OVERVIEW:
Management discussed 2Q12 results, reporting adjusted diluted EPS of $0.62 on revenues of $15.1b. Management reaffirmed all components of 2012 financial guidance provided on 1Q12 call.
Good day, everyone, and welcome to Pfizer’s second-quarter 2012 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
Thank you, Operator. Good morning and thank you for joining us today to review Pfizer’s second-quarter 2012 performance. I’m joined today 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 & Development; Geno Germano, President and General Manager of Specialty Care and Oncology; Amy Schulman, General Counsel, President and General Manager of Pfizer Nutrition; and John Young, President and General Manager of Primary Care. The slides that will be presented on this call can be viewed on our home page at www.pfizer.com by clicking on the link for Pfizer Quarterly Corporate Performance Second Quarter 2012 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 conference 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 2011 annual report on Form 10-K and in our reports on Forms 10-Q and 8-K.

The discussions during this call will 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 31, 2012.

In addition, we will offer some brief comments regarding our preparation and target time line for the potential initial public offering of a minority stake in our Animal Health business, Zoetis. As I am sure you will understand, we are not going to be able to respond to questions on that subject in light of the quiet period imposed by the Securities laws. With that, I’ll now turn the call over to Ian Read. Ian?

### Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Chuck. During my remarks this morning, I will briefly discuss the quarter and provide some context concerning recent late-stage pipeline developments. Beginning with the quarter, our performance was solid. Noteworthy highlights include solid revenue and margin performance compared to the year-ago quarter, despite the negative revenue impact of $1.8 billion resulting primarily from the losses of exclusivity of Lipitor in most major markets as well as Caduet, Xalatan and Geodon in the US.

We had strong performance in Emerging Markets with 14% operational growth quarter over quarter driven by volume growth mainly in key markets such as China and Russia, as well as the timing of government purchase of Prevenar 13 in Turkey and Enbrel in Brazil. Of particular note, China grew 36% operationally, driven in large part by the targeted investments we have made in our Chinese -- our China sales force and the strength of our cardiovascular portfolio in China. We had greater expense discipline resulting from our ongoing efforts to streamline operations and focus R&D programs. Quarter over quarter, adjusted SI&A expenses decreased 16% operationally and adjusted R&D expenses decreased 18%.

The Animal Health and Consumer Healthcare businesses achieved good operational performance quarter over quarter. Animal Health grew 7% and our Consumer Healthcare grew 11% driven primarily by the addition of products from the recent acquisition of Ferrosan and Alacer Corp. And we are continuing to create value for shareholders through share repurchases. During the quarter, we repurchased $1.3 billion of common stock and have purchased about $3 billion since the beginning of this year. On a full year basis, we expect to repurchase approximately $5 billion of common stock.

Regarding Animal Health, we anticipate filing a registration statement with the Securities and Exchange Commission by mid-August for a potential initial public offering of up to 20% ownership stake in the business to be named Zoetis. We are targeting completion of the IPO in the first half of 2013. As we continue to work towards this potential IPO and the potential full separation, we remain open to all alternatives that would maximize the after tax return for our shareholders.

Concerning the pending sale of the Nutrition business to Nestle, we remain on track to close the sale by the first half of 2013. We will work to maximize the after-tax proceeds and expect to allocate those proceeds for share repurchases while also considering other value-creating opportunities with the return on share repurchases remaining the case to beat.

Given our performance year to date, I believe we are well positioned going into the second half of this year. By staying focused on our current course, we are building a sustainable, innovative core and creating shareholder value. A few words about the Innovative Core. The actions we set in motion early in 2011 to improve R&D productivity are starting to bear results. We have a pipeline that I believe includes potential high-value assets at all stages of the development continuum across our key therapeutic areas. Of particular note is the strength of our oncology, vaccines, inflammation and cardiovascular portfolios. And our early-stage portfolio is increasingly comprised of new therapies based on precision medicine approach, an approach we believe yields more targeted treatments to patients. We have Precision Medicine efforts under way at various stages in our pipeline across several therapeutic areas including diabetes, oncology and cardiovascular. We have a sharp focus on the Innovative Core. I believe we’re able to create a portfolio that matches our areas of expertise and that positions us for long-term growth.
In terms of the late-stage pipeline, we are in ongoing discussions with the FDA about the regulatory reviews of Eliquis and tofacitinib and remain enthusiastic about the potential commercial prospects for each of those important therapies. Regarding Eliquis, as we and our alliance partner, Bristol-Myers Squibb previously said, the FDA has requested additional information on data management and verification from the Eliquis ARISTOTLE trial. They have not requested any new studies, and along with Bristol-Myers we are working closely with the FDA and are confident we can address and resolve their questions. We will provide an update when we have new information to share on the status of the review.

Concerning tofacitinib, as you know, the FDA Advisory Committee recommended approval on May 9. Subsequent to that meeting, the FDA requested additional analysis of the existing data in our NDA. We are planning on providing them that information in early August. Given the timing of the additional analysis requested, we anticipate that the FDA may require additional time beyond the August 21 PDUFA date to review this information. In another tofacitinib development, we now have the top line results of our Phase 3 study 1069, also known as ORAL Start. As a reminder, this study was conducted in Methotrexate-naïve moderate to severe RA patients and it evaluated the use of tofacitinib in 5 or 10 milligrams twice daily doses as monotherapy compared to Methotrexate. 1069 included a structural end point. I am pleased to share with you that the study met all of its primary end points at both the 5 and 10 BID doses, including demonstrating statistically significant changes versus Methotrexate in inhibiting structural damage. We are issuing a press release on these top line results following today’s call and will provide more information about this study at upcoming scientific meetings. Because the study only recently read out, it was not part of our NDA submission and is not under FDA review. We are exploring the most appropriate method and timing to submit this information. Overall, we are confident in the efficacy and safety profile of tofacitinib and believe that it would make an important contribution to the treatment of RA.

And now a few comments about the recent top line results with bapineuzumab study 302 in patients with mild to moderate Alzheimer’s disease who carry the ApoE4 genotype. As we recently reported, study 302 did not meet the co-primary clinical end points, no statistically significant benefit was seen in changes in cognitive or functional performance in the bapineuzumab-treated group compared to placebo. Study 302 was the first of four placebo controlled Phase 3 studies complete in the bapineuzumab development program. The Janssen-led study in noncarriers, study 301, has just completed and the data is being evaluated. We plan to report the data to regulators and announce the top line results in August. Of note, both study 301 and 302 have been accepted as late-breaker presentations and will be presented at the European Federation for Neurological Societies meeting in Stockholm in September.

