal Products for Human Use in the EU confirmed their prior opinions on marketing authorization applications for Xeljanz, although with a much closer vote. Given the novel mechanisms or action to Xeljanz, the CHMP wanted to see more data, particularly around safety to better understand the full profile of Xeljanz relative to other agents used in this patient population.

As a result of the reexamination process we addressed several of the questions and had more clarity on the remaining ones. We plan to work with European Medicines Agency to determine what additional data will be needed in order to resubmit a marketing authorization application and anticipate this will result in several years to lay.

Regarding the Xeljanz Phase III psoriasis program it continues to progress. However given the large size and complexity of this data set the analysis and reporting of the data have been more complicated than we anticipated. That said, there is no issue with the integrity of the data and this delay is purely due to operational issues. As a result, we now expect as the top line results from two of our four psoriasis ongoing studies by the end of the year.

One of the studies expected to read out this year evaluates maintenance of efficacy when patients are withdrawn from and then retreated with Xeljanz therapy. The second study compares the efficacy and safety of Xeljanz to Enbrel and placebo. We anticipate reporting the top line results from the two pivotal studies that will be part of our planned

regulatory submission in the second guarter of next year.

For Prevnar sales this quarter were adversely impacted in the U.S. by the variability of CDC purchase patterns and a lower birth cohort in the U.S. as well as the end of a supplementary dose program in Asia. Regarding CAPiTA we continue to accumulate events and based on (indiscernible) spend rates we expect to complete the study this year. Given the size of the study, which is approximately 85,000 patients once the number of events is achieved it will still take several months to complete the necessary database validation and related activities prior to unblinding the results. Given where we are today we expect that we should see top line results in the first half of 2014.

As we announced yesterday, we are moving forward with formally internally separating our commercial and management structure into innovative and value business segments. And we will integrate emerging markets' fully into each of these segments.

One of the innovative business segments will be led by Geno Germano, who'll become Group President Innovative Products. This business segment will generally include products that have exclusivity beyond 2015 across multiple therapeutic areas consisting of immunology and inflammation including Enbrel, cardiovascular metabolic, neuroscience and pain, rare diseases and women's and men's health. XELJANZ and Eliquis, examples of products in this business.

The other innovative business segment will be led by Amy Schulman who will become Group President of Vaccines Oncology and Consumer Healthcare. Each of these businesses will operate in the separate global business. Each has a different operating model with the same specializations around science, talent and market approach.

The Value Product segment will be led by John Young. They will include the brands that have lost their exclusivity and generally a mature patent protected products are expected to lose exclusivity through 2015 in most markets. Some examples include Celebrex, Zyvox, Viagra outside of the U.S. and Lyrica in the EU.

The Value business will also include our biosimilars portfolio and current and future collaborations for broadening our off patent portfolio, such as our existing partnerships with Mylan in Japan, Hisun in China and Teuto in Brazil. While we have decided to integrate emerging markets into the innovative value businesses, these markets will continue to play an important role in Pfizer's long-term success.

We see the fastest-growing emerging markets becoming more aligned with the profile of developed markets. With these changing dynamics we believe this is the right strategic to move for us at this time. I've asked Olivier Brandicourt to lead the transition from the current emerging markets business into each of the three business segments.

And with Amy becoming the Group President of Vaccines, Oncology and Consumer Healthcare, we're appointing Doug Lankler currently our Chief Compliance and Risk Officer to be Pfizer's General Counsel. And additionally, Ray Johnson, Senior Vice President and Associate General Counsel will become the new Chief Compliance and Risk Officer.

All of the leadership changes are effective January 1, 2014. We will be moving towards operating in the new commercial structure at the start of 2014 while we continue to manage our business and report our financial results and the existing structure for the balance of 2013. All the current leaders will continue in their roles for the remainder of this year.

Starting with a release of our financial results for the first quarter of 2014, we will provide greater transparency into the financial profile of each of the three new business segments. Our plan is to provide 2014 baseline management view of profit and loss to each segment. We anticipate providing additional financial detail as we move forward within a new structure effective January 1, 2015.

In summary, I believe this new commercial structure will put us in a better position to assess the capabilities, progress and opportunities, our innovative core and provide our value business dedicated resources required to fully strengthen and grow and position it to be a market leader.

Now, I'll turn it over to Frank to take you through the details for the quarter.

Frank A. D'Amelio

Thanks Ian, good day everyone. As always, the charts I'm reviewing today are included in our webcast. Before I begin, I want to point out that as a result of the full disposition of Zoetis on June 24, 2013; the financial results of the Animal Health business are now reported as a discontinued operation, and the condensed consolidated statements of income for the second quarter and year-to-date for both 2012 and 2013.

Now let's move on to the financials. Second quarter 2013 revenues of approximately \$13 billion, decreased 7% year-over-year reflecting a 3% negative impact from foreign exchange and an operational decline of approximately 4% driven mainly by the loss of exclusivity of several key products in certain geographies, most notably Lipitor and developed Europe for the second quarter of 2012, and multi-source generic competition for Lipitor in U.S. beginning in late May 2012.

