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PFE - Q3 2013 Pfizer Earnings Conference Call

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OVERVIEW:

PFE reported 3Q13 reported revenues of approx. \$12.6b and reported diluted EPS of \$0.39. Expects 2013 reported revenue to be \$50.8-51.8b and reported diluted EPS to be \$3.05-3.15.



CORPORATE PARTICIPANTS

Chuck Triano *Pfizer Inc. - SVP, IR*

Ian Read *Pfizer Inc. - Chairman and CEO*

Frank D'Amelio *Pfizer Inc. - CFO*

John Young *Pfizer Inc. - President and GM Primary Care*

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

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

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Andrew Baum *Citigroup - Analyst*

Steve Scala *Cowen and Company - Analyst*

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's third-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*

Thank you, operator. Good morning. And thank you for joining us today to review Pfizer's third-quarter 2013 performance. I'm joined today by our Chairman and CEO, Ian Read; Frank D'Amelio, our CFO; 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 home page, Pfizer.com, by clicking on the link for Pfizer quarterly corporate performance, third quarter 2013, located in the investor presentation section at 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 2012 annual report on Form 10-K, and in our reports on Forms 10-Q and 8-K. The discussions during this call will also include certain financial measures that were not prepared in accordance with Generally Accepted Accounting Principles. Reconciliation of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's current report on Form 8-K dated today, October 29, 2013.

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

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, Chuck. I will begin with some comments on the quarter. Overall, we delivered good operational performance, generated solid financial results, and continued to see steady progress with many of our inline products and pipeline assets. Operationally, revenues for the Oncology business grew 26%, due to the continued strong performance of new products, primarily Inlyta and Xalkori. We also had another strong quarter operationally from Lyrica, which grew 11%, and from Celebrex which grew 13%. Despite macro economic and other factors, the Emerging Markets business grew 5% operationally, primarily due to volume growth for key products in the Primary Care area, such as Lipitor, Norvasc, Lyrica and Celebrex, especially in China. We still anticipate achieving mid single-digit growth in emerging markets for the year.

Turning to an update on our recently launched and approved products and pipeline assets, earlier this month, we received FDA approval of Duavee, our novel combination therapy for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, and the prevention of post-menopausal osteoporosis. And we anticipate launching this product in the US during the first quarter of next year.

We and our partner Bristol-Myers Squibb continue to focus on improving the performance and physician uptake for Eliquis. In the US, we have seen positive momentum in the week-over-week growth in total prescriptions. And in late September, we launched our direct-to-consumer television advertising campaign. Eliquis also has been launched for stroke prevention and atrial fibrillation in several additional markets including Australia, Spain and Canada, where reimbursement has been established. We also see potential expansion opportunities for Eliquis with additional indications. With Bristol-Myers we submitted an sNDA in the US for VTE prevention in patients undergoing orthopedic surgery.

Turning to Xeljanz, we are pleased with the progress of the launch in the US and various other markets, which continues to be in line with our expectations, particularly in the context of being part of a large, but slow-growth segment within the anti-TNF market. We're seeing a steady increase in prescriptions. Comparing the third quarter with the second quarter of this year, we saw a 53% sequential growth in total prescription volume in the US. Overall, the physician's feedback on Xeljanz has been very positive. Satisfaction amongst users is high. In fact, nearly 3,000 healthcare providers have provided Xeljanz, and over 75% have been repeat prescribers.

We know that before prescribing, rheumatologists want to have a deep knowledge and confidence in Xeljanz's safety profile and clinical experience, particularly given it is a first-in-class product. To date, the vast majority of physicians have reacted favorably to Xeljanz's clinical profile. And we are focusing our efforts on continuing to educate physicians on Xeljanz's clinical data.

We also have several Phase 3 programs under way for Xeljanz. The Phase 3 program in psoriasis is progressing and is one of the largest global clinical trial programs in moderate-to-severe chronic plaque psoriasis to date. There are five studies in the program. Earlier this month, we announced the top-line results from the first two studies, which provided information consistent with our expectations based on the Phase 2 data in psoriasis. The other three studies in the Phase 3 psoriasis program include two pivotal studies and a long-term extension study. We anticipate top-line results for the pivotal trials in the second quarter 2014. And, we will issue a top-line data release after we've received and reviewed the results.

We have initiated a Phase 3 program to evaluate Xeljanz for the treatment of patients with active psoriatic arthritis, which includes two pivotal trials that evaluate the safety and efficacy of Xeljanz, and one long-term extension study. The first data from these trials is anticipated in 2015. And we continue to study Xeljanz for other important inflammatory diseases, with several Phase 2 and Phase 3 programs ongoing. This includes a Phase 3 program in ulcerative colitis and a Phase 2 program in Crohn's disease, ankylosing spondylitis and a topical formulation for psoriasis. We are also moving forward with a once-a-day modified release program for Xeljanz in RA. The FDA recently agreed that a Phase 3 study is not necessary for the once daily dose. And we plan to file a new drug application with the FDA in 2015.



Beyond the Xeljanz and Eliquis Phase 3 programs, we have or will be initiating several Phase 3 studies and we will be reporting on clinical trial data results from our Primary Care, Vaccines and Oncology portfolios. I continue to be pleased with the steps we have taken and the progress we are making towards improving our R&D performance.

Looking at the Primary Care pipeline, there are several promising candidates. This month, we are initiating a Phase 3 program for bococizumab, the proposed generic name for RN316, our PCSK9 monoclonal antibody to lower LDL cholesterol. This is a global program that includes multiple lipid-lowering studies, as well as two cardiovascular outcome studies in more than 22,000 patients. Compared to the PCSK9 inhibitor Phase 3 cardiovascular outcome trials being conducted by our competitors, only our bococizumab Phase 3 program includes a dedicated cardiovascular outcome study in patients who cannot achieve LDL levels lower than 100 mg per DL, despite the use of statins. This is a very high risk patient population with significant unmet need who represent a tremendous cost to our healthcare system.

Our second Phase 3 outcomes trial will address whether driving LDL cholesterol levels well below current guideline-recommended targets will lead to a further reduction in cardiovascular events. Importantly, compared to other programs, our Phase 3 program includes the broadest risk of high-risk patients in need of improved cholesterol management. We are currently completing the final analysis of the data sets of our completed Phase 2b study, and plan to present the results in a presentation at the American College of Cardiology meeting in March 2014.