Looking ahead to the second half of this year, we will continue to work on our cost structure, inclusive of everything from manufacturing, corporate functions, our go-to-market strategy and continuing to execute on our existing R&D plans. Our work across these areas should enhance our ability to create incremental value for our shareholders and invest in potentially new treatments that address unmet medical needs in such areas as cancer, neuroscience, pain and vaccines for infectious diseases. For the foreseeable future, we expect the operating environment will remain challenging and uncertain, especially in Europe, and we will have to offset the impact of upcoming LOEs as well as expirations of co-promotion and licensing rights over the next couple of years as we embark on new product launches and generate growth in Emerging Markets. Despite these challenging market forces, we are demonstrating through our quarterly performance, both in this quarter and in recent quarters, that the fundamentals of our business are strong. Our capital allocation decisions are sound. And our colleagues are skilled at navigating in uncertain and sometimes inconsistent market forces. For these reasons, I remain optimistic about our ability to generate consistent, predictable earnings per share growth over time.

To sum up, we turned in another quarter of solid performance. We remain enthusiastic about the potential commercial opportunities we see for tofacitinib, Eliquis and Prevnar 13 adult. We continue to build a track record of consistent performance that provides us with a firm foundation for steady future earnings per share growth. Now I'll turn it over to Frank for additional details on 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. I want to remind you that the Nutrition business is presented as a discontinued operation in consolidated statements of income for all periods presented given the pending sale of that business to Nestle. As you know, discontinued operations are excluded from adjusted financial results, and consequently throughout 2012, the results of the Nutrition business will be excluded from adjusted results.

Now let’s move on to the financials. Second-quarter revenues of $15.1 billion decreased 9% year over year reflecting an operational decline of approximately 6%, driven mainly by the loss of exclusivity of several key products in certain geographies, notably Lipitor in most major markets.
Adjusted diluted EPS of $0.62 increased approximately 5% which primarily reflects the favorable impact of lower expenses resulting from cost reduction and productivity initiatives and fewer weighted average shares outstanding due to our share repurchases, and the unfavorable impact of the loss of exclusivity of certain products, including Lipitor in most major markets. Foreign exchange negatively impacted second quarter revenues by 3% or $451 million, and favorably impacted adjusted cost of sales, adjusted SI&A and adjusted R&D expenses by $396 million or 4%. As a result, foreign exchange negatively impacted second quarter adjusted diluted EPS by less than $0.01.

In the second quarter, Emerging Markets Biopharmaceutical revenue increased 8% to approximately $2.6 billion, reflecting operational growth of 14% and the negative impact of foreign exchange of 6%. Volume growth of 15% in Emerging Markets, primarily in China and Russia, were partially offset by price reductions of 1% resulting in the operational growth of 14%. The second quarter Emerging Markets Biopharmaceutical revenues approximately 41% was generated by Established Products, 33% by Specialty and Oncology products and 26% by Primary Care products. Established Products revenues generated by sales in Emerging Markets increased 17% operationally year over year.

Specialty Care and Oncology total revenues in Emerging Markets increased 14% operationally and Primary Care revenues in Emerging Markets increased 12% operationally. With respect to BRIC-MT markets, second quarter Biopharmaceutical revenues increased 12% to approximately $1.2 billion, reflecting operational growth of 20% and the negative impact of foreign exchange of 8%. Of the second quarter BRIC-MT Biopharmaceutical revenues, approximately 42% was generated by Established Products, 32% by Specialty and Oncology products and 26% by Primary Care products. Revenues for Established Products sold in BRIC-MT markets increased 24% operationally year over year. Specialty Care and Oncology total revenues in BRIC-MT markets grew 21% operationally and Primary Care revenues in BRIC-MT markets grew 13% operationally.

During the second quarter, Biopharmaceutical volume growth of 24% in the BRIC-MT markets was partially offset by price reductions of 4%, resulting in operational growth of 20%. These markets contributed about 62% of Emerging Market Biopharmaceutical operational growth versus second quarter 2011. Year-to-date operational growth in the BRIC-MT markets was 15% versus the year-ago period, reflecting volume growth of 20%, partially offset by price reductions of 5%.

We’re reaffirming all components of our 2012 financial guidance which we updated in our first quarter 2012 earnings announcement in May to exclude the results of the Nutrition business from our revenue guidance and our adjusted financial guidance. Our second-quarter results reflect our continued solid operational performance, despite the negative impact of the loss of exclusivity, certain products in most major markets, mainly Lipitor in the US and in most major markets. We anticipate filing a registration statement with the SEC by mid-August for a potential initial public offering of up to a 20% ownership stake in the Animal Health business to be named Zoetis. We are targeting the first half of 2013 to complete the potential IPO. As we continue to work toward a potential separation of the business, we remain open to all alternatives to maximize the after-tax return for our shareholders. We expect to complete the sale of our Nutrition business to Nestle by the first half of 2013. Additional repurchases of our common stock remain the case to beat for the use of the after tax proceeds following the completion of the transaction.

Given the potential of our late-stage and emerging pipeline, our strong operating cash flow, streamlined organization and disciplined approach to capital allocation, we remain confident that we are well-positioned for long-term success. Finally, we remain committed to delivering attractive shareholder returns in 2012 and beyond with approximately $3 billion or 136.6 million shares repurchased through July 30. And we continue to expect to repurchase approximately $5 billion of our common stock in 2012. Now I’ll turn it back to Chuck.
Jami Rubin - Goldman Sachs - Analyst

I actually have a number of questions but maybe Ian, if we could just start with sort of a bigger picture. Given the activity around Nutritionals and Animal Health, if you could frame for the investment community your thinking around how you envision the reshaping of Pfizer post the Nutritionals and Animal Health spin, what is Pfizer going to look like? And do you envision an opportunity to further reshape the portfolio going forward?

Secondly, for you, Frank, is it safe to assume that the changes in the FX rates since you reported your first quarter and obviously the euro has dropped quite a bit, would have an impact on the balance of 2013 but that you are able to absorb it and how?

And then my third question, back to you, Ian, and I'm sure there are a million questions on the call relates to the Animal Health spin. Is there a minimum time line for which you would have to wait to spin the 80% of the Animal Health business that you would continue to own after the partial IPO? Just trying to get a sense for how quickly you could fully monetize the entire business once you've taken the 20% to the market. Thanks.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Jami. I'll ask Frank actually to handle both the FX and the Animal Health minimum spin time. And as to your first question about reshaping, when we've completed, I think we discussed this several times, when we've completed the separation of Nutritionals and the potential separation of Animal Health, I basically see us as a Company that has two core businesses with Consumer fitting into either one of those. But the two core businesses, one being what we could call Innovative Co or Growth Co and the other one being a Value Company. The Value Company being represented by large brands sold around the world with reasonably large infrastructure, good channel presence. And the Innovative Co being a Company which has growth from innovative products, a research organization sized for that size of that opportunity.