The decline in Pfizer's share of revenues for the terms of the co-promotion agreements for Spiriva, which are in the final year in the U.S., Australia, Canada and certain European countries. The timing of government purchases of Prevenar in various markets and the transfer of certain product rights to our joint venture in China with Hisun in first quarter.

Adjusted Diluted EPS of \$0.56 decreased 5%, primarily due to the previously mentioned decrease in revenues and the impact of foreign exchange, which were partially offset by a lower effective tax rate, and fewer diluted weighted average shares outstanding, primarily due to our ongoing share repurchase program.

Reported diluted EPS was \$1.98 compared with \$0.43 in the year-ago quarter. So, it's mainly driven by the pre-tax gain of \$10.5 billion associated with the full disposition of Zoetis and to a much lesser extent by the Protonix patent litigation settlement and lower legal charges, which were partially offset by the previously mentioned decrease in revenues and a 5.1 percentage point increase in the effective tax rate on reported income from continuing operations mainly attributable to the tax liability associated with the previously mentioned Protonix patent litigation settlement.

During the second quarter, biopharmaceutical revenues in the BRIC-MT markets declined 2% operationally, primarily due to the timing of government purchases of Enbrel in Brazil and Prevenar in Turkey and the transfer of certain product rights to the Pfizer-Hisun joint venture in the first quarter. These were partially offset by strong volume growth in China, especially for Lipitor and Prevnar.

In these BRIC-MT markets, volume growth of 1% was more than offset by price reductions of 3% versus the year-ago quarter. In addition, foreign exchange negatively impacted BRIC-MT revenue by 1% in the second quarter of 2013. Revenue from all emerging markets increased 4% operationally in the second quarter. If you exclude the portfolio of products whose rights would transfer to our joint venture in China with Hisun, we would have had operational revenue growth of 5% in our emerging markets business and 22% in China, and BRIC-MT operational revenue would have been flat compared with the year-ago quarter.

Operational, biopharmaceutical revenue growth from all emerging markets business is expected to accelerate in the second half of the year to a high single-digit percentage. However, we now expect full year operational revenue growth and our emerging markets business to be in the mid single digit percentage due continued slowing growth in some markets as pricing pressures continue to build and governments take additional steps to contain rising healthcare expenditures.

As we previously stated, because of the continued volatility in emerging markets, we anticipate our performance in that business to fluctuate from quarter-to-quarter.

Foreign exchange negatively impacted second quarter revenues by 3% or \$392 million, and had a net positive impact of 3% or \$228 million on the aggregate of adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses. As a result, foreign exchange negatively impacted second quarter adjusted diluted EPS by approximately \$0.02 compared with the year-ago quarter.

Now, moving on to our 2013 financial guidance, we are reaffirming all components of our full year 2013 adjusted financial guidance that we updated on June 24 to solely reflect the impact of the Zoetis exchange offer. I want to remind everyone that the weighted average shares outstanding used in the calculation of adjusted and reported diluted EPS reflects the net reduction of 405.1 million shares of Pfizer's outstanding common stock as a result of the exchange offer. Because the exchange offer was completed on June 24, we will recognize only a partial year benefit to our full year 2013 adjusted and reported diluted EPS.

As an additional reminder, when we completed the full disposition of Zoetis in June we announced that the expected impact of the removal of the full year 2013 financial contribution of Zoetis and the impact of the partial year benefit from the net reduction in shares of our outstanding common stock due to the exchange offer would result in a \$0.04 decrease to the upper and lower ends of our projected range for 2013, adjusted diluted EPS.

Today, we've also updated our 2013 reported diluted EPS guidance range of \$3.07 to \$3.22 to reflect the gain associated with the full disposition of Zoetis, and income from the previously mentioned litigation settlement.

Now moving on to key takeaways. Second quarter results reflect the loss of exclusivity of certain products in various geographies as well as the continued volatility in emerging markets.

As I previously mentioned, we expect high single-digit operational revenue growth in emerging markets during the second half of 2013, and now expect mid single-digit growth for the full year.

We continue to mitigate the earnings impact of product LOEs with both expense discipline and share repurchases. We completed the full disposition of Zoletis during the second quarter, and we accepted 405.1 million shares of Pfizer common stock in exchange for our remaining interest in Zoetis.

We continue to expect the transaction to be accretive to reported and adjusted diluted EPS on a full year basis in 2014. We are reaffirming all components of our 2013 adjusted financial guidance, we remain excited about the potential of our new product launches in mid-to-late stage pipeline. We've announced our intention to implement the new commercial structure beginning in fiscal 2014, which we except will better position Pfizer in long term success, and we continue to create shareholder value through prudent capital allocation.

In the second quarter, we repurchased approximately \$3.3 billion of our common stock. To date in 2013, we have repurchased approximately 8.7 billion or approximately 309 million shares and have \$13.1 billion remaining under our current authorization. And we continue to expect the repurchase in the mid teens of billions of dollars of our common stock this year, despite the blackout period for share repurchases during and for 10 business days after the Zoetis exchange offer period. Finally, we remain committed to delivering attractive shareholder returns in 2013 and beyond.

