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PFE - Q2 2013 Pfizer Earnings Conference Call

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OVERVIEW:

PFE reported 2Q13 revenue of approx. \$13b and reported diluted EPS of \$1.98.
Expects 2013 reported diluted EPS to be \$3.07-3.22.



CORPORATE PARTICIPANTS

Chuck Triano *Pfizer Inc - SVP - IR*

Ian Read *Pfizer Inc - Chairman, CEO*

Frank D'Amelio *Pfizer Inc - CFO*

Geno Germano *Pfizer Inc - President & GM, Specialty Care and Oncology*

John Young *Pfizer Inc - President, GM - Primary Care*

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

Amy Schulman *Pfizer Inc - General Counsel and Business Unit Lead Consumer Business*

CONFERENCE CALL PARTICIPANTS

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Greg Gilbert *BofA Merrill Lynch - Analyst*

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

Jami Rubin *Goldman Sachs - Analyst*

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PRESENTATION

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.

Chuck Triano - *Pfizer Inc - SVP - IR*

Good morning and thank you for joining us today to review Pfizer's second quarter 2013 performance. I'm 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 slides that will be presented on this call can be viewed on our homepage at Pfizer.com by clicking on the link for Pfizer Quarterly Corporate Performance Second Quarter 2013 which is located in the Investor Presentation 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. Reconciliations 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 disposition 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 Read - Pfizer Inc - Chairman, CEO

Thank you, Chuck. I'll begin with some comments on the quarter. We saw solid operational revenue growth in a number of areas. Within our innovative business, Oncology grew 28% driven by the uptake 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 US, 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 our partnership with Hisun.

We continue to expect that the second half of this year will be stronger than the first half for Emerging Markets, although on a full-year basis we now expect to see operational revenue growth of mid-single-digits rather than high-single-digits. This is mainly due to a slowdown in growth in Brazil and Russia and the impact of cost containment measures in Colombia, Poland, Thailand and Turkey. We completed the full separation of Zoetis into a stand-alone public company. The transactions related to the disposition of Zoetis generated approximately \$17.2 billion of after tax value for Pfizer shareholders. And our Board of Directors authorized a new \$10 billion share repurchase program to be utilized over time. This new program is in addition to the \$3.1 billion of authorization remaining under the Company's current share repurchase program.

Turning to our products and pipeline assets, the launches of both Eliquis and Xeljanz continue to progress in various markets around the world. And we are gaining market approvals for both Xeljanz and Eliquis in additional countries. We are encouraged with the potential for both of these therapies over time.

For Eliquis, we are focused on gaining preferred formulary acceptance, continuing to obtain reimbursement and building physician knowledge and comfort about the drug and its profile. With its unique profile in atrial fibrillation, as the only product with superiority versus warfarin in stroke prevention, major bleeding and a proven mortality benefit, we are confident we'll continue to see steady growth that will build over time.

For Xeljanz, we're seeing good opportunities for patients who are switching from their current biologic therapy as well as patients who are initiating Xeljanz therapy in a second-line setting, that is, following methotrexate but before a biologic DMARD. In fact, almost 50% of our recent prescriptions are in a second-line setting with the remainder being patients who have been on one or more biologic DMARDs and not achieving satisfactory results.

In addition we began our direct-to-consumer campaign in the US early in June and have seen a subsequent uptick in prescription volume. Last month we announced that the FDA had accepted full review of supplementary new drug application to include progression of structural damage in the Xeljanz label. And as of today, Xeljanz will be commercially available in Japan where it will be co-promoted by Pfizer and Takeda Pharmaceutical Company Limited. Overall we remain encouraged by what we are seeing with physicians' and patients' experience 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 a new oral mechanism.

Turning to the status of Xeljanz in Europe, last week we announced that the Committee for Medicinal Products for Human Use in the EU confirmed their prior opinion for the marketing authorization application for Xeljanz, although with a much closer vote. Given the novel mechanism of action for 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 re-examination process, we addressed several of the questions and have more clarity on the



remaining ones. We plan to work with the 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' delay.