We are planning to continue development of tanezumab for the treatment of osteoarthritis, chronic low back pain, and cancer pain. We have just entered into a collaboration agreement with Eli Lilly & Company to jointly develop and globally commercialize tanezumab, which provides that, in addition to certain potential milestone payments to Pfizer, Pfizer and Lilly will equally share product development expenses and potential revenues and certain product-related costs. The tanezumab program is currently subject to a partial clinical hold by the FDA pending submission of nonclinical data to the FDA, which we anticipate submitting in the first half of 2014. In addition, we are initiating a Phase 3 program with our partner Merck for ertugliflozin, our SGLT2 inhibitor for the treatment of Type 2 diabetes.

Turning to vaccines, we expect to have data readouts in three disease areas -- pneumococcal pneumonia in adults, meningitis B, and staph aureus. For pneumococcal pneumonia, the case accrual and CAPiTA trial involving Prevnar 13 adult has been completed. The processing of the cases will take several months to complete and we have not yet seen the data. We expect a read-out of the top-line results early in 2014.

For meningitis B, we anticipate sharing results of the Phase 2 study data in adolescents and young adults, who are the major carriers of this disease, at a key medical congress in the first half of 2014. Of note, our vaccine contains two protein components which elicit a broad immune response against the majority of meningitis B vaccine strains in these immunized individuals. We are encouraged by the efficacy and tolerability data we have seen to date. And have already initiated a pivotal Phase 3 clinical development program that includes Phase 2 and Phase 3 trials that will include more than 20,000 participants. If trial enrollment and recruiting goes as planned, data from this program are expected in the next several years.

For staph aureus, we recently included a Phase 2a study which showed encouraging signals that our vaccine elicits positive immune response. The next step is to move into a Phase 2b study in surgical patients. We anticipate sharing results from the Phase 2a study in the first half of 2014 at a key medical congress.

In oncology, we also anticipate several readouts in 2014. In breast cancer, we expect the final efficacy and safety data from the Phase 2 palbociclib study to read-out in early 2014 to be presented at ASCO in June of 2014 or at another congress next year. We have initiated two Phase 3 studies of palbociclib. One study mimics the trial design of the Phase 2 study in patients with post-menopausal ER positive HER2 negative advanced breast cancer, which has a planned enrollment of 450 patients. The other study is in patients with hormone receptor positive, HR positive and HER2 negative advanced recurrent breast cancer. It compares fulvestrant plus palbociclib to fulvestrant plus placebo. In addition, we expect to start a Phase 3 study for palbociclib in the next few months in early breast cancer for high-risk patients after neoadjuvant treatment.

For non small cell lung cancer, we are expecting top-line results from two Phase 3 studies of dacomitinib in the early part of next year.



We have five programs in various stages to develop biosimilars of innovator products. Our development program includes biosimilars for Herceptin, which is scheduled to start Phase 3 in the next few months. In addition, we have a biosimilar development program for Rituxan, Remicade and Humira that are scheduled for Phase 3 starts next year. And, our biosimilar for Avastin will begin Phase 1 next year.

The ongoing R&D investment level to support our late-stage pipeline opportunities is warranted by the significant revenue potential associated with these programs. And we expect that as these programs further progress, some incremental R&D investment will be necessary. That said, we will balance this need with overall shareholder return. And we will continue to be opportunistic regarding additional internal and externally sourced compounds that can further enhance our research pipeline.

I will close with a few words about the new commercial structure we have announced last quarter. We have been aligning talent, assets and individual reporting systems to support our new operating structure. We remain on track for commencing operations in the new structure at the start of 2014, and for providing a 2014 baseline management view of profit and loss for each business, starting with our financial results for the first quarter of 2014.

In summary, I believe we are making steady progress across the business, by enhancing the quality of the pipeline, demonstrating fiscal discipline in how we deploy our capital, and executing on our business plans in order to drive greater value for our shareholders. Now, I will turn it over to Frank to take you through the details of the quarter.

Frank D'Amelio - Pfizer Inc. - CFO

Thanks, Ian. Good day, everyone. I want to remind everybody that as a result of the full disposition of Zoetis on June 24 of this year, the financial results of the Animal Health business are reported as a discontinued operation in the condensed consolidated statements of income for year-to-date 2013 and third-quarter and year-to-date 2012. As always, the charts I'm reviewing today are included in our webcast. Now let's move on to the financials.

Third-quarter 2013 reported revenues of approximately \$12.6 billion, decreased 2% year-over-year, reflecting a 2% negative impact from foreign exchange. Excluding the impact of foreign exchange, revenues decreased operationally by \$38 million, or less than 1%, primarily due to the negative impact of the continued erosion of branded Lipitor in the US, developed Europe and certain other markets; the ongoing expiration of the Spiriva collaboration in certain countries; a decrease in government purchases of Prevnar and Enbrel in certain emerging markets; and the loss of exclusivity of certain other products, including Lyrica in Canada in February 2013, and Viagra in most major markets in Europe in June 2013. These were partially offset by the growth of certain inline products, including Lyrica, Enbrel, Inlyta and Xalkori globally, and Celebrex and Xeljanz in the US. I want to point out that reported revenue has also included \$67 million from transitional manufacturing and supply agreements with Zoetis, which are expected to continue for approximately two years.

Adjusted diluted EPS of \$0.58 increased 16%, primarily due to the aggregate decrease in adjusted cost of sales, adjusted SG&A, and adjusted R&D expenses of \$341 million, or 5%, due to the benefit of our ongoing cost reduction and productivity initiatives, the nonrecurrence of the \$250 million payment in the year-ago quarter for the acquisition of the exclusive over-the-counter rights to Nexium, which was included in R&D expenses, as well as the favorable impact of foreign exchange on these items of \$166 million, or 2%. These were partially offset by higher SG&A spending to support new product launches. In addition, there were fewer diluted weighted average shares outstanding, due to our ongoing share repurchase program, and the first full quarter impact of the Zoetis exchange offer, which also favorably impacted adjusted diluted EPS.

Reported diluted EPS was \$0.39, versus \$0.43 in the year-ago quarter and favorably impacted primarily by lower legal charges, lower acquisition-related and other costs, and fewer shares outstanding which were more than offset by the loss of exclusivity of certain products, lower income from discontinued operations, and a higher effective tax rate.

During the third quarter, biopharmaceutical revenues in the BRIC-MT markets increased 2% operationally, driven primarily by strong volume growth in China, especially for Lipitor. In these BRIC-MT markets, volume growth of 3% was partially offset by price reductions of 1%. Revenue from all emerging markets increased 5% operationally in the third quarter. If you exclude the portfolio of products whose rights were transferred to our



joint venture in China with Hisun in the third quarter, we would have had operational revenue growth compared to the third quarter of 2012 of 6% in our Emerging Markets business, 4% in the BRIC-MT markets, and 16% in China.