Now, I'll turn it back to Chuck.

Charles E. Triano

Thanks Frank and Ian for the update. Operator, can we please now pull for questions.

Question-and-Answer Session

Operator

Your first question comes from the line of Chris Schott from JPMorgan.

Chris T. Schott - JPMorgan Securities LLC

Thanks very much for the questions. The first one was on the corporate structure. Can you just elaborate a little bit on why three divisions here as compared to simply the innovative and value core franchises you've discussed in the past. I guess is there – I know you're talked about the – is there a scenario where Pfizer could break itself into three companies at some point in the future.

And then my second question was – and just so I am clear can you elaborate a little bit more on what type of P&L granularity we should be anticipating in 2014 and then maybe even looking forward to 2015 for this three operating divisions? Thank you.

Ian C. Read

Thank you, Chris. So, why the three rather than two. Well, I think it basically is very strong operational reasons that the innovative business under Geno has a collection of large disease areas that cut across both the primary care and specialty and they have challenges both capital allocation and of the go-to-market model as we look to be more efficient in how we deliver the message and how we get to see primary care physicians. Whereas the oncology business and the vaccine business have a very distinct culture, they're smaller businesses that I wanted to make sure that you can get, didn't get assumed into a large primary care business. They have specific customers, they have dedicated search facilities and research focus and I thought it was very important for those business to maintain their unique focus and extend it globally. So, that was the primary reason for maintaining or claim a structure where we had two innovative businesses.

On the details, I'll turn it over to Frank.

Frank A. D'Amelio

Yeah. So, Chris, on the P&L granularity for '14 and then as about beyond 2014. For 2014 fiscal year, we will show

revenue for each of the three businesses. We'll show direct cost and we'll show direct expenses and then what we'll do is on expenses that we don't allocate today that we don't allocate to come fiscal 2014, we'll provide some qualitative directional statement. So, that you will be able to model some good full stream P&Ls. Come fiscal 2015, we'll provide that same information and then we'll provide some additional balance sheet information as well. So, that's kind of the rhythm of how we're thinking about this.

Charles E. Triano

Thanks Frank. Next question please.

Operator

Your next question comes from Gregg Gilbert from Bank of America-Merrill Lynch.

Gregg Gilbert - Bank of America-Merrill Lynch

Sure. On the separation, was curious, as you internally separate these businesses, are you considering any changes that could affect the overall tax structure at Pfizer? Then on Palbo, I've a couple of questions. By when will you know that you might not have data in time for San Antonio? I assume it's some time before the actual start of that conference. So, let us know if there's a key date there. And Lilly has a program that's much earlier in that class, but they talk about the ability of their product to be dosed continuously. Any comments on that subject of continuous dosing versus otherwise? Thanks.

Ian C. Read

Great, thank you. I will ask Frank to comment on the tax issue.

Frank A. D'Amelio

So in terms of the tax structure, the creation of these three businesses in and up themselves does not impact in any material way the tax structure, but we are always doing tax planning to see what we can do to be more efficient from a tax perspective.

Ian C. Read

And if, Geno could you respond to the questions on Palbo?

Geno Germano

Yeah, I mean, with regard to the timing on Palbo, we're continuing to accumulate events, and based on the rate of accumulation that we're seeing at this point, we think it's unlikely that we'll be presenting data at San Antonio. So, I don't have a specific date to give you, but I think our best view at this point is, it's unlikely that we'll present at San Antonio. We still expect to accumulate the required events around the end of the year, but unlikely we'll meet the San Antonio date. And then with regard to continuous dosing, I'm really not sure and familiar with the Lilly program. So, I can't really comment on that.

Charles E. Triano

Thanks, Geno. Next question please?

Operator: Your next question comes from Tim Anderson from Sanford Bernstein.

Tim Anderson - Sanford C. Bernstein & Co. LLC

Thank you. A couple of questions on the split up. Can you give us a very rough preliminary idea of how operating margins might compare across those different businesses, could establish products had the highest margins because those products seem to kick off a lot of cash and don't require a lot of support even directional guidance on this sort of thing would very helpful because that's what folks, I think, are going to be interested in as we head into 2014?

And then separately you've talked about meeting three-years of audited financials before you could potentially truly split up the Company if that's what you're ultimately destined to do. There's been some speculation that perhaps you could use historic data for this three-year requirement, which means you wouldn't have to wait until 2017 or so until we really carve it up. Is this a possibility, should we really think of 2017 as being the earliest you could really split things

Ian C. Read

Well, I'll ask Frank to answer the margin issue the best he can and also your hypothetical question on data needed to split.

Frank A. D'Amelio

Sure. So, let me answer the second question first, which is on data requirements. If we were ever to decide to do something external to the Company, obviously we haven't decided anything yet, and which is, it requires three-years of audited financials and our current thinking is those would be prospective. And the thought of trying to retrospectively create those, when we look at everything that we need to be done is, would be extremely difficult. So, the current thinking is clearly that those will be prospective in terms of the three-years of audited financials. So, that's how I'd answer the second question.

