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PFE - Q4 2012 Pfizer Earnings Conference Call

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OVERVIEW:

PFE reported 4Q12 revenues of approx. \$15.1b and reported diluted EPS of \$0.85. Co. expects 2013 reported revenue to be \$56.2-58.2b and adjusted diluted EPS to be \$2.20-2.30.



CORPORATE PARTICIPANTS

Chuck Triano *Pfizer Inc - SVP of IR*

Ian Read *Pfizer Inc - Chairman and CEO*

Frank D'Amelio *Pfizer Inc - CFO*

Olivier Brandicourt *Pfizer Inc - President and General Manager, Emerging Markets and Established Products*

Geno Germano *Pfizer Inc - President and General Manager, Specialty Care and Oncology*

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

CONFERENCE CALL PARTICIPANTS

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PRESENTATION

Operator

Good day everyone, and welcome to Pfizer's fourth-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 of IR*

Thank you, operator. Good morning, and thank you for joining us today to review Pfizer's fourth-quarter and full-year 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 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 at Pfizer.com by clicking on the



link for Pfizer quarterly corporate performance fourth 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 measures can be found in Pfizer's current report on Form 8-K dated today, January 29, 2013.

In addition, we will offer some brief comments regarding the potential IPO of a minority stake in our Animal Health business, Zoetis. As I'm 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 and CEO

Thank you, Chuck, and good morning, everyone. During my remarks this morning, I will briefly recap the progress we made in 2012 improving the performance of our innovative core and in creating value for our shareholders. I'll also discuss our focus for 2013.

2012 was a year of very strong operational financial performance, especially given our LOE challenges. We drove operational growth in many of our key products in the patent-protected portfolio, including Lyrica, Enbrel, Prevnar 13, Celebrex, and Sutent. Operationally, Emerging Markets grew 12%, Animal Health grew 6%, and the Consumer business grew 8%. Also during 2012, we executed on our plans for allocating capital in ways that enhanced shareholder value. We reduced our total adjusted cost of sales, SI&A, and R&D expenses on an operational basis by approximately 10%, which is nearly a \$4 billion reduction versus 2011 levels. We realized significant value for our shareholders through the sale of our Nutrition business to Nestle for \$11.85 billion, and we're on track, subject to market conditions, to unlock value from our Animal Health business by completing our IPO of Zoetis in the near future. And we returned nearly \$15 billion to shareholders through dividends and share repurchases. Our focus on creating a productive and sustainable innovative core is yielding results.

Our fourth quarter was highlighted by two important product approvals, Xeljanz in the US, and Eliquis in the US, Canada, the EU, and Japan. Along with our partner, Bristol-Myers Squibb, we are looking forward to launching Eliquis in the US shortly and believe its strong clinical profile can establish this medication as an important new treatment option in the high-need area of stroke prevention for patients with nonvalvular atrial fibrillation. Our Specialty Care business is in the initial phase of launching Xeljanz in the US, a first-in-class compound with a compelling clinical profile and oral dosing. We believe these factors will position it competitively within the moderate-to-severe rheumatoid arthritis market. We are prepared to invest in both of these products at competitive levels to support their launches.

In addition to Xeljanz and Eliquis, during 2012, we received approval for three additional new medicines, Inlyta for advanced renal cell carcinoma in the US, the EU, and Japan; Bosulif for CML in the US; and Elelyso for Gaucher disease in the US. During the year, we also advanced our early and mid-stage pipeline, most notably in oncology and vaccine areas. We moved forward in Phase 3 studies with dacotinib for non-small cell lung cancer and inotuzumab for aggressive non-Hodgkin's lymphoma. We reported encouraging Phase 2 data for our CDK 4/6 inhibitor for advanced breast cancer. This asset, formerly known as PD-332991, is now called palbociclib. We commenced a Phase 3 study of inotuzumab for acute lymphoblastic leukemia and we began a Phase 3 study for inotuzumab for acute lymphoblastic leukemia, and we began a Phase 3 study for meningitis B vaccines for individuals aged 11 to 25. I believe we are entering 2013 with one of the most robust pipelines in the Company's recent history.