Foreign exchange negatively impacted third-quarter adjusted revenues by 2%, or \$271 million. And had a positive impact of 2%, or \$166 million, on the aggregate of adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses. As a result, foreign exchange negatively impacted third-quarter adjusted diluted EPS by approximately \$0.01 compared to the year-ago quarter.

Now, moving on to our 2013 financial guidance, based on our year-to-date performance and outlook for the remainder of the year, we are narrowing the ranges for certain components of our full-year 2013 financial guidance. We are narrowing the adjusted revenue range to \$50.8 billion to \$51.8 billion, from \$50.8 billion to \$52.8 billion. I want to remind everyone that beginning on November 1, 2013, we enter into the 36-month sunset period in the collaboration agreement with Amgen for Enbrel in the US and Canada. During this period, we expect that our share of the Enbrel collaboration, which is high margin because there is no associated cost of goods sold, will decline significantly. In addition, going forward, the recognition of profits from the Enbrel collaboration will shift from Alliance Revenue to Other Income, as we move to a royalty structure. Furthermore, these royalty payments will be much less than our current level of Enbrel profits. Outside of the US and Canada, however, our exclusive rights to Enbrel will continue in perpetuity.

I also want to point out that our Spiriva collaboration, which is also recorded in Alliance Revenue, will continue to wind down during the fourth quarter 2013, and 2014, most notably in the US and Japan. Currently, the majority of Alliance Revenue is composed of Enbrel in the US and Canada, as well as Spiriva.

Moving on to Adjusted Cost of Goods Sold as a percentage of Revenues, we are narrowing this range to 18% to 18.5%. We are narrowing our Adjusted SI&A expense range to \$14.2 billion to \$14.7 billion, while continuing to absorb launch costs in support of new products. We are narrowing our R&D guidance range to \$6.3 billion to \$6.6 billion, which will support our high-potential late-stage pipeline opportunities. We now expect Other Deductions to be approximately \$400 million. And continue to expect the Effective Tax Rate on Adjusted Income to be approximately 28%. We are narrowing and lowering the Reported Diluted EPS range to \$3.05 to \$3.15. And we are narrowing our Adjusted Diluted EPS range to \$2.15 to \$2.20 from \$2.10 to \$2.20.

Now moving on to key take-aways, third-quarter results continue to reflect the loss of exclusivity of certain products in various geographies, as well as the ongoing volatility in emerging markets. We continue to expect full-year operational revenue growth in our Emerging Markets business to be in the mid-single-digit percentage range. In addition, we continue to mitigate the earnings impact of product LOEs with both expense discipline and share repurchases. We narrowed the ranges for certain components of our Adjusted financial guidance. Our recently launched products are progressing at a measured and steady pace. We're advancing initiatives internally so that we will implement our new commercial structure at the start of 2014. We remain excited about our high-potential, late-stage pipeline assets. And expect to allocate R&D investments to support their advancement, beginning in the fourth quarter of 2013, or early 2014.

Finally, we continue to create shareholder value through the prudent allocation of our capital. To date in 2013, we have repurchased approximately \$13.1 billion, or approximately 46.2 million shares. We expect to expect to repurchase in the mid-teens of billions of dollars of our common stock this year. As a result, we expect to return more than \$20 billion to our shareholders this year between buybacks and dividends. In addition, we expect the first quarter 2014 dividend level to be set by our Board of Directors during our December Board meeting. And finally, we remain committed to delivering attractive shareholder returns in 2013 and beyond.

Now, I will turn it back to Chuck.

Chuck Triano - Pfizer Inc. - SVP, IR

Thank you, Frank. And, operator, please, if we could now poll for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Gregg Gilbert of Bank of America.

Gregg Gilbert - BofA Merrill Lynch - Analyst

Thanks a lot. To the extent that there are a couple of other PCSK9s out there, can you talk about what you needed to see in Phase 2 to make this large investment? And potentially how your product is differentiated, beyond the clinical trial differences you highlighted? And, secondly, Ian, curious how you think the collaboration in Japan is going with Mylan and whether you think that could be a good model in other places or more broadly. Thanks.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, Gregg. Clearly, we have seen in the Phase 2 data sufficient quality of data to encourage us to enter into Phase 3 and believe we have a highly competitive product. So I would ask John Young to give more details on that, and also discuss the Mylan collaboration.

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

Thanks, Gregg. So let me take PCSK9. Our focus is, first of all, we think we actually have a great antibody which came out of our Rinat labs in San Francisco. And I think, in addition to having excellent substrate to take into clinical development, we also believe that we have been able to put together a differentiated, or potentially differentiated, clinical program. So, our program will be the only program investigating both high-risk primary and secondary prevention populations. And when we begin to look at the program in more detail, it includes a dedicated CV outcome study in patients who can't achieve LDL levels lower than 100 milligrams per deciliter despite the use of statins. It is a very high-risk patient population with a lot of unmet medical need. And those patients, as you heard from Ian, really do represent tremendous costs to the healthcare system. So, positive outcome in that population, we believe, will be very significant. And we also combine in our program a second Phase 3 outcomes trial that will address whether driving LDL levels to well below current guideline-recommended targets will lead to further reduction in cardiovascular events.

And I think, lastly, the point to make is that, importantly, compared to other programs, our Phase 3 program includes the broadest range of high-risk patients in need of improved cholesterol management. And, as I said, uniquely includes both high-risk primary and secondary prevention patients. So, overall we believe that the combination of good basic substrate and the antibody, combined with a clinical program that we believe has the potential to demonstrate real differentiation across patient populations with significant unmet needs, will enable us to bring a very competitive profile into what is clearly a potentially very attractive and promising marketplace.

In terms of Mylan, we continue to make positive progress with Mylan in Japan. The collaboration is on track. Currently, we're selling around, about 250 products from the combined companies' generic portfolios. The transition integration of all 200 Mylan succondees to the Pfizer organization has been completed. And we've completed the launch of the collaboration's first generic pipeline products in June. Based on the initial performance, all nine products are forecasted to meet or exceed our full-year plans. So, let me just finish on Mylan and say that we are extremely pleased with the progress that we have made and we are going to look to maintain that momentum into 2014.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, John. I would add that we are also very comfortable and pleased with the quality of the partnership with Mylan.



Operator

Jami Rubin from Goldman Sachs.