Regarding the Xeljanz phase 3 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 to announce 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 or efficacy when patients are withdrawn from and then re-treated 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 quarter of this year -- of next year, sorry.

For Prevnar, sales this quarter were adversely impacted in the US by the variability of CDC purchase patterns and a lower birth cohort in the US as well as the end of a supplementary dose program in Asia. Regarding CAPiTA, we continue to accumulate events and based on historic event rates, we expect to complete the study this year. Given the size of the study, which is approximately 85,000 patients, once a 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 will 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 are 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 Consume Healthcare. Each of these businesses will operate as a separate global business. Each has a different operating model with distinct specializations around science, talent and market approach.

The Value Products segment will be led by John Young. It will include the brands that have lost their exclusivity and generally the mature patent-protected products that are expected to lose exclusivity through 2015 in most markets. Some examples include Celebrex, Zyvox, Viagra outside of the US 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 and 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 move for us at this time. I have 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 are appointing Doug Lankler, currently our Chief Compliance and Risk Officer to be Pfizer's General Counsel. In addition, Rady 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 in the existing structure for the balance of 2013. All of the current leaders will continue in their roles for the remainder of this year.

Starting with the 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 a 2014 baseline management view of profit and loss for each segment. We anticipate providing additional financial detail as we move forward within the 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 of our innovative core and provide our Value business dedicated resources required to further strengthen and globally position it to be a market leader. Now I will turn it over to Frank to take you through the details for the quarter.

Frank D'Amelio - Pfizer Inc - CFO

Thanks, Ian. Good day, everyone. As always the charts I'm reviewing today are included in our webcast. 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 in 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 in developed Europe in the second quarter of 2012 and multi-sourced generic competition for Lipitor in the US beginning in late-May 2012. The decline in Pfizer's share of revenues per the terms of the co-promotion agreements for Spiriva, which are in the final year in the US, Australia, Canada and certain European countries, the timing of government purchases of Prevnar in various markets, and the transfer of certain product rights to our joint venture in China with Hisun in the 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. This was mainly driven by the pretax 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 Prevnar 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 were transferred 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 our 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 in our Emerging Markets business to be in the mid-single-digits percentage due to continued slowing growth in some markets as pricing pressures continue to build and governments take additional steps to contain rising health care expenditures. As we've 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 SG&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 24th 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 24th, 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 to \$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 take-aways. 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 Zoetis 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 our mid-to-late stage pipeline. We've announced our intention to implement the new commercial structure beginning in fiscal 2014 which we expect will better position Pfizer for 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 to 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.

Chuck Triano - *Pfizer Inc - SVP - IR*

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

QUESTIONS AND ANSWERS

Operator

Chris Schott, JPMorgan.

Chris Schott - *JPMorgan Chase & Co. - Analyst*

Thanks very much for the questions. The first one was on the corporate structure. Can you 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? Is there -- and there's just talking about, 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'm 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 these three operating divisions? Thank you.

Ian Read - *Pfizer Inc - Chairman, CEO*

Thank you, Chris. So why the three rather than two? 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 are smaller businesses that I want to make sure that you get -- didn't get subsumed into a larger Primary Care business. They have specific customers. They have dedicated research facilities and research focus. And I thought it was very important for those businesses to maintain their unique focus and extend it globally.

So that was the prime reason for maintaining or creating the structure where we had two Innovative businesses. On the details, I'll turn it over to Frank.

Frank D'Amelio - Pfizer Inc - CFO

Yes, so, Chris, on the P&L granularity, for 2014 and then you asked about beyond 2014. For 2014 fiscal year, we'll show revenue for each of the three businesses, we'll show direct costs and we'll show direct expenses. And then what we'll do is on the expenses that we don't allocate today, that we don't allocate come fiscal 2014, we'll provide some qualitative directional statements 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.

Chuck Triano - Pfizer Inc - SVP - IR

Thanks, Frank. Next question please.