The actions we've set in motion early in 2011 to improve R&D productivity are starting to bear results, and we look forward to additional progress during 2013. We have a pipeline that I believe includes high-value assets at all stages of the development continuum across our key therapeutic areas. As of late last year, our pipeline contained a total of 78 programs, including 59 new molecular entities. There were 17 programs in Phase 3 clinical testing and 8 in registration. Throughout 2012, we concentrated on advancing our pipeline, reducing our cost structure, and returning value to our shareholders. I believe that through the dedication and focus of Pfizer colleagues, we have delivered on each of these goals.

Turning to 2013, as I've discussed with you on previous calls, we have two distinct operating models within the developed markets. One model supports our innovative-driven business, Primary Care, Specialty Care, and Oncology. The second model supports our value-driven business that comprises the off-patent products within our Established Products unit. In terms of the emerging markets, our operational model has a geographic focus that supports both the innovative-driven and the value-driven business. This is working well in these high-growth geographies. That said, as these markets evolve, we will evaluate if our emerging markets operating model should more closely mirror the two distinct approaches we have for developed markets, and the Consumer Healthcare business continues to be important as we pursue Rx-to-OTC switch opportunities. We believe these are the right models for achieving the best performance for the Pfizer over the next several years. During this time, we will be able to focus on the market success of our new products, advance our early and mid-stage pipeline, drive continued growth in Emerging Markets in both our innovative and off-patent portfolio. Additionally, we'll have put behind us our most significant LOEs.

We will also continue to use business development opportunities to supplement both our research and internal product efforts. Our primary focus remains bolt-on acquisitions that are projected to meet or exceed the return on investment of share repurchases. More specifically in 2013, you will see us focused on -- continuing to maximize the value of our in-line portfolio, including key in-line assets such as Lyrica, Celebrex, Enbrel, Viagra, and Plevnar 13; maximizing the performance of the products approved in the last two years; continue to advance the mid- to late-stage pipeline in vaccines, oncology, cardiovascular inflammation; focusing on the high-growth, high-margin off-patent opportunities; focusing opportunities in key growth markets such as China, Brazil, Russia, India, Turkey, and Mexico; continuing to work on managing our expenses and driving ongoing efficiencies within our manufacturing network so we have a lower and flexible cost base that allows us to respond to pricing pressures in our upcoming LOEs; and continuing to return capital to shareholders through dividends and share repurchases.

In summary, our results in 2012 demonstrated that we are focused on the right areas and are making visible progress towards sustained value creation. In 2013, we must maintain our momentum by continuing to execute, by delivering on the potential within our pipeline, and by demonstrating fiscal responsibility in how we use our capital. We are committed to helping patients by delivering innovative medicines and creating value for our shareholders. Now I'll turn it over to Frank for additional details on the quarter and our 2013 financial guidance.

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 again remind you that the Nutrition business is presented as a discontinued operation in the consolidated statements of income for all periods presented. As you know, discontinued operations are excluded from adjusted financial results. Consequently, throughout 2012 until its sale on November 30th, the results of the Nutrition business have been excluded from adjusted results. Now let's move on to the financials.

Fourth-quarter 2012 revenues of approximately \$15.1 billion decreased 7% year-over-year, reflecting a 2% negative impact from foreign exchange, and an operational decline of approximately 5%, driven mainly by the loss of exclusivity of several key products in certain geographies, notably Lipitor, in all major markets. Adjusted diluted EPS of \$0.47 decreased 4%, primarily due to the previously mentioned decrease in revenues, which was partially offset by an aggregate operational decrease of 9%, in adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses, primarily resulting from cost reduction and productivity initiatives and fewer weighted average shares outstanding due to our continued share repurchases. Reported diluted EPS was \$0.85, compared with \$0.19 in the year-ago quarter. In addition to the factors previously mentioned, reported diluted EPS was favorably impacted by the gain on the sale of the Nutrition business to Nestle and lower overall costs, which were partially offset by the negative impact due to the loss of exclusivity of certain products in several geographies and higher restructuring charges.

Foreign exchange negatively impacted fourth-quarter revenues by 2%, or \$271 million, and unfavorably impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses by \$161 million, or 1%. As a result, foreign exchange negatively impacted fourth-quarter adjusted diluted EPS by approximately \$0.05.