And we have started already down this path of managing the Company that way by our BU structure where we have basically Innovative Co inside the BU structures of Specialty and Oncology and Primary Care. And then outside of that we manage Emerging Markets in a more traditional method of country-based organizations. So through '13 and '14, we will continue to refine our operational structure to maximize the values of those two distinct businesses and we will see how the value of those two businesses are reflected in our growth and our share price and then take decisions based on that. Frank?

Frank D'Amelio - Pfizer Inc. - CFO

Sure, thanks, Ian. So Jamie on the FX question, if you look at our basket of currencies and you look from our last earnings call where our guidance was based on mid-April rates and then you look at this earnings call where our guidance is based on mid-July FX rates, currency has moved against us and it's moved against us for the year to the tune of a few cents. We absorbed that in our guidance and obviously reaffirmed guidance as a result. The way we did that was through combination of things, but primarily our cost reduction and productivity initiatives. If you look at our numbers for the quarter, on a year-over-year basis, our adjusted cost of sales, our adjusted SI&A and our adjusted R&D all in were down about 12% operationally. And so it's that performance, and it's down 10% operationally on a year-to-date basis, that allowed us to mitigate the adverse effect of foreign exchange from the previous quarter to this quarter.

In terms of the other question you asked about the time line on Animal Health and make sure I've got it right which was from the time of the potential IPO to the time of I'll call it the potential full separation, what are we thinking about? I'll tell you how we think about this which is typically you want a quarter or two of some operational performance of the Company so you can kind of demonstrate what I call the rhythm of the businesses. So I think one will be you want a quarter or two of operating performance to demonstrate rhythm. And then two, the other thing that will inform us is the macro economic conditions, what's going on in the markets and I think those things in combination will drive the time line between a potential IPO and then a potential full separation.
First on Eliquis were the issues raised by the FDA in the CRL likely to be raised by other regulatory bodies around the world, and have you been proactive about that? Secondly, Ian, what’s your latest thinking on whether to weed or feed your generic business over the coming months and years? And third, can you talk about the decision to drop the Acura program and what can we read into regarding Embeda, Remoxy and your commitment to that franchise? Thanks.

Thank you, Gregg. Well I’m going to ask John to answer the Eliquis question and also the Acura question. Regarding weed or feed our generic business, I mean we have Greenstone in the US. It’s a well run business. I think it’s an important part of our overall established products presence. We continue to invest where appropriate in branded generics and generics. We take a regional approach to that. We’ve done investments in Brazil, we’ve done investments in China. This is a very local business and we’re committed to being successful in the presence in these BRIC-MT markets. So we will continue to be opportunistic on how we strengthen those businesses. John, would you want to take the Eliquis and the Acura question?

Okay. Thanks, Gregg. So if I take Eliquis first of all, as we obviously previously stated the CRL that we received from the FDA requested some additional information on the data management and verification from our pivotal ARISTOTLE study, which as you know was a very big study, around about 18,000 patients with atrial fibrillation. I think one point which is really important to make is that it’s our belief that the information requested doesn’t impact the outcome measures of the trial and importantly, as Ian’s already said, we haven’t been requested to conduct any additional studies. So our confidence in the results from both the ARISTOTLE trial and the AVERROES trial hasn’t changed. In terms of our discussions with other regulators around the world, both in the EU and other countries, those discussions are progressing aligned with the timelines per our filing dates that we’ve previously announced.

If I then pick up on the King products, just to give you an update on where we are there. With Embeda, as we previously communicated, we are very confident that we’ll be able to return Embeda to the marketplace. And we expect to submit a prior approval supplement to the FDA by the first half of 2013.

On Remoxy, as we previously stated there, based on the work completed by our technical team over the past several months, we remain cautiously optimistic we’ll be able to bring Remoxy to the marketplace. We have preliminary results from two bioavailability studies that are currently being analyzed along with data from experiments designed to optimize the formulation composition analytical methods for that product. And upon completion of those analyses, we’ll determine the timing and the nature of our engagement with the FDA to address the complete response letter that we received in June last year. And at this time we’re certainly hoping to meet with the FDA in the fourth quarter of 2012.

So lastly, if I just pick up briefly on Acura, we decided to return the license development and commercialization rights to three smaller early-stage immediate release assets to our development partner Acura based on our ongoing portfolio prioritization for not only our opioids portfolio but in line with our standard practice. I think it’s important to say in regard to those particular technologies, that immediate release wasn’t a high priority area for Pfizer but we do continue to work on Oxecta that was launched earlier on this year.
Thank you, John.

Next question, please, Operator.

Marc Goodman from UBS.

Yes, first, can you help us just quantify on Prevnar some of the one-offs just so we understand what the underlying growth is for Prevnar? Second, can you talk about where you are in taking expenses out of the business. I mean, are we halfway through the nine inning game, are we three-quarters of the way through? I know you've talked about Europe as an area that you're really focusing on and trying to take some costs out and could you give us some specifics on kind of what you have left to do there?

And then third, just on the gross margin, can you just remind us again like what's going on kind of behind the scenes on the gross margin, which seems to be much stronger than we would expect? I didn't hear the numbers that you had called out as far as FX related. And then I was just curious I mean obviously with Lipitor going off, everyone thought the gross margin would fall off much more and yet it's not. Thanks.

Okay, thank you, Marc. I'll ask Frank to take the European gross margin first, probably, and then ask Geno to make some comments on overall vaccine growth.

So on gross margins, let me run the numbers and then I'll answer the question which is -- and I'll do it in terms of just cost of goods sold as a percentage of revenue. So this quarter it was 17.7%. It was down from 18.3% in the year-ago quarter. But if you adjust that 17.7% for foreign exchange, it was actually about 19%, which is I'll call it in line with the guidance we provided for the year. Now, what's going on there, Marc, is clearly the benefit of cost reductions, and I'll talk to that in the second question that you asked me, and then kind of what's working against that was really the impact of Lipitor. But when you put that all together, you get the 17.7% that we reported but it had the benefit of foreign exchange, which if you removed would take you to about 19%. And the FX benefit to COGS this quarter was about $285 million. So it reduced COGS by $285 million, which is how I get from the 17.7% to the 19% or so.

In terms of where we are, I think you said, you used the baseball analogy in terms of what inning are we relative to cost reduction. I would describe it as we're not in the early innings anymore. I think we're clearly in the middle innings but clearly with opportunities quite frankly throughout the business. We continue to work on things like streamlining our manufacturing network through productivity initiatives and working on the productivity of each of our individual plants. We've announced that over the next several years we believe we can further reduce our plant network strategy-- our plant network by another 10 facilities or so. So still lots of opportunities there.