Operator

Gregg Gilbert, Bank of America Merrill Lynch.

Greg Gilbert - BofA Merrill Lynch - Analyst

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?

And then on Palbo I have a couple questions. By when will you know that you might not have data in time for San Antonio? I assume it's sometime 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 Read - Pfizer Inc - Chairman, CEO

Great. Thank you. I'll ask Frank to comment on the tax issue.

Frank D'Amelio - Pfizer Inc - CFO

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



Ian Read - Pfizer Inc - Chairman, CEO

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

Geno Germano - Pfizer Inc - President & GM, Specialty Care and Oncology

Yes. 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.

Chuck Triano - Pfizer Inc - SVP - IR

Thanks, Geno. Next question please.

Operator

Tim Anderson, Sanford Bernstein.

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

Thank you. A couple 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 Established Products have the highest margins because those products tend to kick off a lot of cash and don't require a lot of support or even directional guidance on this sort of thing would be 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 needing three years of audited financials before you could potentially truly split up the Company if that's what you're ultimately decide 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 you really carve it up. Is this a possibility or should we really think of 2017 as being the earliest you could really split things up.

Ian Read - Pfizer Inc - Chairman, CEO

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

Frank D'Amelio - Pfizer Inc - CFO

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. And obviously we haven't decided anything yet, which is it requires three years of audited financials. And our current thinking is those would be prospective.

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 would 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 start 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 come 2014. And then we'll get lots more clarity when that time comes.

Chuck Triano - *Pfizer Inc - SVP - IR*

Thanks, Frank. Next question please, operator.

Operator

Jami Rubin, Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

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 only -- you would always view share buybacks as the case to beat, but with your stock at a 12 to 13 multiple, there really is no case to beat relative to a share buyback. So I'm wondering how you're 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.

Ian Read - *Pfizer Inc - Chairman, CEO*

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 parts of our franchises or portfolio. We've always tried to analyze it in the light of new capabilities or strengthening capabilities we already had. We've tended to talk in terms of bolt-ons. And you have to think that bolt-ons would be -- you'd easily consider single-digit in billions of bolt-on for this Company. And we've also said we'll look at any type of acquisition, never say never to larger acquisitions if it made sense.

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

Do you want to add anything to that, Frank?

Frank D'Amelio - *Pfizer Inc - CFO*

Yes, let me just add quickly to that and then I'll answer the question about split versus spin, which is -- and, Jami, when we look at deals, remember in terms of the case to beat being buybacks, it's also over what time frame? So is it year one? Is it year two?

And then 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, its 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 in 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.

Chuck Triano - Pfizer Inc - SVP - IR

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

Operator

Mark Schoenebaum, ISI Group.

Mark Schoenebaum - ISI Group - Analyst

Hi, guys. Excuse me. Thank you very much for taking the question. Maybe I can build on Jami's question around use of cash. I think in the past I've heard you say things like your priorities are cancer, vaccines and also general practitioner drugs.

I wondered if you could clarify or confirm that and when you say never say never to 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 a possible move for Pfizer?

And then under the new structure, will -- have you decided, will BD be centralized or will each unit have independent BD M&A functions within them? And maybe just a quick R&D if I can, do you expect the NGF antibody to return to clinical development? Thank you.

Ian Read - Pfizer Inc - Chairman, CEO

Okay. So you asked about BD in seg -- by segments. Clearly, BD that builds on a capability that allows you to synergize your expense base are easy to 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 risks, and you look at the uncertainties, and you make your decisions as you go forward. We've been up to date primarily focused on bolt-ons.

Frank, do you want to talk about BD? Certainly I would say part of the rationale for creating these global businesses is that you now -- 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. But, Frank, do you want to add to that?

Frank D'Amelio - Pfizer Inc - CFO

Sure. On the BD org structural question, the way we approach this is the BD resources are centralized. However, there is a matrix from a client support perspective. So when you look at any of the business 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 they're reporting is transparent. They're living with those folks, they're co-locating 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 Read - Pfizer Inc - Chairman, CEO

John, do you want to add something?