Jami Rubin - *Goldman Sachs - Analyst*

Thank you. This is either for Ian or John. I'm just wondering if you could talk about how you plan to monetize the Value business. Just how do you see this business growing? What are the opportunities on the table that will help to unlock value? And are one of those opportunities to sell the business? And if so, is there a time limit? Do you have to wait a certain amount of time? I know that you have talked about the other businesses, if you were to spin them up, spin them out, you would have to wait three years. But is there a similar limit if you were to sell this business? Would you sell part of it? And, also, if you were to sell it, would you be willing to accept someone else's stock in exchange for it? And a follow-up question on PCSK9, your competitors are not planning on getting -- I don't believe, large outcomes trials to gain FDA approval. Do you feel that you need these outcomes trials for approval or is this just to broaden your label and for further differentiation? Thanks.

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

Jami, thank you for those questions. On PCSK9, I will ask John to comment on that first. But I think the issue is, in this marketplace, our trials are constructed so as to be able to demonstrate value to society and payers. John, do you want to add anything more to that?

John Young - *Pfizer Inc. - President and GM Primary Care*

Yes, I think in terms of the program, as I've already said, we believe we've put together a really robust and potentially differentiated program. Clearly, we know that LDL-C is a very well-established surrogate for cardiovascular risk. But certainly we know from dialogue and discussion we've had with the FDA that it is conceivable that regulators may require demonstration of a beneficial effect on CV events before approving a new class of agents such as PCSK9 inhibitors. At a minimum, robust LDL-C lowering, along with a comprehensive long-term safety database, will likely be required for differential approval of bococizumab and potentially of other medicines in the class, as well. And the bococizumab Phase 3 program is designed to address the potential for regulatory authorities to require, in addition to LDL-C lowering, a -- robust long-term clinical safety database and cardiovascular outcomes data for approval.

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

Mikael, do you want to add anything vis-a-vis the development of PCSK9 from a technical point of view?

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

Yes. We have put in a lot of technical capabilities, how to develop antibodies, with the most potent and biopharmaceutically appropriate characteristics. And when you look at the class, I think you can see emerging data suggesting some of the antibodies being very potent, and some being intermediate. And as Ian alluded to, we were very encouraged by the potent effect of our antibody in Phase 2 and its really robust LDL lowering, tolerability and low frequency of anti-drug antibody.

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

Thank you. And Jami, on your questions on the Value -- or, we call it, Established Products business unit -- right now we're focused on setting up the new organizational model where we have two Innovative businesses and one Established business. You know we're doing that because we firmly believe those businesses have different characteristics, and we want management uniquely focused on maximizing the growth opportunities of those businesses. So, John, who is running that part of the business, will clearly be looking at how to maximize the growth in the emerging markets, how to maximize our supply chain advantages in the developed markets, what growth opportunities there are in sterile injectables, either



organically or inorganically, are there other BD activities that can be undertaken in that business such as 505(b) filings. And, frankly, it is simply too early to speculate on the future developments of those business. Right now, as an organization, we are focused on getting them up and running, the management up and running, in place, looking at all of the different growth opportunities I just discussed, looking at supply chain. And once those businesses are up and running, and once there is transparency, then we will see how the market evaluates the sum of the parts of those businesses.

Operator

Chris Schott from JPMorgan.

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

Great. Thanks very much. Just following up on that, Ian, how long, do you think, are you going to want to see these three business units running separately before you will be comfortable and in a position to evaluate and make that decision on the next steps for Pfizer with regards to the strategic alternatives for your portfolio of businesses? Is that something that's going to take a year? Is it something longer? I'm thinking that next year is about setting them up. As we go out to '15, is that a time frame where it is reasonable to think about a decision on some of these? The second question I had, and similarly following up on Jami's question, if you were to decide that the Value core was something that made sense to separate from Pfizer, are there structures that would allow you to do that prior to 2017, if that's the right decision? Or is that something that's unreasonable to think about from a timing perspective. I am just trying to get some clarity on the timing if, in fact you went that direction with the business. Thanks very much.

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

Thank you, Chris. I don't have a fixed time line in my mind. Right now, we are really focused on the operational aspect, unless -- you know, the value of these businesses will come from their exquisite execution and management making them valuable by focusing on growth. And as that occurs, we will evaluate our options in a timely manner. And I'll ask Frank to comment on the actual mechanics of any type of transaction.

Frank D'Amelio - *Pfizer Inc. - CFO*

So, Chris, the way to think about that is, I will call it public transactions versus private transactions. In a public transaction, three years of audited financials are required. So, think about three years prospectively of audited financials. In a private transaction, a sale of a partial business, of an entire business, of some sort of a joint venture, in anything like that, it depends on a significance test. And there are three elements to the significance test. There is an asset test, an income test, and an investment test. And what really drives the requirement there for audited financials is, based on the size of the acquirer, and then the income, the assets, and the investment of what is being acquired compared to the acquirer's income, investments, and assets. And that can range anywhere from zero in terms of audited financials to up to three years. So that is really what will drive the audited financial requirements. But, once again, to punctuate what Ian said, what we're all about doing is getting these businesses to operationally hum and execute with excellence.

Operator

Tim Anderson from Sanford Bernstein.

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

Thank you. Two questions, please, if I could just go back to the split-up. Can you better characterize the possibility that Pfizer does not split itself up, in the complete sense of the word? You previously alluded to the idea that if the market appropriately revalues Pfizer, once they better appreciate



the financials for those different divisions, that perhaps a full split-up would not be necessary. So my question is, is it reasonable possible that you don't fully split up? And then on palbociclib, when might we start to see data in non breast cancers? It seems like you should either have data in hand already or you should very closely have it in hand on tumor types in the blood cancer area, in colorectal and in lung. And can you say so far that you haven't had any failures in any of these other tumor types?

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, Tim. This issue of split is totally dictated by what our view will be on how to maximize shareholder value at the appropriate time. So, when these businesses are operating, when there is transparency for analysts, when they have had time to establish a track record, then we will look at that and we will make decisions based on how best to maximize the value to shareholders, irrespective of size or composition or structure of residual companies. Because this management team is focused on producing shareholder value. And that is how we will take the decision. And I don't really think I can add anything more than that, other than to say that our guiding star is how to create shareholder value. Geno, would you like to talk about palbo?

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

Sure. Tim, let me just comment that our highest priority is to efficiently advance our breast cancer program right now with palbociclib. As Ian mentioned, we have initiated two of the Phase 3 trials. We will initiate another Phase 3 trial in breast cancer this year. And, frankly, we are looking at other breast cancer populations to explore further, as well. We're firmly in the lead here and we're really excited by the data. And this is our highest property. Notwithstanding that statement, we are exploring the use of palbo in a number of other tumor types, as you said, including melanoma and lung cancer, et cetera. These are primarily Phase 1 level studies, and we're not reporting any data at this point.

Operator

Mark Schoenebaum from ISI Group.