In SI&A, we continue to streamline our corporate functions. In R&D, we continue to execute on our engines for sustainable innovation product in terms of the therapeutic areas that we focused on and the therapeutic areas that we discontinued and the work that we do in those areas. So if I
had to net it all out, I’d say we’re in the middle innings and they’re still— with everything that we’ve accomplished, there’s still significant opportunities going forward.

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

Geno.

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

Yes, Marc just to comment on Prevnar, on the Pediatric business, business is good in Europe and the United States. And what we’re seeing now is a return to kind of the stable growth that we’ve experienced in the past now that the catch-up opportunity is fundamentally completed. So we’re looking at quarterly and year-to-date results on the developed markets that are similar to a baseline that we can expect going forward. Japan, we continue to see strong growth as the formal immunization, national immunization program is continuing to roll out there. Remember, that’s Prevnar 7 and we’re continuing the registration process to introduce the 13-valant and expect to pursue a catch-up opportunity when we do have the 13-valant there as well.

And then in the Emerging Markets, we continue to see very strong growth of the Prevnar business for the quarter and year to date on what’s becoming a reasonable base now, not just good growth on a small base. On the adult side, we’re making good progress. As you know, in the US this is a business that’s driven by ACIP recommendations. Fortunately, the ACIP did make a recommendation to support immunization of immunocompromised patients. That’s a good step in the right direction.

We’ve also seen progress with some quality measures through CMS that we expect to help open the door for additional growth for Prevnar adult going into the end of the year and the beginning of next year. And around the world, we continue to see registrations in all of the developed and Emerging Markets for adult and we’re starting to see promotion and some limited uptake there as we start to introduce the adult vaccine on a global basis.

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

Thank you, Geno.

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

Operator, if we can move to our next question, please?

**Operator**

Mark Schoenbaum from ISI Group.

**Mark Schoenebaum - ISI Group - Analyst**

Hello, guys. Congrats actually on a really nice quarter. The-- I had a couple questions. The first, you may not answer but I thought I’d ask it, on Bapineuzumab, is there a consideration that you may file in the noncarriers group even if you missed your primary endpoint but you see interesting signals in subgroups?

Second question is on EM, this plus 14% year on year is very impressive and well above your annual guidance. I was looking for a little more color on that. Do you recommend we extrapolate that forward or should we keep kind of long-term growth rates a little lower than that? Third on tofa,
any more color on what the FDA has asked for and can you get the ORAL Start data in the FDA’s hands before they write the label? And I ask specifically around structural progression.

And finally a really quick one, I know you guys have said in the past you plan on breaking out -- sorry, you said you were considering breaking out the Value business versus the Growth business for reporting purposes in the Ks and Qs next year, I’m just wondering where that decision stands? Thanks a lot.

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

Thank you, Mark. Well you’re quite right, we can’t comment on the Bapi situation because we haven’t seen the results of the trial yet, it’s still blinded to us. So when we do have those results, we’ll think about all the things you asked the questions on.

On breaking out the Value and Growth Co, once we get through the potential separation of Animal Health and the separation of Nutritional, we’ll step back and look at the business and see what is the best way to ensure that the analysts have transparency on to what we see as the core drivers of the business. So we want to be transparent there. With that, I would ask perhaps if Olivier could give a little more context around Emerging Markets, the growth in different marketplaces. And on tofa, Geno may want to make some comments on tofa for us.

**Olivier Brandicourt - Pfizer Inc. - President, GM - Emerging Markets and Established Markets**

So in Emerging Markets, we continue to be optimistic and we see attractive opportunities across Emerging Markets and all of that of course related to increased population and wealth of these nations. And while we are seeing a low amount which is currently spent on healthcare of course. So as you have seen, we have posted 14% operational growth for Q2 and it’s driven by very good performance in BRIC-MT. You’ve seen the results for BRIC-MT is about 20% operationally but it’s 24% in terms of volume growth and there is an impact of 4% of price. So we will continue, we know that, to expect to see quarter-to-quarter volatility in Emerging Markets and it’s more appropriate probably to look at our results on a 12-month basis and our goal for this year and future years is to grow our Emerging Market business by high-single digits over time.

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

Thank you, Olivier.

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

Okay, so with regard to tofa, we think-- we see the review progressing very nicely. We filed the NDA at the end of last year. We had a very quick Advisory Committee meeting in May, a very positive outcome. In fact, the only thing material that the Advisory Committee would have liked to have seen more of is more structured data and now we have the additional structure data, so we see that as a positive development.

With regard to the analyses that the FDA has requested, it’s basically a routine analysis. It’s a very large NDA. We have five Phase 3 pivotal trials, 5,000 patients and they’ve asked for some additional analyses. This is very common to request additional analyses and even to do their own analyses. And we’re busy putting that together and we plan to have it to them certainly ahead of the action date so that they can determine their next step. So with regard to the 1069 structure data, the FDA is aware that we have the top line results and we will find the most appropriate way to get the data to them for consideration in future labeling.

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

Thank you, Geno. Go to Tim.
Chuck Triano - Pfizer Inc. - SVP - IR

Next question, please, yes.

Operator

Tim Anderson from Sanford Bernstein.

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

Two questions on Prevnar 13, then a couple others. Can you get any real commercial traction in adults ahead of CAPiTA or does it all really depend on that? Also, have you done an interim look at those results? I believe one was built into the protocol. On tofacitinib, do you expect to get both the 5 and the 10-milligram doses approved? And then last question, in terms of the next round of pipeline products beyond the ones like tofacitinib and Eliquis, what are the two or three products that excite you the most?

Ian Read - Pfizer Inc. - Chairman, CEO

Okay. Thank you, Tim. So we'll ask Geno to discuss the adult indication opportunity of Prevnar 13 and the tofa question on dose. And then ask Mikael Dolsten to comment a little bit on the next wave of products. Thank you.

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

So I mean, with Prevnar 13 adult, look what we know is that there's a huge disease burden out there. We've-- I think I've quoted the statistics many times before, in the US we know there's 300,000 hospitalizations a year for pneumococcal pneumonia, 20,000 deaths associated with pneumococcal pneumonia. So we believe there is an opportunity to build a business on the basis of just the need for the vaccine alone. But having said that, it's true that it is a -- the-- historically in the vaccine business, it's CDC recommendations that are the real drivers and the CDC recommendation is likely to be most influenced by the CAPiTA trial. So we're going to do the best we can to build this business from the ground up from now until we have those CAPiTA results and certainly the CAPiTA results will be a major driver, and hopefully that gives you a sense for what our thinking is.

In terms of the interim look on the CAPiTA trial, the interim look I believe was only to give a sense for how many events had occurred and we don't have any insight into the number of events that have occurred in the placebo group versus the vaccinated group. So we don't have any insight into early read on effectiveness. As you know, this is an event-driven trial and we'll have a final result when there are accumulation of enough events to determine the outcome.