In the fourth quarter of 2012, Emerging Markets biopharmaceutical revenues were approximately \$2.7 billion, which reflects operational growth of 20% and the negative impact of foreign exchange of 3%. The revenue growth in Emerging Markets this quarter was driven primarily by strong volume growth in China, overall emerging market growth, as well as the timing of government purchases of Enbrel in Brazil and Plevnar 13 in Turkey compared with the year-ago quarter. Volume growth of 22% in Emerging Markets was partially offset by price reductions of 2%, resulting



in the 20% operational growth. Of the fourth-quarter Emerging Markets biopharmaceutical revenues, approximately 42% was generated by established products, 34% by specialty and oncology products, and 24% by primary care products.

Fourth-quarter biopharmaceutical revenues in the BRIC-MT markets were approximately \$1.2 billion, which reflects operational growth of 26% and the unfavorable impact of foreign exchange of 4%. Of the fourth-quarter BRIC-MT biopharmaceutical revenues, approximately 46% was generated by Established Products, 29% by Specialty and Oncology products, and 25% by Primary Care products. During the fourth quarter, biopharmaceutical volume growth of 30% in the BRIC-MT markets was partially offset by price reductions of 4%, resulting in operational revenue growth of 26%. Full-year operational growth in the BRIC-MT markets was 16% versus the year-ago period, reflecting volume growth of 20%, partially offset by price reductions of 4%.

As you can see, in 2012 we met or exceeded most components of our financial guidance, including achieving the top end of our full-year 2012 revenue guidance and exceeding our adjusted diluted EPS guidance. Our 2012 adjusted R&D expenses of \$7.3 billion reflect opportunities to accelerate investments in promising late-stage pipeline assets, including palbociclib in advanced breast cancer. However, I want to point out that we expect full-year 2013 adjusted R&D expenses to be in the range of \$6.5 billion to \$7 billion. And as I previously mentioned, reported diluted EPS was primarily favorably impacted by the gain on the sale of the Nutrition business.

Now moving on to our 2013 financial guidance, which incorporates the full-year contribution from Zoetis. I'd like to comment specifically on a few elements of the guidance. First, we expect reported revenues to be in the range of \$56.2 billion to \$58.2 billion. I want to point out that this range includes the absorption of an anticipated \$4 billion negative impact due to the loss of exclusivity of certain products in several geographies and to the near-term expiration of certain co-promotion agreements. In addition, it's important to note that approximately \$200 million of 2012 revenues associated with products that Pfizer is contributing to the Pfizer Hisun joint venture in China announced in 2012 will not be recorded as Pfizer revenues in 2013. The results of the joint venture will be recorded in other income. We expect 2013 SI&A to be in the range of \$15.6 billion to \$16.6 billion, the midpoint of which is less than the 2012 actual spending level. This range includes spending in support of key product launch opportunities such as Eliquis, Xeljanz, and Prevnar 13 adult. These are significant product opportunities, and we intend to appropriately fund and support these launches to be competitive. In addition, we plan to essentially offset those incremental expenses through our cost-reduction initiatives.

We also expect our 2013 tax rate on adjusted income to be approximately 28%, which, among other items, includes the federal R&D tax credit renewed by Congress under the American Taxpayer Relief Act for both 2012 and 2013. Finally, we expect adjusted diluted EPS to be in the range of \$2.20 to \$2.30. This range includes a \$0.02 unfavorable impact for certain ongoing costs associated with the potential separation of Zoetis, including the interest expense on Zoetis debt, certain duplicative costs for Corporate support and manufacturing functions, and other costs, as well as a \$0.02 negative impact, reflecting the difference in actual foreign exchange rates in 2012 compared with the mid-January 2013 exchange rates. As always, we will continue to monitor foreign exchange fluctuations, and we'll update the potential impact, if any, on our 2013 expectations. I want to point out that with all other things being equal, the inclusion of the \$0.02 of cost related to the separation in Zoetis and the \$0.02 impact of recent foreign exchange movements has negatively impacted our 2013 adjusted diluted EPS guidance range by \$0.04. Excluding these items, our adjusted diluted EPS guidance range would have been \$2.24 to \$2.34.