Mark Schoenebaum - ISI Group - Analyst

Thank you very much for taking my question. If I could turn back to the PCSK9s, if I may. Might you help us out with a timeline for the completion of the outcomes trials and let us know if there are opportunities in those trials for early stoppage based on interim results? And then could you also tell us what the dosing that is being used in the trial? Is it once a month, twice a month, et cetera? And then on CAPiTA, if I might, can you just walk us through the steps that need to occur after you see the CAPiTA data to ensure that sales pick up? I know you have to wait for certain recommendations, certain bodies, I wonder if you could just walk us through that. And is there a scenario where that trial misses statistical significance on its primary endpoint, Mikael, but that trends are robust enough that you could still see a recommendation coming out of the relevant bodies? Or do you really think you need to show statistical significance? Sorry for my long-winded question. Thank you.

Ian Read - Pfizer Inc. - Chairman and CEO

John, if you could talk a little bit about PCSK9 again, bococizumab, and then we will hand it over to, I think, Geno for the commentary on the CAPiTA.

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

Thanks, Mark. Obviously, it is fair to say that all of the PCSK9 programs are in relatively early stages of their clinical development. And, as I mentioned in answer to an earlier question, one of the things that all of the programs, including ours, will have to be determined, is the data sets as they emerge, and what will be required for approval. That is something that we'll continue to have dialogue with the agency about. So, I think it is really



premature to determine if there is any interim readout of data that would lead to an earlier approval, either a lipid-lowering indication or of the outcome indication. Mark, can you remind me of the second part of your question?

Mark Schoenebaum - ISI Group - Analyst

Dosing.

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

In terms of dosing, okay. The dosing schedule that we are taking into our clinical program is a twice-a-month dosing schedule. As you heard already from Mikael, we will be presenting the results of our Phase 2b study early next year. And from the analysis that we have done of that data so far, although it is incomplete at this point, but certainly we believe that that twice-a-month dosing schedule actually provides, really, the optimal consistent cholesterol-lowering rate across the dosage interval in order to obtain the optimal clinical effect and ideally the optimal clinical outcomes. So we feel really positive among the twice-a-month dosing schedule being the optimal dosing schedule for bococizumab.

Ian Read - Pfizer Inc. - Chairman and CEO

That being said, Mikael, do you want to add on something about the technology that we're excited about there?

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

Yes, to build on the excellent way in which John described our PCSK9 clinical strategy, it is a really well-behaving antibody. The twice-monthly administration schedule is the logical next step, as John described. However, we think that as part of a potential life cycle management strategy, there are opportunities to also explore once-monthly schedule. That may include the use of technology such as the Halozyme technology, for which we have an exclusive license within the PCSK9 class. And we are now performing early tests on the suitability of that technology to extend half life and also lower the volume that you need to inject. The antibody itself at the high dose has the potential for once-a-month, but we would rather see a technology like this to give a really convenient opportunity. So, as you can see, as we go forward with twice monthly, we have a life cycle management potential to offer additional regimens.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, Mikael. And Geno, CAPiTA?

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

Sure. With regard to the steps for CAPiTA, as we have indicated, we have completed accumulation of the required number of events. We're in the process now of finalizing the analysis of those events and completing the data management associated with creating our top-line results. And we are, at the same time, in discussions with the CDC and members of the ACIP, and the pneumococcal working group to ensure their understanding of the protocol and the potential outcomes, so that when we have the data, they can move on the data rapidly. So, we're in ongoing discussions with them -- and this is obviously in the United States -- so when the data is available, the working group will be exposed to the data, and will do their grading process and prepare for bringing those data and their assessment to the formal ACIP committee. The ACIP committee meets three times a year -- in February, in June, and in October. It is unlikely that we will have data available for the February meeting. But we are targeting the June meeting. It could occur in June or it could occur in October. So that is the US situation.

Ex-US, in most cases we don't have the pneumonia indication in most ex-US markets. Therefore, the CAPiTA trial results will form the basis for the pneumonia indication and we will file those applications. And depending upon the review times, we would expect to see the pneumonia indication



appear in the 12- to 14-month time frame beyond those filings. So, hopefully that gives you some sense of the steps and the timing associated with CAPiTA. With regard to the outcomes, there are multiple end points including vaccine type, non bacteremic pneumonia, vaccine type, all-cause pneumonia -- or vaccine type pneumonia -- and invasive pneumococcal disease. There are a number of different scenarios that can play out depending upon the outcomes. Obviously we're targeting the most favorable outcome, which would be demonstration of effect, positive effect, on prevention of vaccine-type non bacteremic pneumonia.

Operator

Marc Goodman from UBS.

Marc Goodman - UBS - Analyst

A couple of things. First, can you help us quantify the impact of these government purchases for Prevnar and Enbrel, with the lumpiness there, and how that is going to impact the next quarter? Second, in China, it looks like the growth continues very strongly there. Why are you not having the problems that some of the other players are having there? Can you just talk about the dynamics? Or maybe it is impacting you, and the growth would have been even better? And then, Geno, maybe you can just talk about some of the dynamics of the new oncology drugs that have launched and what is happening there and how those ramps are going. Thanks.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, Marc. If I understood the question, you would like to understand some of the seasonality or lumpiness in government purchases of Enbrel and Prevnar. So, perhaps, if John can talk about that in the emerging markets, and then deal with China. And then, Geno, if you will talk to Prevnar and the oncology products.

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

Thanks, Marc. Clearly there is some volatility. You've heard that the emerging markets, while they clearly represent overall significant continued opportunities for growth, but we do see quarter-on-quarter volatility, as you know. And particularly that is the case in the area of government tenders. So, without going into all of the details, but to give you a sense of some of the moving pieces, with Prevnar NIP shipments in Turkey this year, for example, we certainly have seen a fall in sales in Turkey this year. We had NIP sales last year. We haven't seen those year-to-date. In Brazil, we have seen decreased institutional purchases for Enbrel and also for Prevnar in the AFME, or Africa Middle East region. Enbrel Brazil shows around about a 2% decline this quarter and a 12% decline year-to-date, just to give you a sense of the rhythm of the business in Brazil.

And I think, overall, obviously the emerging markets represent a tapestry of markets around the world. But I think the high level message is, as we have always seen, we will see some quarter-on-quarter volatility, particularly in the area of institutional purchases. But overall the performance, the underlying performance of the business in the emerging markets for both Enbrel and Prevnar 13 remains very positive. But we have seen in those markets, in calling out Brazil and Turkey particularly, some volatility over the third quarter.