With regard to tofa, 5 milligrams and 10 milligrams, I think the question was do we expect both? We certainly believe that we've demonstrated through the five pivotal trials that we've done a very consistent and robust effect of both the 5 and the 10-milligram, had a certainly acceptable safety profile. So the advisory committee had a review of the two doses and we know that they were supportive of both doses. We know rheumatologists would like to have both doses available and we believe that our NDA supports both doses. So that's our feeling on the two doses. And I don't know if the next round of innovative products was Mikael.

Ian Read - Pfizer Inc. - Chairman, CEO

Mikael was going to comment on that.
Mikael Dolsten - Pfizer Inc. - President - Worldwide Research & Development

So thank you for showing interest in our rich portfolio beyond tofacitinib and Eliquis. So I’ll just give you a couple of examples in four of our therapeutic areas. In vaccines, you will see really a rich pipeline evolving. We have agreed with regulators in major regions about meningitis B study design. And we are starting at a Phase 3 now. We also have a very exciting Staph aureus program where we are industry-leading and we have completed a first Phase 2 and are heading into the second Phase 2.

Oncology as Ian alluded to, it’s really a growing, exciting area for us. We have tofacitinib as the leading antibody drug conjugate for hematological malignancies and also best-in-class dacomitinib for lung cancer based on precision medicine. And you may not have seen our CDK drug that’s going into breast cancer. Also based on precision medicine.

Finally, immunology and inflammation, please note our life cycle management of tofacitinib going to inflammatory bowel disease, psoriasis. But also our really best-in-class IL-6 antibody for both lupus and inflammatory bowel disease opportunity. And also beyond Eliquis in cardio metabolic, you should keep an eye on programs such as pancreatic glucokinase activator and also PSK kinase field.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Mikael.

Chuck Triano - Pfizer Inc. - SVP - IR

Thanks, Mikael. Operator, next question, please.

Operator

Chris Schott from JPMorgan.

Chris Schott - JPMorgan Chase & Co. - Analyst

First on the gross margin trends, looking at your second half I think to hit the midpoint of your range it does imply a fairly substantial drop in margins. Could you just elaborate a little bit more on that? I know we had some currency benefit first half, but it does seem like quite a big step down.

The second question was on the established product division. I think we’ve had new leadership there since our last call, I mean is there any change in focus or priorities for that division? And then finally one that I don’t know if you’ll comment on, but as we think about the Value versus Established or versus Growth core here, when we get out to 2014 or ’15 you’ve had more time to evolve the strategy and if we’re not getting the value for those businesses in your share price would you be open to splitting those franchises apart or do you see meaningful structural issues that would not allow you to do that given the shared resources? Is that even something I’d say I guess on the table as we look out a few years? Thank you.

Ian Read - Pfizer Inc. - Chairman, CEO

Okay. So on the Established -- I’ll ask Frank to answer the gross margin question in a moment, on Established Products and Emerging Markets, Olivier Brandicourt has taken over the leadership of those two areas. He has a long experience in pharmaceuticals both in Emerging Markets and Developed Markets, so I would ask him to make a brief comment on what he sees as to the Established Products.
But before he does that, on the question on Value and Growth Co, we are focused at Pfizer on shareholder value and ensuring shareholder value. So we will evaluate those questions you posed and we will take the decisions that will best drive shareholder value at that time. I think that’s the best way really to answer that question and one that we continue to show that we are focused on ensuring shareholder value is optimized.

Olivier Brandicourt - Pfizer Inc. - President, GM- Emerging Markets and Established Markets

All right on Established Products, I must say I’m very optimistic and I see very attractive opportunities with this business, which is very new to me. So we have a strategy which looks at both segments of the LOE market, branded and generics. For the brands, we are trying to leverage our leadership, not only in quality but also in reliability of supply which has been a problem as you know in many countries, and also in the enhancement of product value. For the generics themselves, we focus our investment in different what we call profitable pockets of the market and more specifically the sterile injectable and oral solids when they are very much differentiated. So we posted about 18% operational growth during Q2 and of course that was very much driven by the fact that we have inherited in this division a few LOE products, and Lipitor being the largest one, both in the US and in Japan.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Olivier.

Chris Schott - JPMorgan Chase & Co. - Analyst

All right, thanks, Olivier.

Frank D’Amelio - Pfizer Inc. - CFO

And then on the second half COGS relative to the first half, what I’m going to do is I’m going to bump it up a level and talk not just about COGS but about earnings as well in terms of the second half of the year versus the first half of the year. And we’ve got a couple of factors that will impact all of the second half of the year or a portion of the second half of the year that didn’t impact the first half at all or impacted it only partially and these are I’ll call them negative factors. So for example, in the US with Lipitor, Lipitor began facing multi-sourced generic competition in the US on May 30. So not an impact for the entire first half of the year, but that’ll be an impact for the second half of the year. That will obviously adversely affect cost of goods sold, it’ll also adversely affect EPS.

Same thing in Lipitor in Europe, where once again began facing multi-source generic competition in March and May. So you’ll get the full year effect of that, at least the second half you’ll get the full impact of that. Now same thing with Geodon which in the US began facing multi-source generic competition in March of this year. Then if you go out for the remainder of the year, we have anticipated LOEs for Detrol in the US and Europe and Revatio in the US in September which will adversely affect earnings and that has an impact on our overall other things like cost of goods sold as well. So it’s those kind of factors that we factored into our guidance that’ll impact the second half of the year that didn’t have as much of an impact in the first half of the year.

Chuck Triano - Pfizer Inc. - SVP - IR

Thanks, Frank. And Operator if we can please move to the next questioner.

Operator

Steve Scala from Cowen.
Steve Scala - Cowen and Company - Analyst

Many of the pressure points Frank you just identified will linger into 2013. Would you be able to provide any perspective on 2013 relative to the trend versus 2012? Can we anticipate an up year, a flat year or what? Secondly on Spiriva, what markets has Pfizer already given back to BI and what significant markets are to be given back in the second half of the year? And then thirdly, did you formally drop your follow-on CETP inhibitor, and if so, was it because the agent wasn't optimal or do you feel the area is too speculative? Thank you so much, bye.

Ian Read - Pfizer Inc. - Chairman, CEO

Okay. So Frank, if you could handle the impact into 2013 and then we would ask John if you could take the question on Spiriva. And finally Mikael on the CETP.

Frank D’Amelio - Pfizer Inc. - CFO

So in terms of what I said on the previous question relative to the second half of the year and then how that impacts 2013, let me just start with we haven’t provided guidance yet on 2013. That’s something we’ll do obviously later on. But in terms of just I’ll call it positive items and negative items, I went through some of the negative items. Some the positive items that’ll have a positive rhythm going into 2013 include things like the strength in some of our in-line products.