Now, moving on to key take-aways. We achieved the top end of our full-year 2012 revenue guidance and exceeded our adjusted diluted EPS guidance. Our initial 2013 financial guidance includes the full-year contribution from Zoetis. We recently completed a \$3.65 billion offering of Zoetis senior unsecured notes, and we remain on track to complete a potential initial public offering of up to a 19.8% ownership stake in Zoetis in the near future. In November, we completed the sale of our Nutrition business to Nestle for \$11.85 billion. During the fourth quarter, we received US regulatory approvals for Xeljanz and Eliquis. We continued to create shareholder value through prudent capital allocation. In 2012, we repurchased \$8.2 billion, or 349 million shares. As of December the 31, 2012, we had \$11.8 billion of authorization remaining under our current repurchase programs. Overall, we returned almost \$15 billion to our shareholders in 2012 through dividends and share repurchases. Finally, we remain committed to delivering attractive shareholder returns in 2013 and beyond. With that, I'll turn it back to Chuck.

Chuck Triano - Pfizer Inc - SVP of IR

Great. Thanks for the commentary, Frank. And operator, at this point, if we could please poll for questions.



QUESTIONS AND ANSWERS

Operator

Thank you.

(Operator Instructions)

Tim Anderson, Sanford Bernstein.

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

Thank you. On your tax rate guidance in 2013, can you say what it would be without the double-counting of the R&D tax credit? You had at one time -- actually, at the time of the Wyeth merger, suggested a long-term rate of 30%. Seeing what Bristol-Myers has done on lowering its tax rate remarkably, I'm wondering if you have any ability to restructure any of your legal entities as well? A second question, and it's obviously one that you get asked about a lot, but can you give us your latest thoughts on potentially carving up the drug side of the business into truly separate companies like you're doing with Zoetis? You've been alluding to this possibility for quite some time now, but I think investors don't really know what sort of odds to assign to it. Would you say it's higher probability? Is it fifty-fifty odds, or is it lower probability?

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Tim. I'll ask Frank to take care of the tax rate guidance and explain the 30% tax rate and any other comments you want to make on taxes.

Frank D'Amelio - Pfizer Inc - CFO

Sure. Tim, on the 28%, which is down from 29.3% in 2012, even if we didn't have, I'll call it the double benefit of the R&D tax credit in 2013, our tax rate would be closer to 28% than to 29%. That's the way to think about it. By the way, what will happen in 2013 is we'll record the 2012 benefit in Q1, and then 2013 benefit we'll record throughout the year, just in terms of the accounting mechanics of the R&D tax credit. In terms of legal entity restructuring, the way I think about that is our tax planning. We do tax planning all the time. If you look at our tax rate over the last couple years, it's gone from 30% to last year slightly higher than 29%, and now our guidance for this year is approximately 28%. We'll obviously continue to do tax planning, but the one thing I'll say is trying to project tax rates beyond 2013, given everything that's going on, and with the uncertainty with just corporate tax reform, I think is not a prudent thing to do. Our current guidance is approximately 28%, and obviously, we'll do everything we can to meet or exceed that guidance.

Ian Read - Pfizer Inc - Chairman and CEO

Tim, on your additional question on the business models, I think I've been talking for some time now when discussing this with investors that I see that we have two models -- or two businesses within Pfizer today -- major segments, one being the innovative core and one being what we call value, which is basically post-LOE products. And we have made their operational separation in the developed markets, in the US and in Europe and in Japan, in Australia, in Korea, and places like that. We haven't made that separation in the Emerging Markets where we run it from a geographic basis, although in the major markets, we are moving towards creating units within those geographies that specialize in Oncology or Primary Care or Established Products. I believe that at some point, the markets will separate globally, and there will be an innovative market distinct from an Established Market, and I think Pfizer will continue to evolve into being managed that way. So I hope that answers your question. Right now, as I think I had said in my opening comments, Emerging Markets is working well. Our structure in the developed markets is working well. We are focused on the new launches, the pipeline, our capital allocation, expense discipline, and we will continue to evolve our model as we see value opportunities.

Chuck Triano - *Pfizer Inc - SVP of IR*

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

Operator

Chris Schott, JPMorgan.

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

Great. Thanks very much. Two questions here, maybe one following up on Tim's questions. I think you've talked about as the emerging markets evolve that we might see the business model evolve. Following up on that, does it make sense for Pfizer to keep both a value and innovative core under the same umbrella if we get to a point where the emerging markets that structure doesn't -- the current regional structure does not make sense? The second question is coming back to the bolt-on acquisitions. Can you remind us how large a bolt-on acquisition you would be considering at this point? What are the priorities for you? When the Company -- if a larger deal were to come along with the right fit, is that an opportunity for Pfizer, or is that really not in the cards as we consider capital deployment over the next couple years? Thank you.