Ian Read - Pfizer Inc. - Chairman and CEO

And in China, we continue to operate as we have always operated, where globally we operate with a heightened sense and a strict sense of compliance obligations. I don't believe our business in China has been particularly affected by anything other than just the macro economic situations that are occurring across the emerging markets. The growth rate has slowed up somewhat in China compared to the previous year, but continues to be robust. And we continue to expect our Chinese business to perform well.



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

Just, Marc, a couple of comments on Inlyta and Xalkori, which we are really pleased with the progress that is being made there. For the quarter for Inlyta, we did \$83 million, which is about 200% above what we did last year same quarter, and double-digit increase over our prior quarter. About half of that is in the US where we grew by about 50% relative to last year. So we're seeing nice continued, fairly robust uptake of Inlyta. Physicians are really pleased with this product. Patients are responding well. We have about a 30% share, second line, in the US, and about a 35% share of second line in Japan. So we're doing well. We think, in many cases, our future growth will come from expansion of use beyond academic medical centers, and with oncologists who are very familiar with the drug. And we think there is good opportunity for further growth there.

And Xalkori is also becoming a great product. \$73 million for the quarter, up about 25% from last year and about 10% from the previous quarter. The trick there, it is the same story, we need to get the diagnostic in full use. We're at about 66% in the US, and a little bit less in Europe and Japan. So we will continue to work on that and continue to identify the appropriate patients and grow that business.

Operator

Seamus Fernandez from Leerink Swann.

Seamus Fernandez - Leerink Swann & Company - Analyst

Just first off, on potential moves between now and 2017, how should we be thinking about the prospects? I know that there is a group at Pfizer that is, I believe, constantly looking at opportunities to do incremental separations. Do you see that as a possibility? Is that something that Pfizer is consistently looking at between now and 2016? And do you see opportunities for value creation there? I guess that is more a question for Ian. And then, separately, on tanezumab, can you just update us again on where we stand with the anti-NGFs, scientifically, the move forward in osteoarthritis, chronic low back pain and cancer pain? And, again, how we should think about the potential changes in the development path as you partner with Eli Lilly. Thanks.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, Seamus. We set up the organizational construct because we believe it is the best way to focus and maximize the different parts of our business, as each segment represents, in my opinion, different models. It also gives us a lot of optionality going forward, as we look at ways of creating shareholder value. So, going back to your question, we are always looking at ways of maximizing shareholder value. And I think this construct gives us the maximum optionality and ability to look at different ways of creating that value. And we will take those decisions at the appropriate time as the opportunities mature. So with that, I will ask John to talk about tanezumab.

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

Okay, thanks, Seamus. Just to give you an update, I think as you know, in December 2012, the FDA placed a partial clinical hold on the development of NGF inhibitors, including tanezumab. That partial clinical hold was unrelated to the prior hold that related to bone- and joint-related safety. The latest clinical hold was based on peripheral nervous system effects observed in animal studies conducted with NGF inhibitors by other manufacturers. In April this year, we reached an agreement with the FDA on the path for removal of that partial clinical hold.

And to answer the questions which led to the partial clinical hold, I do think it was initiated to demonstrate sympathetic nervous system safety and the requisite nonclinical study in July of this year. And that study is progressing on schedule. So, we intend to submit the results from that study in the first half of 2014. And assuming a positive review of the nonclinical data by the FDA, and removal of the clinical hold, we are preparing to resume the Phase 3 studies for tanezumab early in 2014. So we are very excited about the deal that we announced today with Eli Lilly. And we believe that represents a very positive opportunity for us to collaborate, to take tanezumab into Phase 3 clinical development and ultimately, we believe, into the marketplace which clearly has significant need and opportunity for new pain treatment options. And so we're very excited about the potential for tanezumab, assuming that we are able to deliver positive data from those nonclinical studies. So hope that helps, Seamus.



Operator

John Boris from SunTrust.

John Boris - *SunTrust Robinson Humphrey - Analyst*

Thanks for taking the questions. First question for Frank, when you take a look at the Alliance Revenue, at least consensus estimates for Alliance Revenue in '14 and '15, I think they are around \$1.7 billion, \$1.8 billion. Are you comfortable with those numbers being where they're at in light of the expiration of the majority of your agreements? And then when you look at the consensus revenue estimate of \$50.5 billion for '14, can you just maybe walk us through some of the pushes, pull, or influencers, on losses of exclusivity that influence that number? And are you comfortable with it? Secondly, on the Mylan Pfizer agreement that you have in Japan, can you help us understand some of the accounting around that? And also the level of penetration that you got into the generic market in Japan. A very attractive opportunity there, especially in light of what the Japanese government is trying to push there. And then, lastly, just a pipeline question on the SGLT2, can you help us understand what the points of differentiation are, especially in light of there being three other entrants potentially in that market, before you enter? And then any thoughts around a combination strategy that you might have with Januvia. Thanks.

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

Thank you, John. Frank, do you want to address some of the projections in the question?

Frank D'Amelio - *Pfizer Inc. - CFO*

Yes. I think the way I will do this for 2014 in total is maybe some of the head winds and then some of the tail winds. In terms of head winds, no surprises. We continue to have some losses of exclusivity that will affect us in 2014. Enbrel entering the 36-month sunset period is one of them. Spiriva in Japan is another. So, there will be some LOEs that we will experience that will impact 2014. We said previously \$3 billion to \$4 billion in LOE impacts for the next couple of years. That is clearly what we're expecting for 2014.

If you look at some of the tail winds, we continue to expect growth in emerging markets. Some of our new products, we have had some nice growth in Xalkori, Inlyta, Xeljanz. We expect to see new product growth continue in a steady and measured way. And we have had some nice performance in some of our inline products -- Lyrica this quarter, Celebrex this quarter, 11%, 13% globally. So lots of opportunities there.

And in terms of addressing head winds, in addition to the opportunity areas on the top line, we will continue to manage our corporate expense structure, we will continue to use our balance sheet and our capital structure to help us manage the LOE and revenue head winds, like we've been doing over the last couple of years.

In terms of Alliance Revenue, let me just run the numbers and then I will answer the question. If you look at the Alliance numbers this quarter, \$700 million, down from \$900 million in the year-ago quarter, down 22%. Year to date, down 15%, \$2.6 billion to \$2.2 billion. The majority of the Alliance Revenues to date are really from Enbrel and Spiriva. And going forward, the Alliance Revenues are going to come from Rebif, which is in the numbers today, and then obviously Eliquis growing. So that will be the rhythm of the numbers relative to the Alliance Revenues. But clearly, on a going forward basis, the Alliance Revenues will be declining, and they will be declining significantly.

In terms of Mylan accounting, I think the simple answer is we record the revenues from the products that are coming out of the collaboration.