So for example, this past quarter Lyrica, Enbrel, Prevnar 13, Celebrex, all had very strong operational growth. Lyrica globally 18%, Enbrel 15%, Prevnar 13, 14%, Celebrex, 7%, and internationally, even stronger growth rates. For example, Prevnar 13 internationally grew 33%. These are all year-over-year operationally. So certain key products in the in-line portfolio have been growing very nicely. We expect those to continue to grow nicely going into 2013.

Our new products, things like Xalkori, Inlyta, those are products that we expect and obviously the products that we talked about before like Eliquis for example. Then geographic expansion. So we had emerging market growth this past quarter of 14%, 15% on volume. BRIC-MT markets grew 20% operationally, 24% on volume. We expect to continue to see growth in those areas as well. And then obviously we’ll continue to try to allocate our capital in ways that will be an enabler of growth on a going forward basis. So those are some of the kind of the positive rhythms and the negative ones that’ll impact 2013 and we’ll provide guidance on ’13 like we always do when we close out this year and then provide guidance for 2013.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Frank. John, could you make some comments on Spiriva?

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

Yes, sure. So thanks for your questions, Steve. So based on our 10-year contract with Boehringer Ingelheim, the termination date differs country by country and it’s calculated from the launch date of the product in each country. The EU countries will begin contract exit in the 2012/13 period. US, Japan in 2014 and the last country is finishing in 2016, aligned with our contract.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you. Mikael?
Mikael Dolsten - Pfizer Inc. - President, Worldwide Research & Development

Yes. As you know, we and others were regionally interested in CETP inhibitors as a mean to help regulate good cholesterol HDL and reverse cholesterol transport. Our view currently is that that field has uncertainty and we have not been keen in progressing until there is more signs that understands the potential role of this mechanism as a way of changed risk factors in cardiovascular disease. Instead, we think further focus on LDL lowering and also anti-inflammatory mechanism has been the main focus now.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Mikael.

Chuck Triano - Pfizer Inc. - SVP - IR

Thanks, Michael. Next question, please, Operator.

Operator

Catherine Arnold from Credit Suisse.

Catherine Arnold - Credit Suisse - Analyst

First of all, on tofa I wondered your comments about the Start study and achieving your primary endpoint on all doses bodes very positively. Obviously with the advisory committee there was some debate regarding the radiographic changes and the implications of those with Pfizer coming out with one dose having a positive effect and the FDA coming out with a different answer based on a different analytical method. So I guess I just wondered, could you express sort of your confidence that there won't be this difference of opinion in terms of the radiographic effect of both doses?

And then on Bapi, I wonder if you could comment if you will address any pulled data findings in press releases prior to the meeting in Sweden. And then I know you'll love this last question so I can't help myself. But it's in regards to your definition of top line and what you're putting in the press release. Should we assume that when you report study 301 that that definition will continue to be nothing below the primary endpoint in efficacy, meaning if there are any trends positive or negative in the subpopulations we won't know that until Sweden? And then I would assume the top line definition, and this is going to a conversation with Chuck, in regards to the side effects with an incidence of greater than 1%. Thanks.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Catherine. I didn't quite understand the question on pull on Bapi. Could you expand on that, what were you trying to get at? You can't come back, okay. Well then we'll go to tofa with Geno. We'll try and answer your Bapi question and we'll also go to the top line question you have with John.

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

So hi, Catherine. Just a comment on the structure data. The data as you know that was presented to the advisory committee and discussed during the Advisory Committee was from 1044 and in that study we had a different population. These were patients who had experienced methotrexate for the most part, and one of the design challenges for that trial was that the patients were on placebo for a very short period of time and then their structure progression was extrapolated. And I think it was acknowledged by the Advisory Committee that this is a very difficult study designed to demonstrate the difference in structure progression between the active group and the placebo group.
What we found in that study was that neither the placebo group nor the tofa group progressed very much and the separation was significant at the 10-milligram but not at the 5-milligram on the primary analysis. Other secondary analysis did demonstrate significance at both 5 and 10. So there was a lot of discussion around the study design and why the results were what they were and the sensitivity analyses, and I think it was acknowledged that it was a difficult way to demonstrate a difference in structure.

Now on the other hand, the 1069 study is a different study in a different patient population. These are patients who hadn’t been exposed to methotrexate. They were progressing more rapidly in their disease and the separation between methotrexate and tofacitinib is much more pronounced, and clearly there was significance at both the 5 and 10-milligram doses. And I think that this absolutely establishes the disease modifying capability of the drug and that’s what the FDA is—should be basing their decision on. So we feel pretty good about these results.

Ian Read - Pfizer Inc. - Chairman, CEO

Yes the only thing I’d add to that of course there’s a timing issue. The FDA hasn’t formally got the 1069 and so we’ll have to see how we best incorporate that into the eventual label of tofacitinib. Olivier could you answer the Bapi question, if you understood them?

Olivier Brandicourt - Pfizer Inc. - President, GM- Emerging Markets and Established Markets

Hopefully, Catherine, you will have the answer to your question. Just as a status update, so we have announced last week of course the 302 core primary endpoint results. And we believe that it was the right decision to make, not only to inform regulatory authorities but also the right decision for patient investigators because patients needed to be re-consented in the overall program, the entire program.

The second decision we’ve made was as an alliance was to expedite the interim analysis on the ongoing 3001, the international carrier study. The results will help us inform the risk benefit profile of the asset and we know that we have enough patients who have completed the study to do a pretty strong interim analysis and futility analysis. So the other decision we’ve made was for the Extension study. We have discontinued that study because we think the clinical benefit was just not demonstrated.

To your question regarding 301, 301 will be reported to you in the format of top line results and only co-primary endpoints will be reported and that will happen during the month of August. And finally, all results including secondary endpoints and biomarkers, all of that will be reported as you know in Stockholm early September.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Olivier.

Chuck Triano - Pfizer Inc. - SVP - IR

Next question, please.

Operator

Seamus Fernandez from Leerink Swann.

Seamus Fernandez - Leerink Swann & Company - Analyst

So first off, for Ian, as we kind of look forward at the different opportunities in the business, what aspects are you most excited about? Are you really more excited about what you’re seeing in the innovation portion of the business and if there are products that you would call out that you’re
particularly excited about, given your long history, which ones would you call out? And then -- and again, more on sort of the near term and longer term pipeline if you would.

Second, as it relates to tofacitinib, Geno, maybe you could just comment on should we think about this data that FDA has requested as sort of the typical major amendment type of situation that normally results in a three month addition, obviously not speaking for the FDA but more just speaking in your experience.