On the first question on operating margins, the way I think about this is we're going to provide 2014 guidance. We're going to stop providing more granularity relative to these three businesses. So, Tim for the time being I really don't want to start projecting the margins on those businesses until we start showing them from 2014 and that will give lots more clarity when that time comes.

Ian C. Read

Thanks Frank.

Charles E. Triano

Next question please, operator.

Operator

The next question comes from Jami Rubin from Goldman Sachs.

Jami Rubin - Goldman Sachs & Co.

Thank you. Just to follow-up on that last question. Frank is there a difference in SEC requirements for a spin versus a split. And then a question for you Ian on M&A, you've done an amazing job returning cash to shareholders, which we've all strongly applauded. But you also say that with respect to M&A that you would always use share buybacks as the case to be, but with your stock at a 12 to 13 multiple there really is no case to beat relative to a share buyback. So I am wondering, how you are thinking about M&A going forward especially as it relates to the potential to split the Company into multiple parts that might require more growth drivers or M&A activity? Thanks.

Frank A. D'Amelio

Thank you. So, on the BD issues we look at BD not as a strategy but as a way of creating shareholder value and strengthening cost of our franchises or portfolio. We always try to analyze it sort of in the light of new capabilities or strengthening capabilities we already had. We've tended to talk in terms of bolt-ons and you'd have to think that bolt-ons would be you'd easily consider single-digit in billions of bolt-ons for this company. And we've also said, we'll look at any type of acquisition, never say never to larger acquisitions that made sense.

Regarding when would we consider our share price to be at a level that BD would be more effective. Well, you know, it depends on what deal we are looking at in BD, how it's priced and where our expectations are of our multiple is going in the next two to three years. So, I don't know I can answer that in a hypothetical way, but more in a look at each case by case. We look at each deal. We're active in looking at deals. We can pair to what we think the value of buybacks are and we take the decisions on a deal by deal basis. Do you want to add anything to that, Frank?

Frank A. D'Amelio

Yeah, let me just add quickly to that and then I'll answer the question about split versus spin which, and Jamie when we look at deals remember in terms of the case to [BP] in buybacks, it's also over what timeframe. So, is it year one, is it year two and then, well, how do we feel about the certainty of being able to achieve those EPS projections based on assumptions on synergies and the like. So, in my mind to lan's point, it's deal by deal situational and then over

what timeframe do we see that being, I'll call it, accretive relative to the buybacks. And then the terms of the split versus the spin question and is there any difference in required financials, the answer is no. Both scenarios require three years of audited financials.

Jami Rubin - Goldman Sachs & Co.

Thanks, Frank.

Charles E. Triano

Operator, can we move to the next question please?

Operator

Your next question comes from Mark Schoenebaum from ISI Group.

Mark Schoenebaum - ISI Group

Hey guys. Excuse me. Thank you very much for taking the questions. Maybe I can build on Jamie's question around use of cash, I think in the past I've heard you say things like your priorities for cancer vaccines and also general practitioner drugs, I wondered if you could clarify or confirm that and when you say, you never say never do a larger deal, maybe you could just expand on that, is that just a theoretical statement or is that something that we should be thinking about as possible move for Pfizer? And then, under the new structure, have you decided will BD be centralized or each unit have independent BD M&A functions within them? And then, maybe just quick R&D if I can, do you expect the NGF antibody to return to clinical development? Thank you

Ian C. Read

Okay, so, you asked about BD by segment. Clearly, BD that builds on a capability, it allows you to synergize your expense space, is how easy they get done than BD when you're going to a totally new space.

So, while we look at any good intellectual property that we could bring to patients and use our capabilities to bring to patients, they're easy to get done, if you've got some inherent synergies. On a big deal, all I would say is, look we're focused on creating value for shareholders and you do the analysis and you look at the risk and you look at the uncertainties and you make your decisions as you go forward. We've been up-till-date primarily focused on bolt-ons.

Frank, do you want to talk about the BD? Certainly, I would say, part of the rationale for creating these goal businesses is that, I now feel I can have management teams tasked on creating both organic and inorganic growth, and they're obviously going to have close ties and working with our BD organization. Frank, do you want to add to that?

Frank A. D'Amelio

Sure. On the BD org structure question, the way we approach this is, the BD resources are centralized, however there's matrix from a client support perspective. So, when you look at any of the businesses, they'll have folks that are dedicated to them, that literally from a business perspective are on their team. Who they report to, from my perspective, is irrelevant. We matrix, this in such a way that their reporting is transparent. They're living with those folks. They're collocated with those folks. They're working with those folks on a dedicated day-to-day basis. That's how we do it, quite frankly for just about all of our enabling functions.

Ian C. Read

John you want to add something?

John Young

Yeah, thanks for the question about tanezumab, which is our NGF antibody. Just sort of a quick update on that, on the 19 of July this year, we actually received notification from the FDA that the partial clinical hold for tanezumab has been lifted. You may know that the partial clinical hold have been placed on the development of all the NGF inhibitors back in December 2012 based on observation and some animal tox studies conducting in NGF inhibitors in development through other manufacturers.