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

John, do you want to make any comment on the penetration in the market or is it too early to do so?



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

Yes, I think it is really too early, John, to talk about penetration and market share, specifically, other than to say that we are on track. We have met all of our milestones in terms of the transfer of Mylan colleagues into the Pfizer organization. We are currently selling around about 250 products from the combined companies' generic portfolios in the marketplace. And the project plan is in place to transition all Mylan inventory to Pfizer distribution, which is a real strength of our organization in Japan. Processes and work are in place to address any quality supply risks.

In terms of manufacturing and development, initiatives have kicked off to build manufacturing capacity for collaboration volumes. And I think the overall message on Mylan is the joint venture is certainly progressing very much according to our plans.

In terms of our ertugliflozin, we, as you know, entered into a worldwide collaboration, except Japan, with Merck to develop and commercialize ertugliflozin, our ertugliflozin-containing fixed-dose combinations with metformin and Januvia tablets. It is our innovative proprietary SGLT2 inhibitor for treatment of Type 2 diabetes. And we are initiating Phase 3 clinical trials with our partner Merck. I certainly don't want to comment in detail about competitors in this class, other than to say that our two lead competitors have had probably a troubled regulatory pathway in the US and Europe. And we believe that the dialogue that we have been able to have with the FDA, as well as the strength of the molecule, certainly has enabled us to put together a development program, combined with the strength of our partnership with Merck, that gives us a very good runway into the marketplace.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, John. Mikael, do you want to comment on the technical aspects of our product and differentiation?

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

Yes, let me build on that excellent discussion that John had on ertugliflozin. It is a highly selective molecule for the SGLT2 transporter. And as you will learn when you explore that class, there is difference in the selectivity among the molecules. It's highly potent. It is a very low dose which is really a key characteristic, when you aim to combine with other drugs, such as a market-leader Januvia and metformin. It performed very well in the Phase 2 studies, with robust lowering of our hemoglobin A1c, and also favorable effect on blood pressure. So we think really these unique characteristics of our best-in-class molecules, combined with long experience with Januvia, allows for a very favorable long-term opportunity here.

Operator

Alex Arfaei from BMO Capital Markets.

Alex Arfaei - BMO Capital Markets - Analyst

Good morning, and thank you for taking the questions. Two, if I may. Ian, I wanted to get your latest thoughts about entering the cancer immunotherapy market. Perhaps partnering palbociclib for breast cancer with one of the leading PD1s. It seems like that could be a pretty promising combination. And a follow-up, we recently heard some negative comments from your peers about entering the biosimilar market, including commercial risks. So I'm just wondering, what is that's made you confident to proceed with a fairly aggressive biosimilar strategy? Thank you.

Ian Read - Pfizer Inc. - Chairman and CEO

In the biosimilar market, each company takes its own view of the commercial opportunities. We feel that we have the technology and the ability to bring biosimilars to the market that will be very well characterized. We believe that in that marketplace, we don't see it reacting like the small molecule generic market. We believe it will probably act more like the sterile injectable market. We bring to that commercialization the credibility



and the quality of Pfizer's manufacturing and research. And we think it is a reasonably low-cost development opportunity for products that have a high commercial opportunity. So, we think it is a good appropriate allocation of resources for the potential payoff. Geno, would you like to talk about the immunotherapy. And, if you want, pass it off to Mikael, as well, between the two of you.

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

Alex, it is obviously a pretty active, exciting time with all that is happening with the checkpoint modulators, using monotherapy in various combinations across many different tumor types. We see this as an emerging field, with a lot of experimentation going on to identify appropriate patients and appropriate combinations. And we're actively exploring a number of mechanisms ourselves internally with our 4-1BB monoclonal antibody and some of the vaccine approaches that we have access to, as well as looking at potential partnerships.

Ian Read - Pfizer Inc. - Chairman and CEO

Mikael, do you want to add?

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

Yes, I think Ian described it very well. We have, of course, invested heavily in our signal transduction inhibitor. And as you mentioned palbociclib is one of the real example of potential breakthrough drugs here. But the ability to combine small molecule, large molecule with cancer immunotherapy is going to have a very interesting potential. And we have, as Geno alluded to, a number of internal activities but are also open for partnership, which in general we have shown is a great way to grow value in this industry.

Operator

Tony Butler from Barclays Capital.

Tony Butler - Barclays Capital - Analyst

Thanks very much. And back to biosimilars. You alluded to the notion that there would be some incremental R&D costs. Could you provide some color around that, please? And then, secondly, if I may, one question on meninge B, the 20,000 patient study, could you provide some timing for total enrollment and when that might read out? And moreover, Mikael, do you need high titers to both proteins in order to provide appropriate killing of the bacteria? Thanks very much.

Ian Read - Pfizer Inc. - Chairman and CEO

Tony, I wasn't quite sure of your question on the biosimilars. The incremental R&D expenditures per se, because of biosimilars, is because what I think I described as a very strong cohort of Phase 3 products coming in development in the near future. And one that we are also, where appropriate, partnering to ensure that we maximize shareholder return. Mikael, do you want to talk about the titer issue?

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

Yes. Thank you for your interest in Mening B. And we do think it is a very important vaccine. It is the missing component in meningococcal strains, the meningococcal B. We have three trials that are well underway -- efficacy, and safety and lot consistency trial. And we believe that you should aspire to raise relevance titers to both proteins. Together these two proteins, that were carefully selected during our development process, they will cover the great majority of meningococcal strain, which is a unique feature of our vaccine. And we noticed in our Phase 2 trial robust titers and good tolerability. As you know, we are focusing on adolescent population, which is the main carrier of the disease.



Frank D'Amelio - Pfizer Inc. - CFO

Thank you. And, Tony, just to expand, the biosimilar spend, we have been spending, and it is in our baseline spend of our development programs. So I didn't particularly see that as a driver of our R&D spend.

Ian Read - Pfizer Inc. - Chairman and CEO

And, Geno, just on the timing of enrollment or anything, do you have comments there for Mening B?

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

We are enrolling now. And I think we anticipate completing enrollment in the 2015 time frame.

Operator

Andrew Baum from Citi.

Andrew Baum - Citigroup - Analyst

Good morning. A couple of questions, please. First, Ian and Frank, back to portfolio management, could you give us some guide to the total cost and the phasing of those costs for the operational separation of the Established Product business, just in helping us understand how optionality pans out. And then, second for Mikael, could you give us an update on the Phase 1 anti 4-1BB CD137 trial. It has been running for two-and-a-half years in a very refractory patient population. What are the chances we could get data prior to 2015? Thank you.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, Andrew. Frank, if you could take us through the implications of the structuring and the costs and the timing of that, et cetera. And then Mikael can answer the second question.