Ian Read - *Pfizer Inc - Chairman and CEO*

Thank you, Chris. Going back to the possibilities of EM and why it would make sense for Pfizer to have those two businesses, I think there's not really a lot of point on speculating over this. Today, we have both businesses. You certainly in an innovative side need to be careful that you have -- it tends to be more volatile, and the established products allows you to take short-term movements in volatile -- in the business. But that being said, we will look at it. We will, I believe, move towards a separate management, and at that point, we'll be able to evaluate whether shareholders would prefer to have the option to invest in two distinct companies or not. I don't think that is a short-term priority right now for us. The priority is to evolve our internal model and measure how successful those businesses are and what management and leadership they require and are they distinct enough to go further.

On the bolt-on acquisitions, we've said that we are focused on generating shareholder return. I'm going to make a few comments and ask Frank to add to it if he wants to. So we use -- we look at bolt-on acquisitions as a way of adding high-value businesses or intellectual property to Pfizer that can generate positive returns to shareholders above what we see as the opportunity of share buy-back's. Bolt-on's, I don't want to give you a precise number. We did King at \$3.6 billion. So what's a bolt-on? Middle multiples of that number. You pick it. Where our market cap is \$180 billion, what would you consider a bolt-on for that size of company? Now, as regards larger opportunities, we look at everything from the point of view of, does it add value to Pfizer shareholders. If it adds value, we never say never. We consider opportunities. But right now, we continue to be focused on running our internal business and looking for those bolt-on opportunities.

Frank D'Amelio - *Pfizer Inc - CFO*

I'll add maybe three items to Ian's comments. I think first, the way we think about biz dev in general is it's not a strategy in and of itself. It's an enabler of our strategy. So that would be point number one. I think the second thing in terms of bolt-on's -- I think Ian sized it perfectly. King was several billion dollars. We viewed that as a bolt-on, the way to think about that. In terms of the priorities, which is something you asked, no changes. I think our priorities remain our focused therapeutic and disease areas, including the emerging markets. That's clearly where we've been biasing, and I think that's where we'll continue to bias. In terms of the large deals, just to punctuate what Ian said, there's no new news here. We always say we never say never, but our focus has been and continues to be on bolt-on acquisitions.



Ian Read - Pfizer Inc - Chairman and CEO

It continues to be on bolt-on acquisitions and those acquisitions that add value to Pfizer shareholders. (multiple speakers)

Frank D'Amelio - Pfizer Inc - CFO

Sure.

Operator

Jami Rubin, Goldman Sachs.

Jay Olson - Goldman Sachs - Analyst

Hi, this is Jay Olson on behalf of Jami Rubin. Couple questions. First off, with the focus on optimizing both your innovative- and your value-based businesses -- and we appreciate the significant progress being made in the innovative side with new product launches and pipeline progress -- we wonder if you could elaborate a little on some of initiatives you're taking to optimize the value-based business? Second of all, I understand your comments may be restricted but could you help us understand what might be a fair timeline for your potential decision to monetize the remaining 80% of Zoetis? Would a share exchange be something you would consider if Zoetis shares trade at a premium to Pfizer? Thank you.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Jay. I'll ask Olivier, who runs the Established Product business and Emerging Markets, if he can comment on work we're doing to grow the -- what we call the value business. And then Frank will answer the question on Animal Health.

Olivier Brandicourt - Pfizer Inc - President and General Manager, Emerging Markets and Established Products

I thank you for your question. What we're trying to do in the Established business division is to maximize the performance of those products in the LOEs phase and supporting their life cycle, potentially with line extension and changing product formulations. We also have recently built on the opportunity to quickly provide very reliable source of product in a shortage situations, and we've been very active on the US market in that space. We may also move on sterile injectable. We think it's a high-value space for the post-LOE market. In the space of differentiated formulation, I don't know if you've seen recently, but we launched Quillivant XR in January, the first and only product which is in liquid formulation and extended release for kids between 6 and 12 years old with ADHD. We think we're going to be through that enhance and better formulation, very competitive in that marketplace. So just providing a few examples of what we're doing.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Olivier. I'd probably add to that we also have an active program in biosimilars, which I would consider probably in the post-LOE space. Frank?