John Young - Pfizer Inc - President, GM - Primary Care

Yes, thanks for the question about tanezumab, which is our NGF antibody. Just a quick update. On the 19th 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 had been placed on the development of all the NGF inhibitors back in December 2012 based on observation and some animal tox studies conducted on NGF inhibitors in development through other manufacturers.

So the partial clinical hold was lifted on a commitment by Pfizer to submit nonclinical data before initiating dosing in clinical trials. And thereafter to limit any dosing duration until the additional nonclinical data has been submitted and reviewed by the FDA. So there was record that nonclinical data studies have already been started and with the lifting of the partial clinical hold, and on the assumption of positive review of the nonclinical data by the FDA, we're preparing for a resumption of phase 3 clinical studies in 2014.

Chuck Triano - Pfizer Inc - SVP - IR

Thanks, John. Next question please.

Operator

Alex Arfaei, BMO Capital Markets.

Alex Arfaei - BMO Capital Markets - Analyst

Good morning and thank you for taking the questions. First on the R&D and perhaps M&A 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 a dividend increase given your relatively low payout ratio? Thank you.

Ian Read - Pfizer Inc - Chairman, CEO

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

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

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

Ian Read - Pfizer Inc - Chairman, CEO

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

Frank D'Amelio - Pfizer Inc - CFO

Dividend?



Ian Read - Pfizer Inc - Chairman, CEO

Dividend.

Frank D'Amelio - Pfizer Inc - CFO

Sure. 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 decreases 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 look -- if you use the midpoint 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 Read - Pfizer Inc - Chairman, CEO

Thank you, Frank.

Chuck Triano - Pfizer Inc - SVP - IR

Next question, please.

Operator

Mark Goodman, UBS.

Marc Goodman - UBS - Analyst

Good morning. First is PCSK9, the subcutaneous, I think we're supposed to hear about that in mid-year, just wondering update there? Second on Xeljanz, I know you're working on a once-daily version. I was curious if you can update us there. And then there were a couple of products in the US that were very strong, Lyrica and Celebrex, was there stocking that drove that or can you help us there? Thanks.

Ian Read - Pfizer Inc - Chairman, CEO

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

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

Yes. Thank you for your 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 the important long term CV outcomes value for the patients, physicians and payers. Our own antibody is now fully enrolled in phase 2b 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 2b and look at the opportunity for subcutaneous delivery at various time intervals and make a decision at end of this year about the next step forward.

Ian Read - Pfizer Inc - Chairman, CEO

Thank you, Mikael.

Geno Germano - Pfizer Inc - President & GM, Specialty Care and Oncology

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 - Pfizer Inc - President, GM - Primary Care

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 US and the value proposition that continues to resonate very well with physicians.

Chuck Triano - Pfizer Inc - SVP - IR

Thanks, John. Our next question please.

Operator

David Risinger, Morgan Stanley.

David Risinger - Morgan Stanley - Analyst

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 applying 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 Read - Pfizer Inc - Chairman, CEO

Okay. 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, we are effectively collapsing most of the Primary Care and Specialty business into one BU, so we do not believe that is -- the collapsing of those BUs are going to be dilutive.

On the field force in Emerging Markets, it really depends country by country. But if you take a country like China, the vast majority of the sales force will sit 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 force between BUs.

I'd ask Frank to talk about the three years and the possibility by divestiture prior to that. And then we'll go to Mikael.

Frank D'Amelio - Pfizer Inc - CFO

Sure. So on the tax-free question that you asked, Dave, the way I think about this is, taxes aside, we'll need to file -- if we would ever do anything externally, we haven't decided, we would need to file a 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, our current thinking is this is all about getting these three businesses to hum internally, to operate with excellence inside the Company. And our current thinking is all around three years of prospective financials that would be auditable.

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

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 a focus on this year, we already touched upon our phase 2b in PCSK9 that we'll get data readout in -- during this second half of the year.