So, there partial clinical hold was lifted on a commitment by Pfizer to submit non-clinical data before initiating dosing

in clinical trials and thereafter limiting dosing duration until the additional non-clinical data has been submitted and reviewed by the FDA. So, those record at non-clinical data studies have already been started and with the lifting of the partial clinical hold and on the assumption of a positive review of the non-clinical data by the FDA, we're preparing for resumption of Phase III clinical studies in 2014.

Charles E. Triano

Thanks John. Next question please.

Operator

Your next question comes from Alex Arfaei from BMO Capital Markets.

Alex Arfaei - BMO Capital Markets

Good morning and thank you for taking the questions. First on the R&D and perhaps M&A's front, either for Ian or Geno. Could you comment on the extent to which cancer immunotherapy is a priority for you? And then, for Frank, you've obviously returned a lot of cash to shareholders in terms of buybacks, but any thoughts on the dividend increase, given your relatively low payout ratio? Thank you.

Ian C. Read

Mike, do you want to take the R&D question?

Mikael Dolsten

So, we have a broad effort in quality in immunology and we certainly have interest also in the cancer immunology area. On one hand we some vaccines in the cancer immunology area that are starting to move into pre-clinical development, but we also have some monoclonal antibodies. Let me mention the 4-1BB or CD137 checkpoint activating antibody that we now have in Phase 1 study in hematological and solid tumors and are following with quite some interest that are antibody and other assets.

Ian C. Read

Thank you, Mikael. Frank, do you want to ...?

Frank A. D'Amelio

Dividend?

Ian C. Read

Dividend.

Frank A. D'Amelio

Sure. So let me just run the numbers on the dividend and then I'll answer the question which is when we announced the Wyeth acquisition back in 2009, we cut the dividend in half, from \$1.28 to \$0.64. Since then we've increased the dividend 2009 to 2010, 2010 to 2011, 2011 to 2012, 2012 to 2013 from \$0.64 to \$0.72 to \$0.80 to \$0.88 to \$0.96. 12.5%, 11%, 10% and 9% dividend increases over the last four years.

Our cadence is always at our December Board meeting. We typically – Ian and I make a recommendation to the Board relative to what we expect or what we want the dividend to be for the following year. Once the Board approves that we come out with a release to let everyone know what the new dividend will be. That's what we are expecting to do this year.

And then in terms of just absolute dollar amounts, at the current dividend level we'll be paying more than \$6 billion in cash to our shareholders this year.

So big number and you mentioned the payout ratio, if you use the mid-point of our guidance and then use the \$0.96 you get about 45% which is roughly in line with the industry, maybe a couple of points below. But we've been closing that gap over the last couple of years with our increases.

Ian C. Read

Thank you, Frank.

Charles E. Triano

Our next question please.

Operator

Your next question comes from Marc Goodman from UBS.

Marc Goodman - UBS Securities LLC

First is PCSK9 the subcu I think we are supposed to hear about that in mid-year, just wondering an update there. Second on Xeljanz I know you are working on a once daily version I was curious if you could update us there. And then there were a couple of products in the U.S. that were very strong, Lyrica and Celebrex, were their stocking that drove out or can you help us there? Thanks.

Ian C. Read

Okay, Mikael do you want to talk about PCSK9 results and then Geno will talk about Xeljanz and John on Lyrica and Celebrex.

Mikael Dolsten

Yeah, so, thank you for the interest in PCSK9. We do believe there will be a limited number of entrants in this new drug class. We think it has potential to be a very important drug class with substantial, clinical and commercial potential. Key here will be to over time demonstrate important to see the outcome value for the patients, physicians and payors.

Our own antibody is now fully enrolled in Phase IIb and we'll soon complete that study. We have seen interim results showing potent antibody with a competitive profile, and we will assemble all the data from the Phase IIb and look at opportunity for subcutaneous delivery at various time intervals and make a decision at end of this year about the next step forward.

Geno Germano

Thank you Mikael. With regard to the XELJANZ once-a-day program, we do have a delayed release formulation that we're moving forward with. We've had dialogue with the FDA on the development plan and we have determined that the registration package will be comprised primarily of pharmacokinetic data, PK data without a requirement for a clinical Phase 3 trial, which will accelerate the development of that program. So, we expect to be filing by early 2015.

John Young

Mark, with regard to your question about the operational performance of Lyrica and Celebrex, essentially both products have seen strong operational growth in the quarter and year-to-date. We haven't seen any effect of stocking or changes in inventory levels in the marketplace. In fact, those have been very steady, and really the performance that you're seeing is really just a reflection of the combination of both price and volume in the U.S. and a value proposition that continues to resonate very well with physicians.

Charles E. Triano

Thanks, John. Next question please?

Operator

Your next question comes from David Risinger from Morgan Stanley.