And then lastly as it relates to Bapineuzumab, Mikael, if you could just kind of give us your thoughts on biomarkers that would be important to future development of Bapineuzumab as we look at the data, should we really be focusing in on PIB/PET markers or should we be looking at CSF and tau as a potential marker going forward? Thanks a lot.

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

Thank you, Seamus. So on the tofacitinib question, I think you expressed it well in the way you described the type of data that the FDA is requesting. I'm not speaking for the FDA, we continue to work with them, but we would look at the way you expressed it as being very similar to the way we see it and we'll just have to wait and see what happens with the FDA. On the -- what I'm excited about, frankly, is I'm excited about the state of the Company, about the imperatives we have, about what we're doing on innovative core and seeing real momentum and enthusiasm both at the ground level with the colleagues who are working in research and R&D, and also excited about our opportunities as a global Company in Emerging Markets with our strategies in the BRIC-MT, driving our in-line brands and also looking to launch our innovative products in those marketplaces.

So while Emerging Markets will be turbulent, we'll have ups and downs, there is in a way an irreversible move to higher GDP, higher healthcare spend, which represents a huge opportunity for an innovative Company like Pfizer to be successful in over the short and medium and long term. So Emerging Markets is a really exciting place for us, for all of our portfolio. And in the developed world, in Japan, the growing strength of innovative core is also hugely promising both in Oncology with Dacomitinib, with inotuzumab, with the CDK program, with Xalkori and the potential for Xalkori in CMET, which is a large opportunity. Our inflammation portfolio and the expansion of tofacitinib into our extensions such as Crohn's and UC. Our vaccine program is extremely strong. We have one of the best vaccine teams in the industry and we have a broad vaccine opportunities. We continue to invest in CV, both PCSK9 and the other molecules that Mikael mentioned.

So frankly, I'm enthusiastic about the short term and very enthusiastic about what I see coming through in the next-- from now to the next five years as our pipeline matures with a very strong Phase 1, Phase 2 program. The remaining question was to Mikael on --

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

Biomarkers.

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

On biomarkers so--

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

I think you mentioned some-- I think you already mentioned it once that our most widely monitored in the field, on one hand the PIB/PET to look at the amyloid. Are you lowering amyloid, that's number one. And are you affecting downstream signs of damage, such as p-Tau level in CSF. And I think those will be very important and we'll see what we learn from this study. And over time you will also see incorporation of more early cycle metric sensitive tests as this field moves forward. Olivier, do you want to add your point on top of it?
Olivier Brandicourt - Pfizer Inc. - President, GM - Emerging Markets and Established Markets

The only point I can make is refer to what we have in the current program, which answers I think partially the question. So we do have PET/PIB as a marker of amyloid beta. While in the CSF, we are looking for amyloid beta data and Tau and we also have volumetric MRI. So that gives you already a sense of what we’re doing already.

Ian Read - Pfizer Inc. - Chairman, CEO

Great. Thank you, Olivier.

Chuck Triano - Pfizer Inc. - SVP - IR

Our next question, please.

Operator

Tony Butler from Barclays Capital.

Tony Butler - Barclays Capital - Analyst

Ian you didn’t call out Inlyta and Xalkori with respect to overall products and what those revenues may be. And while they may represent precision medicine as you’ve alluded to, the question is are you putting additional resources behind them? And then what lessons have you learned with respect to R&D that may help you win next generation precision medicine in Oncology, for example, comes out, would it be more to Sheamus’ point, more to have biomarkers available at that time and be utilized with those medicines?

The second question is around again Emerging Markets. Tremendous operational growth of 14% especially when you look at 9% in Q1 and I just am interested in what changed between Q1 and Q2 other than a couple of the tenders that really led to that jump?

And then lastly, and to be fair, in Q1 in August I think it was Olivier that made the reference that once the 301 study was available you would announce the data in tandem for Bapineuzumab. And I am just curious and I haven’t heard it yet, what actually changed with respect to splitting out 301 and 302? Thanks very much.

Ian Read - Pfizer Inc. - Chairman, CEO

Okay so Tony, on Inlyta and in Xalkori, probably an oversight given the richness of the number of products I wanted to mention. We’re extremely excited about Inlyta. It’s going well object its first launch. I think this product has a lot of legs to it and a lot of opportunity. It’s going to be a product that I think its profile will develop over time and we are very optimistic about its performance in the marketplace.

And with Xalkori, I think the issue on Xalkori is as you know we’re changing medical practice. We need to get doctors to have the test done to identify the specific needs of Xalkori. It’s frankly slower than we expected to achieve the changes given the 3% to 5% of the population that may have the translocation. But we will continue to invest in that, and as I say, I think Xalkori may have substantial opportunity on the CMET side as well.

Mikael, do you want to comment a little bit on what you see, what we've learned on the precision medicine side and the strategies we'll use? And then I'd ask Olivier to comment further on the reason for the change on what we previously announced on Bapineuzumab.
Mikael Dolsten - Pfizer Inc. - President Worldwide Research & Development

Yes. As Ian said, it’s very exciting to be a pioneer in bringing such a transforming product as Xalkori forward. I think the two things on the learning side, currently the diagnostic practice is very much one test, one drug, and I would like to see that change. So it would be a panel of tests for a disease like lung cancer that I think will drive the utilization of the first drug in multiple drugs and grow the marketplace. And also the need to engage all the players that are involved in precision medicine, from the treating medical oncologist to the pathologist and also to the diagnostic labs and the payers. So I think as this [swell] of precision medicine stakeholders become more familiarized, I think we will see an even more significant momentum. And the way you develop those relationships I think we are in a unique position, given our learnings here.

Olivier Brandicourt - Pfizer Inc. - President, GM Emerging Markets and Established Markets

Okay, Tony, on Emerging Markets. So we have very clear -- a very clear set of strategies which we are applying in Emerging Markets for the last two or three years and I believe they are the right strategies. So we are maximizing of course our innovative portfolio and we are building capabilities into behind that portfolio. And you heard about the results. It’s very good results we’ve got with Prevnar. I could have mentioned Sutent, Enbrel did also very, very well during the quarter, and Lipitor especially in China.

So second one is to participate in a more meaningful way in the off-patent segment. As you heard, we've made acquisition in Brazil. We signed a partnership with in Hisun in China to that matter and we are penetrating that segment very effectively. And you’ve seen the growth of Established Products in Emerging Markets for this quarter has been 17% which is much larger than what we have seen in the previous quarter. We also executing very specific program in terms of access, supporting governments in Emerging Markets, China and their healthcare agenda around cardiovascular medicine, very, very active there.

And finally, I think we are taking advantage now to our commercial infrastructure and the leadership we have put in place in Emerging Markets in the last two or three years. So that’s how I would summarize the answer. And then your question on 301 --

Ian Read - Pfizer Inc. - Chairman, CEO

Why they were separated, the press releases were not together.