On Xeljanz psoriasis, Ian has touched upon the two trials that will have a readout this year that will give us some first insight 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 explanation of tofacitinib. You heard about Prevnar in adults that we are expecting, CAPiTA can complete during the later part of this year. Within the vaccines franchise, we are also now in the finalization of our report from Staphylococcus aureus, PoC trials that we will share during the later part of this year. I'm very encouraged by the profile I've seen so far when it comes to this unique technology that we are deploying for a very broad immune response to Staph aureus.

In Oncology, we have the two dacomitinib trials for a second, third line and third line and fourth line that we expect to have data this year that will be probably shared early next year.

And you heard earlier Geno's comment on palbociclib that we expect to have the final pieces of the data come together this year. And we have previously had very good dialogues with FDA on the breakthrough designation so we expect a continued very close dialogue and our guidance how to best use those data to the benefit of patients.

And on top of that, in phase 2, let me just point to a couple of intriguing areas. We have a best-in-class IL6 antibody, a very long-acting antibody with a good potency and we expect readouts this fall in Lupus and later next year in Crohn's. We have a readout in COPD related to a P38 inhibitor. We have our second biosimilar that have a readout this year, Rituximab. We have earlier communicated positive data from our first biosimilar product -- to Herceptin.

And then we are 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.



Chuck Triano - Pfizer Inc - SVP - IR

Excellent. Thank you, Mikael. Next question please.

Operator

Tony Butler, Barclays Capital.

Tony Butler - Barclays Capital - Analyst

Thank you very much. Some brief questions on the new structure if I may.

If we could go 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, that 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 100% of the R&D allocated to the three structures? And I say this because I might -- if they were split apart, one could argue if all of the R should go in one of the Innovative areas versus one of the others or not at all or could be less than.

And then similarly in the Established Products group with respect to R&D allocation, I could actually argue under the Pfizer umbrella there's very little R&D, but yet I suspect if it were stand-alone, if you look at Teva, Mylan as examples, 6% of total - 6 to 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 Read - Pfizer Inc - Chairman, CEO

So on Teuto, what the business -- global business units will do is they will be champions of projects in BD. Though 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. But I'll ask Frank to comment on that.

Frank D'Amelio - Pfizer Inc - CFO

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 stuff that we're working our way through and we'll work our way through that through the year and obviously give you guys update 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, point one.

And then you mentioned EP 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 business as a percentage of revenue will have a lower spend than Innovative co-businesses as a percentage of revenue. And once again, how we best derive -- direct and guide you for next year is some of the sub-ledger detail that we're working our way through.



Ian Read - Pfizer Inc - Chairman, CEO

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

Chuck Triano - Pfizer Inc - SVP - IR

Thanks, Ian. Next question, please.

Operator

Steve Scala, Cowen.

Steve Scala - Cowen and Company - Analyst

Thank you. First on Xeljanz, is the CHMP 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 Read - Pfizer Inc - Chairman, CEO

Geno?

Geno Germano - Pfizer Inc - President & GM, Specialty Care and Oncology

Yes, Steve, 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 -- or at least some of the CHMP members, a small majority wanted to see additional safety data. And in particular wanted to understand 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 registration trials, we have post-marketing studies that we are kicking off from the US registration. So we have multiple ways, and then of course we have the 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 the moment what we'll need to do to 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 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's 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



group so it is difficult to predict. And we are coming very close to the target number of events and hope to be able to present more clarity in the very near future.

Ian Read - Pfizer Inc - Chairman, CEO

And on EM, we've always said that EM is -- will be volatile. And we'll see swings quarter-on-quarter and even year-to-year. I think we'd all agree that secularly that that's where we're seeing the vast majority of volume growth is coming from in the foreseeable future as these economies continue to spend more on healthcare. And the growth rates are going to fluctuate depending on how the volume's doing and what pricing pressures you're getting in the quarter.

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 it in our 2014 guidance. But overall, we are -- we continue to be very bullish on the underlying demand for healthcare in Emerging Markets.