David Risinger - Morgan Stanley & Co. LLC

Yes, thanks very much. I have three questions on the new business structure and then a pipeline question. So, first, is it dilutive to create three business units and build the matrix, and enabling functions? Second, could you discuss

breaking up the sales forces in emerging markets and implying them to the new segments? And then third, regarding the three years of audited financials, I'm assuming that's to affect tax free exits, but would you consider divesting one of the units, for example, established products before you have three years of audited financials or is that just not realistic given the necessity to ensure tax-free transactions. And then for Mikael, could you just tell us what the key pipeline disclosures are to watch through year-end including whether you're going to provide any updates on your Breakthrough Therapy discussions with the FDA on Palbociclib. Thank you.

Ian C. Read

So, we don't believe this new structure will be dilutive to our present structure. In fact, we assume that there will be some modest savings, as we go to that structure. You have to remember, we already have in the developed markets, we already have a primary care, a specialty care vaccines and oncology business and then we have an emerging markets business in the rest of the world and we are effectively collapsing most of the primary care and specialty business into one BU. So, we do not believe that those standing up to those BUs are going to be dilutive.

On the field force in the emerging markets, it really depends country by country, but if you take a country like China, the vast majority of the field force will fit in the value business and we will have internal service agreements to provide field force support for the innovative products. I do not see that at all as an operational issue it's something we've been doing for quite some time is sharing field forces between BUs.

I'd ask Frank to talk about the three-years and the possibility of divestiture prior

to that and then we'll go to Mikael.

Frank A. D'Amelio

So, on the tax-free question that you asked, Dave, way I've been, I think about this is tax is aside, we'll need to follow – if we would ever do anything externally, we haven't decided, we would need to follow registration statement, those registration statements require three years of audited financials, so that's the way I think about that.

In terms of something prior to three-years of audited financials, now our current thinking is this is all about getting these three businesses to hum internally, top rates with excellence inside the Company and our current thinking is all around three-years of prospective financials that would be auditable.

Mikael Dolsten

So, David thank you for your interest in our pipeline and I'm very excited about the pipeline both short-term and over the next couple of years. With the focus on this year, we already touched upon our phase 2b PCSK9 that will get data readout in – during this second half of the year.

Fairly as Ian has touched upon the two trials that we'll have a read out this year that will give us some first insights, how Xeljanz is performing this new indication. We also have I would like to say in psoriasis a topical study that now is running which I think is a very interesting further exploration of Tofacitinib. You heard about Prevnar in adult that we are expecting to complete during the later part of this year.

Within the vaccines franchise we are also now in the finalization of our reports from staphylococcus aureus PUC trials that we will share during the latter part of this year. I'm very encouraged by the profile I have seen so far, when it comes to this unique technology that we are deploying for a very broad immune response to stop aureus. In oncology, we have the two dacomitinib trials for second third line and third line or fourth line that we expect to have data this year that we'll be probably shared early next year. And you have heard earlier Geno's comment on Palbociclib that we expect to have the final pieces of the data coming together this year, and we have previously had very good dialogs with FDA on the breakthrough designation. So, we expect to continue a very close dialog and our guidance how to best use those data to the benefit of patients. And on top of that in Phase II, let me just point to couple of intriguing areas.

We have a best-in-class IL6 antibody and very long-acting antibody with a good potency and we expect read outs this fall in Lupus and late next year in Crohn's. We have a read out in COPD related to a piece of data inhibitor. We have our second biosimilar that have a readout this year Rituximab. We have earlier communicated positive data from our first biosimilar product Herceptin. And then, we're broadening our inflammation efforts to also involve the intersection of cardiovascular disease with a readout from a novel PDE5 inhibitor in chronic kidney disease. So, I do look forward to share with you the output from all of these studies in the next years to come.

Ian C. Read

Excellent. Thank you, Mikael. Good comment, our next question please?

Operator

Your next question comes from Tony Butler from Barclays Capital.

Tony Butler – Barclays Capital, Inc.

Thank you very much. Some brief questions on the new structure if I may, if we could back to the notion of business development, and if we use an example say in established products with your partnership with the Brazilian company Teuto, I believe there is an option to actually buy the entire company. So, the question is, is that a decision by John Young and his Group. They make a recommendation to you, Ian and Frank and the Board, how does that capital actually get allocated if that were to occur?

The second question is around R&D to the structures is 100 – this may seem silly, but is the 100% of the R&D allocated to these three structures and I say this because I might, if they were split apart one could argue if all are should go in one of the innovative areas versus one of the others or not at all could be less then?

And then, similarly in the established products group with respect to R&D allocation, I could actually argue under the Pfizer umbrella there is very little R&The, but yet I suspect they were standalone if you look at Teva and Mylan as examples, 6% of total, 6.8% of total revenue is actually R&D. So, I'm just trying to understand when we see this in January, Frank, how does it actually look, if you could provide some additional granularity? Thanks again.

Ian C. Read

On Teuto, what the global business units will do is they will be champions of projects and BD, but we need to maximize the use of BD across the Pfizer portfolio. So, the decision is taken at the corporate level and the BU leaders have to champion the deals.

On the R&D, clearly there are parts of R&D that are specific to the BUs and parts that are general infrastructure underneath it and I think we'll work through that as we go. I'll ask Frank to comment on that.