Olivier Brandicourt - Pfizer Inc. - President, GM Emerging Markets and Established Markets

All right, so initially we were thinking to put 301 and 302 together because we thought that it was best view, the results would be more meaningful in that context. However, the clarity of the results we've got on 302 led us -- led the alliance to take the decision on reporting the top line results.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you, Olivier. I think on Emerging Markets, we've always said that we're going to get volatility quarter to quarter and different markets react at different times. And clearly in this quarter a lot of the BRIC-MT markets were all firing on four cylinders at the same time. I don't believe we see long term or medium term of 14% growth rate in Emerging Markets. We remain committed to our sort of high single digit for a full year growth rate. Thanks, Ian. Next question, Operator.

Operator

David Risinger from Morgan Stanley.
David Risinger - Morgan Stanley - Analyst

I have I guess three questions. The first is I'm not quite clear on the Eliquis time line from here. Can you please clarify that in terms of the FDA process and potential approval? Second, with respect to Bapineuzumab, the FDA and Pfizer and others agreed to two primary endpoints for Phase 3. Could you just discuss why the FDA is interested in seeing both cognition and function and the relative importance of cognition versus function? And then third, I was hoping that you could just characterize what the pipeline news flow is to watch in the near term beyond Bapineuzumab. So what clinical trial readout should we be focused on in the near term? Thank you.

Ian Read - Pfizer Inc. - Chairman, CEO

Okay. Mikael, could you sort of take the questions on Bapineuzumab and on the pipeline news flow?

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

Okay. So I think you first asked about the endpoints here on cognition and function. Over the last few years we have seen from an initial more focus on the importance when we show impact on a function of performance of patients whether you use physician scores or patient reported outcome. And it was the kind of view of many regulatory agencies that you needed to look at the combined impact on cognition and function. However, I should say as we see this field move forward, there's growing interest in actually cognition as a standalone parameter both in diseases like Alzheimer's and schizophrenia which I think again opens up opportunities for drug development here.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you. On the Eliquis time line, John.

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

Okay, thanks, David. As you heard from BMS on their call last week, we've already -- the alliance has already met with the FDA and we have an agreed plan on the requested information and we're working hard to provide that information to the FDA in September. And we're really working as expeditiously as we possibly again across the alliance to address the outstanding questions and move the application forward.

As you know, the FDA may take up to six months to review our response to a complete response letter once submitted. But we're already working with the agency and we are hopeful that the review can be completed within a shorter period of time. The alliance will issue a communication when the FDA accepts our resubmission and we'll be able to provide you with more information at that time.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you. And Mikael, you'll make some brief comments on the pipeline flow. I would say that I think we have -- we've had a very rich year this year and still pending of course Eliquis and tofacitinib and Bosutinib news and very, very strong in our Phase 2. And do you want to comment on some of the more closer two Phase 3 studies, Mikael?

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

Yes. So it's been -- I'm thrilled about the interest in the pipeline and opportunity. So I'll pick a few that haven't touched so much on this time. In vaccines, I think there is opportunity for a potential transformative change when it comes to management of staphylococcus aureus, as you know, a tremendous healthcare burden with moderate resistance. And we are in the mid of a Phase 2 trial with our Staph aureus vaccine here.
When it comes to the whole class of antibody drug conjugate, I'm really thrilled with the strong data we have previously reported for trastuzumab. We're expanding now also from lymphoma into leukemia, starting soon Phase 3 studies. And I should say also there is a drug in our pipeline, an IV mTOR 3K inhibitor that I'm quite excited about and you will see that in addition to what we mention about CDK.

And finally, one example of an opportunity with risk but also high reward, the P38 inhibitors has been around for some time and we have actually quite exciting study in COPD and which could open potentially for a drug with disease modifying effect. So I think that gave you a mix of things of transforming capacity that's all in our pipeline, in addition to all the others that we have had an opportunity to discuss.

Ian Read - Pfizer Inc. - Chairman, CEO

Yes and I think David, just a comment on that. I think we've had -- we will have this year and potentially in the first quarter of next year or early next year we'll have had quite a bolus of really exciting approvals from potentially Eliquis, tofacitinib, we've had Inlyta, we've had Prevnar 13 adult, we've had Xalkori. So I think we've had a rich bolus of approvals this year and potentially in the beginning of next year. And then where we need to see us progress our Phase 3 cohorts and our Phase 2s into Phase 3s, a really strong differentiated, clinically differentiated products is the thing to look at.

Chuck Triano - Pfizer Inc. - SVP - IR

Thanks, Ian. And Operator, we have time for one more question.

Operator

Michael Tong from Wells Fargo.

Michael Tong - Wells Fargo Securities, LLC - Analyst

Most of my questions have been answered but just a couple. First one for Ian, as you think about Innovative versus Value Co in several years' time, what current synergy exists between the two businesses as they operate now and do they represent necessarily an impediments as you think about further breaking or further separating the two businesses? And then secondly, can you provide us with an update as to your biosimilar efforts, where they stand now and how you see that space playing out?

Ian Read - Pfizer Inc. - Chairman, CEO

Yes. So I think right now I would say at this moment in time on the synergies, clearly we have large Primary Care products that require substantial infrastructure and that is synergistic to our -- in our Emerging Markets to our branded products that sell on quality. And whether those synergies remain important really depends on how our portfolio is shaped over the next two to three to four years. So if the portfolio moves more in a direction of Specialty Products, then the potential synergies between a Value Co and an Innovative Co may be less in the future than they are today. So it really depends on how the portfolio develops, and that’s why I think this is a matter of looking at this as an evolving situation as we look at our options and we look at how to manage those businesses. And the last question was?

Chuck Triano - Pfizer Inc. - SVP - IR

Biosimilars.
Biosimilars, Olivier.

Olivier Brandicourt - Pfizer Inc. - President, GM - Emerging Markets and Established Markets

So biosimilar, we want to build on Pfizer's experience now in biologic development, manufacturing and of course commercialization. Second, the biosimilar market is expanding and is expected to grow from something around $1.5 billion today to $22 billion in 2020. So we want to build on that and we have successfully obtained IND for rituximab Pfizer product as well as trastuzumab biosimilars for Herceptin. And we have started clinical trials already.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you.

Chuck Triano - Pfizer Inc. - SVP - IR

Great and thank you everybody for your attention this morning.

Frank D’Amelio - Pfizer Inc. - CFO

Thanks, everyone.

Ian Read - Pfizer Inc. - Chairman, CEO

Thank you. Bye-bye.

Operator

Thank you for participating in today’s Pfizer second-quarter 2012 earnings conference call. This concludes the conference. You may now disconnect.