Frank D'Amelio - Pfizer Inc. - CFO

Yes. I think in terms of implementation costs, there are not material implementation costs. In fact, as we look at the new structure, there are some opportunities for synergies to the tune of a couple hundred million dollars, minimal amounts in 2014 as we're basically getting the structure in place. Then we see an opportunity in 2015, 2016, to capitalize on the new structure and generate a couple hundred million in operational synergies. So that is how I think about the puts and the takes on that.

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

For 4-1BB, the mechanism seems to activate the immune cells, particularly T cells. And you're right, we have been exploring it for quite some time to fully understand its property. And we have studies ongoing, dose escalation studies, both as monotherapy and in combination with Rituximab in hematological patients. We are also looking at the combination of 4-1BB with other immunotherapies as part of our plans. And we will share the data as this protocol wraps up at relevant conferences.



Operator

Steve Scala from Cowen.

Steve Scala - Cowen and Company - Analyst

Thank you. A couple of follow-ups. With respect to the headwinds from the wind-down in the Enbrel North America and Spiriva collaborations, would an estimate of \$1 billion reduction in net income for these collaborations be a reasonable guess for all of 2014? That's the first question. Second is, how do you assess the Herceptin biosimilar opportunity, given that the standard of care in HER-2 positive breast cancer is evolving so quickly, and that evolution may limit Herceptin's role over time? Meanwhile, Roche says it will compete aggressively, and there may be other biosimilar competitors, as well. So, is a shrinking market with unknown number of competitors attractive? And then, lastly, on the staph vaccine, you said data in 2014. On the second-quarter call you had said data later this year. So, any reason for that slight delay? Thank you.

Ian Read - Pfizer Inc. - Chairman and CEO

Frank, if you could comment on the Alliance Revenue, and then John on Herceptin and the nature of that marketplace, and the pressures from managed care. And I think Mikael, on the timing.

Frank D'Amelio - Pfizer Inc. - CFO

On the Alliance Revenue, I ran the numbers before on Alliance Revenue. We will provide an update on the 2014 revenue number in the guidance for 2014 on our next earnings call. We will incorporate into that number, obviously, the impact of the Alliance Revenue decline, on a year-over-year basis. So, on the next earnings call, we will provide the details on 2014.

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

And in terms of the question on biosimilars, almost by definition, biosimilars don't lead clinical practice. They follow it. So, clearly today, we know that overall the biosimilars marketplace, the biotherapeutics marketplace, is around about \$100 billion marketplace globally for all biotherapeutics. And that marketplace is expected to grow to around about \$300 billion by 2019. So, the first point to make in terms of our presence in the biosimilar marketplace is biotherapeutics overall is a very significant opportunity. And the biosimilar segment of that is expected to grow from its current value of around about \$1.4 billion to potentially around about \$22 billion by 2020. So the key point to make there is it is a big opportunity.

In terms of Herceptin, clearly don't want to comment on our competitors and any additional therapeutic research that they are doing, other than to say that, today, Herceptin remains a standard of care for that particular patient population. And so at the point that we have a biosimilar available to enter into the marketplace, then we believe that that would be a potentially good option for physicians and healthcare systems to use in patients for whom Herceptin or that molecule trastuzumab is an appropriate clinical choice.

Ian Read - Pfizer Inc. - Chairman and CEO

Mikael, on timing.

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

Yes, so we have completed successfully a Phase 1/2 trial. And our Herceptin is a very good biosimilar version of the originator. And we are now in the plans of starting a Phase 3 that will be initiating dosing within the next couple of months. And just to add to what John said, clearly, as you discussed, there will be always an evolving marketplace in many of these indications which are driven by a continuous flow of product. We do see



still that many of these new regimens include combinations with Herceptin, biologicals on top of Herceptin, instead of traditional chemotherapeutics. And we anticipate that our molecule could offer a quality alternative.

Ian Read - Pfizer Inc. - Chairman and CEO

And on the staph aureus, I haven't looked at the transcript, perhaps we misspoke. I think perhaps we said we had data or had internal data on staph aureus in that time period, but we intend to take it to a congress next year. So probably that was the confusion we created. And if we did, we apologize for that.

Chuck Triano - Pfizer Inc. - SVP, IR

I think that's right, Ian. I think it was a presentation of the data. Next question, please.

Operator

David Risinger from Morgan Stanley.

David Risinger - Morgan Stanley - Analyst

Yes, thanks very much. I just have two questions. First, with respect to the CAPiTA outcomes trial, could you just talk about the reason for the delay in the results, just recap why it has been delayed so long? I'm guessing you are going to say it is simply event accrual. But is there any way to read anything positive or negative into the delays relative to the expected timing when CAPiTA was started many years ago? And then, separately, with respect to biosimilar Herceptin, do you have agreement with the FDA on how that trial will be run in the US? And, also, when do you plan to file biosimilar Herceptin in the US and ex-US? Thank you.

Ian Read - Pfizer Inc. - Chairman and CEO

Geno, if you would like to talk about CAPiTA.

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

I think on CAPiTA, David, you're right, I probably will say that it is event-driven. And when we have some number of events, we have the number of events. But just to comment on a couple of factors. The incident of infection often coincides with the severity of the flu season, for example. If the flu seasons have been milder, then you may not have as many events, and that can be a factor contributing to accumulation of events. And then there is overall efficacy or effectiveness of the vaccine. Obviously, if the vaccine is extraordinarily effective, then the only events you are going to accumulate are the ones in the placebo group. You won't accumulate any or very few in the vaccine group. That would be a good problem to have. And we will know soon what the real answer is.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you, Geno. John, could you talk about Herceptin?

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

Yes. I don't want to talk in detail about filing timelines. But in terms of your question about the regulatory pathway, certainly the EU and the US have increasingly provided more guidance on the pathways for regulatory approval, which include extensive analytical and preclinical data, robust comparative clinical and immunogenicity data, as well. And that development is consistent with our development strategy for our portfolio of biosimilars, including trastuzumab. We anticipate a Phase 3 start for that program by the end of the year, and we will be progressing that program in line with that guidance as expeditiously as possible.

Chuck Triano - Pfizer Inc. - SVP, IR

Thanks, John. And I think with that, we will complete our call. Thank you very much, everyone, for your attention this morning.

Ian Read - Pfizer Inc. - Chairman and CEO

Thank you.

Operator

Ladies and gentlemen, this concludes today's Pfizer's third-quarter 2013 earnings conference call. Thank you for participating. You may now disconnect.

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