Frank A. D'Amelio

So Tony, let me provide a little more granularity and see if this is helpful, which is – so, before, when I talked about direct expenses to the new businesses, clearly the post-POC expenses that are in the business units today, would continue to be in the business units tomorrow. Then, if you look at, I'll call it the pre-POC spend that we have, that resides in Mikael's organization today, and what we call WRD, Worldwide Research and Development, that doesn't get allocated to the business units today.

We're looking at how best to guide you all relative to that spend, and that's the stuff that we're working our way through, and we'll work our way through that through the year and obviously give you guys updates as we go, but we are looking at how best to basically, how best to communicate that to you all, so that you can model this appropriately, kind of point one.

Then, you mentioned DP, and if I could give you a little bit more direction, the answer is, of course I can. If you look at the overall R&D spend, the value of business as a percentage of revenue will have a lower spend, and innovative cobusinesses as a percentage of revenue and once again, and how we best direct and guide you all for next year is some of the sub-ledger detail that we're working our way through.

Ian C. Read

And Tony, this is part of the, one of the benefits, I expect to get out of having global businesses with Presidents who are champions, so the R&D today that would probably go to establish a smaller type of R&D that is safety, registration, regulatory some of biosimilars, and then some work around special formulations and that type of work. John's role will be to look at that and as you say compare it to what he needs to do it to drive growth and look at competitors in our Q4 capital allocation is appropriate into his R&D and this is what the benefit you get out of this type of focus on businesses.

Charles E. Triano

Thanks Ian. Next question please?

Operator

Your next question comes from Steve Scala from Cowen.

Steve M. Scala - Cowen & Co. LLC

Thank you. First on Xeljanz, the CHMP is seeking longer term safety data or is there a potentially rare and/or serious issue that they are requiring clarification upon? Secondly, is CAPiTA's delay due to a lower than expected event rate or is it due to some other reason? And then thirdly on emerging markets, may we anticipate high-single digit growth will return in 2014 and beyond or is this a business where mid-single digit growth is more likely? Thank you.

Ian C. Read

Geno?

Geno Germano

Yeah, Steve, so, with regard to CHMP and XELJANZ, obviously we're somewhat disappointed at the outcome following what was really a positive scientific advisory group meeting and a positive view from the rapporteurs this time around. Ultimately CHMP members, at least some of the CHMP members, a small majority wanted to see additional safety data and in particular wanted to understand kind of the full profile of Tofacitinib with a new mechanism of action relative to other agents that are used in this patient population. So it's not entirely clear whether we're looking for longer term data or a larger database.

As you know, we continue to collect safety data. We have long term extension trials. We have registries. We have a post-marketing study that we are kicking off from the U.S. registration. So we have multiple ways and then of course we have psoriasis and psoriatic arthritis programs. We have a number of mechanisms to generate additional safety data and we'll obviously continue to do that. It's not entirely clear at that moment what we'll need to do achieve a registration. We do anticipate we'll need to do some additional clinical work, and as Ian mentioned before, we think this could require several years of delay in Europe. So that's the best way I can kind of characterize the situation there with the CHMP.

With regard to CAPiTA, it's difficult to predict what the event rate is going to be. It is going to depend on various dynamics like the severity of the flu seasons, the efficacy of the vaccine. So if it's a highly effective vaccine then the only cases that you're accumulating are cases in the placebo growth. So it's difficult to predict and we becoming very close to the target number of events and hope to be able to present more clarity in the very near future.

And On EM, we've always said that EM will be volatile. And we'll see swings in quarter-on-quarter and even year-to-year. I mean we'd all agree that secularly that's where we are seeing the vast majority of volume growth that's coming from in the foreseeable future as these economies continue to spend more on health care and the growth rate is going to fluctuate depending on how the volume is doing and what pricing pressures you are getting in the quarter. And so I would say it's really too early to tell or to reset expectations for where we think long-term growth in the emerging markets are going to go and we'll look at in our 2014 guidance. But overall we continue to be very bullish on the underlying demand for healthcare in emerging markets.

Charles E. Triano

Thanks Jim. Next question please, operator.

Operator

Your next question comes from Andrew Baum from Citi.

Andrew Baum - Citi

Yeah good afternoon. Couple of questions, first on the immunotherapy assays, you mentioned Mikael the CD137, when do we get the first read out in NHL is that next year? And then, same topic, before you divested Tremelimumab to Astra you obtained some rights, perhaps you could outline what invitation you have retained?

And then separately for Ian, one of your competitors is having very visible issues in China, to what extent do you think that the ongoing investigations over fraud are going to impact pricing or demand in that market?

Ian C. Read

Okay, Mikael.

Mikael Dolsten

We're now running the Phase Ib studies here with our 4-1BB. We think we'll have a real interest in antibody and we have seen some encouraging early signs of activity here. I would expect as we finalized the Phase I studies here we will use conventional on-quality conferences to report outcome. We also have behind it a couple of other antibodies, such as OX40 and [Gitter].