Frank D'Amelio - Pfizer Inc - CFO

On Zoetis, I want to reiterate what Chuck said at the beginning of the call, which is we're in a quiet period, so I'm very limited in what I can say. What I can say is we remain on track to complete a potential IPO for up to a 19.8% stake in Zoetis in the near future. The road show is taking place. Relative to beyond the IPO, assuming one is completed, we'll have a number of alternatives that are available to us for distributing the remaining shares. Obviously, we'll do what's best from an after-tax-return to our shareholders.



Operator

Mark Schoenebaum, ISI Group.

Mark Schoenebaum - *ISI Group - Analyst*

Maybe I can ask a couple pipeline and product-related questions. Number one, on PD-991 -- I think this is the first earnings call since the fantastic data a month or two ago. Just wondering if you could clarify your plans in terms of filing timeline's? Also, if you can help us understand the market opportunity for that, that would be great. Also, two major product launches this year at Pfizer, arguably the highest-profile launches in all of bio-pharma's, with Xeljanz and Eliquis. I'd love it if you could give the investment community any advice or wisdom when we think about those launches and maybe compare and contrast them? Thank you.

Ian Read - *Pfizer Inc - Chairman and CEO*

Thank you. On PD-991, palbociclib, I would ask Geno to comment on that and on that, as you say, outstanding data we got in the first of the Phase 2 trial. Then perhaps Geno would make some comments on how we see the evolving launch of Xeljanz. Then John Young could make some comments on the launch of Eliquis. Thank you.

Geno Germano - *Pfizer Inc - President and General Manager, Specialty Care and Oncology*

Okay. For palbociclib, as you mentioned, we had some really terrific data that we were able to present in San Antonio last year. That trial is -- continues into this year. There are two patient cohorts. The first patient cohort has completed, and the second patient cohort will complete later this year. We're expecting to present full data by the end of the year. As the data emerges, we will continue to discuss the data with the agencies around the world and determine the best pathway to bring this product to patients. Our current focus is on the ER-positive, HER-2-negative advanced breast cancer patient population. We expect to initiate a Phase 3 trial in this population to confirm the results that we saw in Phase 2 in the very near term, and we're anxious to proceed with that program. We also have plans to initiate additional Phase 3 programs in other breast cancer patient populations and then to explore the utility of the drug in tumors outside of breast cancer as we go through the rest of this year.

With regard to Xeljanz, we're off to a very good start. We're very pleased with the execution of the launch plan so far. It is early days, but the response from physicians has been very favorable. They're particularly pleased with the second-line indication and the ability to use Xeljanz without the need for methotrexate. These are kind of recurring themes that we're hearing. We did expect that the majority of initial trial will be in the post-TNF patient population. We think that, that's reasonable going forward, although we are hearing of physicians trying the drug in both the post-methotrexate and the post-TNF patient population. Most physicians are putting a handful of patients on the drug and want to see the patients come back to evaluate them. We're pretty optimistic that when they see those patients return that they will be pleased with the results, given the outcome of our Phase 3 trials, and in particular, the feedback from patients on patient-reported outcomes, which were actually very favorable in our Phase 3 program. So we're on track. We feel good about Xeljanz and I guess with that, I'll turn it over to John Young. C

John Young - *Pfizer Inc - President and General Manager, Primary Care*

Okay. Thanks, Geno, and thanks for your question, Mark. Obviously, we're very excited about the opportunity that we have with Eliquis, along with our partners BMS. I think clearly since the last call, in little more than six weeks, Eliquis received back-to-back approvals in the US, the 27 countries of the EU, Canada, Japan, South Korea, for reducing the risk of stroke and systemic embolism in patients who have nonvalvular atrial fibrillation. So we've already launched in the UK, Germany, Denmark, and the launches will progress in the EU over the coming months. In terms of the profile, which you know very well, clearly Eliquis is the only oral anticoagulant. It's demonstrated superior risk reduction versus Warfarin in the three critical outcomes of stroke prevention, major bleeding, and all cause-mortality in patients with nonvalvular atrial fibrillation. As a result, we certainly believe it offers a compelling profile for Cardiologist's and Primary care physicians, as reflected in our approved labels.