Chuck Triano - Pfizer Inc - SVP - IR

Thanks, Ian. Next question please, operator.

Operator

Andrew Baum, Citi.

Andrew Baum - Citigroup - Analyst

Good afternoon. Couple of questions. First on the immunotherapy assets, you mentioned, Mikael, the CD137. When do we get the first readout in NHL? Is that next year?

And then same topic, before you divested tremelimumab to Astra you maintained some rights. Perhaps you could outline what indications 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 Read - Pfizer Inc - Chairman, CEO

Okay. Mikael?

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

Yes. So we just now running the phase 1b studies here with our 4-1BB. We think we have a really interesting antibody and we've seen some encouraging early signs of activity here. I would expect as we finalize the phase 1 studies here, we will use conventional oncology conferences to report outcome.

We also have behind it a couple of other antibodies such as OX 40 and GITR. So you should see it as a second wave of checkpoint inhibitors trying to benefit from the early enthusiasm around the PD1 space, but building on that and bringing the field further on.



Tremelimumab, we did retain particularly the rights to use it for vaccines. And I shared with you some enthusiasm about our cancer vaccines platform. And I can inform you that you 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 Read - Pfizer Inc - Chairman, CEO

Thank you. And on China I can't really comment on individual cases. I would say what we've seen in China is that as the government focuses 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 have 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.

Chuck Triano - Pfizer Inc - SVP - IR

Thank you, Ian. Moving along, next question please.

Operator

Seamus Fernandez, Leerink.

Seamus Fernandez - Leerink Swann & Company - Analyst

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 Coke Bottling or a 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 in distribution, reimbursements, what is it specifically?

And are we talking about more similar to the US or more similar to Europe? Thanks.

Ian Read - Pfizer Inc - Chairman, CEO

Thank you. So on the cost of goods, about in terms of absorption, 50% of our plants are absorbed through the Value business and 50% are absorbed through the Innovative business. There are a limited number of clients that are specific to one business or the other. So I would expect that internally, it is simply a cross-supply issue between the plants. 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 on -- 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 to the decision makers and their investment in general. Part of our restructuring into the Innovative one, Innovative



two and the Value business are response to that in a sense that 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 it, Turkey, you can see Turkey has gone to a full reimbursement model more like Europe. There's very -- 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 for pharmaceuticals and their pricing requests. In summary, I talked really about the way the markets have been internally regulated in terms of compliance, in terms of the rules that are similar in Europe and the US.

So I just see these markets evolving, and also you're beginning to see more commonality in the requirements they ask for registration. And that's really the sense in my comment about they're evolving to looking more like mature markets.

Chuck Triano - *Pfizer Inc - SVP - IR*

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

Operator

Damien Conover, MorningStar.

Damien Conover - *Morningstar - Analyst*

Great. Thanks for taking the questions. 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 would be any precedent set up for any sort of transfer of Value that could be used if the entities actually fully separated?

And then second question on the breakup was just had 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, was still wanted to know if that Rx to OTC switch was still a major driving force behind that business thing underneath the Pfizer umbrella? Thank you.

Ian Read - *Pfizer Inc - Chairman, CEO*

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 LOE, we'll move them over to the Value business. And they'll be managed that way.

In 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 the, Amy, would you like to take the Consumer?

Amy Schulman - *Pfizer Inc - General Counsel and Business Unit Lead Consumer Business*

Sure. With respect to the pipeline that we have for Rx to OTC switches, we continue to feel very comfortable with the pipeline. It's robust and assuming regulatory approval, we will proceed with the Nexium launch in 2014. And then we have a number of other promising molecules in the pipeline, some of which we've talked about previously.



Chuck Triano - Pfizer Inc - SVP - IR

Great.

Ian Read - Pfizer Inc - Chairman, CEO

Thank you, Amy.

Chuck Triano - Pfizer Inc - SVP - IR

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

Ian Read - Pfizer Inc - Chairman, CEO

Thank you.

Operator

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

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