So you should see it as second wave of checkpoint inhibitors trying to benefit from the early anti-cells around the PD-1 space but building on that and bringing the field further on.

Tremelimumab, we did retain particularly rights to use it for vaccines, and I shared with you some anti-cells about our cancer vaccine platform, and I can inform you that it do include Tremelimumab as one of the options for adjuvant effect on cancer vaccine. So, that was a really good way for us to plan, when we did that retention.

Ian C. Read

Thank you. And on China, I can't really comment on individual cases. I would say what we've seen in China is that clearly as government, focusses in spending more on healthcare. They clearly want to be good buyers of value of pharmaceuticals, so we'd expect to continue to have robust conversations and debates with them as we go forward, as to the value of the innovation we bring. I think you'll continue to see as they've been doing, they do price reviews of segments of the market and they reset prices and normally, volume responds to different price points. So I think that will continue in China, as we go forward.

Charles E. Triano

Thanks you Ian. Moving on, next question please.

Operator

Your next question comes from Seamus Fernandez from Leerink.

Seamus Fernandez - Leerink Swann, LLC

Thanks very much. Just a couple of questions here. First, can you talk a little bit about how you are going to be thinking about cost of goods and some of the overlapping dynamics there, is this a situation where Pfizer might consider a co-bottling or [Lonza] type structure over time, should the units be split out or how is that going to operate as we think about it?

Separately, can you also talk a little bit about Europe and infrastructure there, relative to the overall industry's profitability, one of your competitors commented on that and I think that might be particularly relevant as perhaps particularly relevant for Geno's business unit?

And then finally, as it relates to the emerging markets, Ian you mentioned specifically that you see the emerging markets – some of the larger emerging markets starting to operate more similarly to the developed markets. Can you just give us a little bit of a better sense in what regard that is, is it on distribution, reimbursement what is it specifically and are we talking about more similar to the U.S. or more similar to Europe?

Ian C. Read

Thank you. So on the cost of goods, about in terms of absorption, 50% of our plans are absorbed through the value business and 50% are absorbed through the innovative business. There are a limited number of plans that are specific to one business or the other. So I would expect that internally simply a cross supply issue between the plans and if there was anything ever externally done, I think this is easily handled by supply agreements. Today Pfizer purchases about 30% of its requirements from external suppliers. So, this is easily handled in the ordinary course of business.

The next question was Europe and infrastructure, look the pricing squeeze that Europe has applied to the industry over

the last few years, which has accelerated from low-single digits to mid-single digits is, of course, pushing companies to look at what their infrastructure is, how they deliver the educational messages decisions and their investment in general, part of our restructuring into the innovative one, innovative two and the value business, a response of that in the set we effectively are merging our primary care and our specialty BU into one. So, I expect in Europe, you'll continue to see pharmaceutical companies look for more cost efficient ways to deliver their message, to physicians.

And on the EM issue, I think if you look at Turkey, you can see Turkey has gone to a full reimbursement model, more like Europe, this out of pocket has now become less important in Turkey. The government is more influential, so they tend to be more dominant in the way they make acquisitions of pharmaceuticals and their pricing requests.

In sophistication, I talk really about the way the markets have been regulated in terms of compliance, in terms of the rules that are similar in Europe and the U.S., so I just see these markets evolving and also you're beginning to see more commonality and the requirements, they ask for registration, and that's really the sense of my comment about their evolving to looking more like mature markets.

Charles E. Triano

Thanks, Ian. And Operator, if we could please take our last question?

Operator

Your final question comes from Damien Conover from Morningstar.

Damien Conover – Morningstar Research

Great. Thanks for taking the question. Just had a question on the restructuring. Wanted to see how products would flow from the innovative pieces to the value piece post-2014, and whether or not there'd be any precedent set up for any sort of transfer of value that could be used if the entity is actually fully separated. And then second question on the break up was just a question on the consumer health business, and if I remember correctly, one of the driving reasons to have that business within the Pfizer umbrella is to help with any sort of RX to OTC switches and given that it's going in the vaccine and oncology bucket, I still wanted to know if that RX to OTC switch was still a major driving force behind that business underneath the Pfizer umbrella? Thank you.

Ian C. Read

Thank you, Damien. So, I think the movement of products between the businesses will continue as they have been in the last three years as products that are innovative one, [go whether] we will move them over to the value business and they'll be managed that way. Any hypothetical situation where there was – the two businesses weren't in the same corporate shell, then you would make your decisions based on what's the best way to continue to commercialize those products at a later date, but that's really very early to speculate on. And then, Amy, would you like to take the consumer.

Amy W. Schulman

With respect to the Type 1 that we have for RX to OTC switches, we continue to see feel very comfortable with the pipeline. It's robust and assuming regulatory approval we'll proceed with the [DEXIN] launch in 2014 and then we have a number of other promising molecules in the pipeline, some of which we talked about previously.

Damien Conover

Great. Thank you.

Ian C. Read

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

Charles E. Triano

Thank you.

Operator

Ladies and gentlemen, this does conclude the Pfizer's second quarter 2013 earnings conference call. Thank you for

participating. You may now disconnect.

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