We expect Eliquis to be widely available in most US pharmacies by the end of January. Our US sales teams from Pfizer and BMS are at the internal launch meeting as we speak and will be on the road speaking to physicians on Monday next week. Overall, we really believe that Eliquis's differentiated profile, combined with the extensive experience that Pfizer and BMS bring to the cardiovascular commercial market, certainly positions us well to succeed. Given the strength of the Eliquis data, the superior risk reduction versus Warfarin in those three critical outcomes of stroke prevention, we believe that peers will certainly want to ensure that patients with nonvalvular atrial fibrillation have access to this clinically important medicine. We expect steady progress as we penetrate this market over the course of 2013 and beyond.

Operator

Andrew Baum, Citi.

Andrew Baum - Citigroup - Analyst

Three questions. First, for Ian, do you see opportunities for the industry to remove excess capacity infrastructure from within its EM and Established Markets products through a reorganization, is there a consolidation of distribution channels? Second, for Mikael -- for Frank. I'm interested in how tax efficient you think your existing EM established products business is and how much would alternate business structures further enable you to optimize that? Finally for Geno, apologies. Could you talk to whether there's a pre-planned interim analyses for your recently initiated first-line PD-991 trial? Thank you.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Andrew. Excess capacity in emerging markets. I think right now, probably if you go back to the US market in the '90s, most companies are focused on trying to get as large a share as they can in these vast -- in these quickly growing economies. I don't think people are focused right now on taking out infrastructure. However, I do agree with you that just like we saw in the US and Europe, there clearly will be at some point opportunities to rationalize infrastructure in those geographies. As the second question, I didn't really understand. EP and emerging, did you -- I didn't really understand, I'm afraid, Andrew. Perhaps you can come back and reposition it. Geno, could you comment on palbociclib?

Geno Germano - Pfizer Inc - President and General Manager, Specialty Care and Oncology

Yes, in the Phase 3 program, again, we're in ongoing discussion with the Agency, and our focus is really on finding the best way forward to reveal data that will enable the best decisions on making the drug available to patients. So we will discuss interim analyses as part of that assessment.

Ian Read - Pfizer Inc - Chairman and CEO

Perhaps I could just say on emerging markets and EP, we have a clear vision of both businesses. We're getting what we believe are strong results. In EP, you could see the successful switch to -- of Lipitor. You could see the Quilivant launch, focus on sterile injectables, focus on major markets. In emerging markets, we have strong, geographic-based organizations that are driving value in both our innovative and our post-LOE products. Olivier, do you want to add anything to that?

Olivier Brandicourt - Pfizer Inc - President and General Manager, Emerging Markets and Established Products

I think there is a strong integration of EP products into EM, and as we said, very valuable. They represent basically about 45% of our revenue, growing very strongly this quarter as you've seen at 21%. Very often, that is the result of combining innovative and EP products into the same sales force. For instance, cardiovascular sales force have both Lipitor and Norvasc. In many geographies, Lipitor is still in the end is still protected, where Norvasc is not, but you do optimize the two brands that way. There are plenty of synergy's to build on.



Andrew Baum - Citigroup - Analyst

Thank you.

Operator

Alex Arfaei, BMO Capital Markets Gregg Gilbert, Bank of America Merrill Lynch.

Gregg Gilbert - BofA Merrill Lynch - Analyst

It's Gregg Gilbert. Thanks. First question is on Emerging Markets growth in 4Q. I realize that could be a lumpy growth line, so perhaps you could set the bar at what a reasonable growth rate goal would be annually in '13 and possibly beyond? My second question, along the lines of maximizing value for the value business, the strategies so far for the developed markets portion seems to be focused on Pfizer brands that lose exclusivity, coupled with alliances with generic companies that do generic R&D. Going forward, could the strategy also include one, internal development of small molecule generic's, and/or two, outright acquisitions of companies in that space? Again, I'm thinking more about developed markets than the emerging piece. Thanks.

Ian Read - Pfizer Inc - Chairman and CEO

Okay. Olivier, could you take the fourth quarter and also refocus the comments on the strategy in the developed markets with the EP?

Olivier Brandicourt - Pfizer Inc - President and General Manager, Emerging Markets and Established Products

Right. Thank you, Greg. You've seen we posted 20% operational growth, and that is a result -- actually a very good result -- across geographies. In BRICMT, we have actually posted 26% operational growth but 30% in volume and offset by pricing, but very strong across geographies and portfolio. Specialty is running at 45% of growth this quarter, and as I mentioned before, Emerging Markets at 20%. Now, having said that, you have a lot of one-time items this quarter, right, especially Enbrel in Brazil and Plevnar in Turkey and Mexico. If you exclude those one-time items, you get to 16% growth for the quarter. So there are still volatility quarter-to-quarter in Emerging Markets. We remain committed to grow our Emerging Markets division by high-single-digit growth in the coming years. So that's --

Ian Read - Pfizer Inc - Chairman and CEO

And then on the established products in the developed markets, what are the key strategies to grow the business, such as sterile injectables and launches of Quilivant, et cetera?

Olivier Brandicourt - Pfizer Inc - President and General Manager, Emerging Markets and Established Products

Right. We remain focused on established products, to your point. We are not focusing in generic and the generic portfolio outside the US, where we have a strong position, as you know, with Greenstone. Outside the US, it's mainly emerging product -- established products. We're looking to bring sterile injectable, and as I mentioned before, new and differentiated formulation of established product.

Ian Read - Pfizer Inc - Chairman and CEO

Yes, I suppose in the developed market, we would say that business is a combination of Greenstone, a quality supplier that closes market gaps, with quality product. We've done that also in the oncology space. We're bringing important and sterile injectable products. We're trying to launch

innovative formulations, and as distinct from established products in the emerging markets, where it's still a primary care business. It's field forces, it's selling quality, and it's selling the brand name of the products in Pfizer.

Operator

Alex Arfaei, BMO Capital Markets.

Alex Arfaei - BMO Capital Markets - Analyst

Okay. Question on Zoetis and its impact on Pfizer. We know from the information that's available that the Zoetis business is a lower-margin business. If you were to proceed with full separation, how should we think about the margin expansion for Pfizer. On the CAPiTA trial, we know it's expected this year. I'm just wondering if you have a narrower timeline for it and if you could provide us any insights as to how we could quantify the adult opportunity? Thank you.

Ian Read - Pfizer Inc - Chairman and CEO

Frank, if you could take the first part, and Geno, the second?

Frank D'Amelio - Pfizer Inc - CFO

On the impact of Zoetis on our numbers -- and once again, I'm limited in what I can say. But the intent here is assuming we were to complete an IPO, we would issue -- we would revise our guidance in early April after Zoetis has filed its 10-K, which would be at the end of March. So at that time, we would revise our guidance by line item and then therefore, you could see the impact it would have on our numbers.

Ian Read - Pfizer Inc - Chairman and CEO

Geno.

Geno Germano - Pfizer Inc - President and General Manager, Specialty Care and Oncology

With regard to CAPiTA, the program -- the trial -- it continues to accumulate patients. As you know, it's an event-driven trial, so we really don't know what the date will be when the final event is -- has been identified. Once we have all the events accrue, we will complete the assessment, then -- do the analyses and report the data. We expect that to happen later this year. With regard to the magnitude of the opportunity, assuming positive results, we think that having a vaccine with demonstrated ability to prevent non-bacteremic pneumococcal pneumonia would be a valuable asset. There are over 300 million adults over 50 years of age in the developed markets, and I think the number expands to over 700 million in the global marketplace. So we think that the opportunity is substantial.

Operator

Marc Goodman, UBS.

Marc Goodman - UBS - Analyst

Yes, good morning. Geno, maybe you can give us some color on some of the oncology launches, how they're going? Second of all, Olivier, I'm curious in the emerging markets, given all the cost-cutting going on in the overall Company, I was curious how much investment is occurring in



the emerging markets? Where are we -- have we invested significantly more for 2013 versus 2012? Maybe we could get what the key Phase 2 readouts are for 2013 for data? Thanks.

Ian Read - Pfizer Inc - Chairman and CEO

All right. Geno, Oncology. Olivier, if you could make some comments on the question there, and Mikael, will you do the Phase 2?

Geno Germano - Pfizer Inc - President and General Manager, Specialty Care and Oncology

For Oncology, just a couple of comments about Xalkori. We've got a full year now in the US. Xalkori achieved \$100 million in sales in 2012, primarily in the US. It's now approved and launched in the US, Europe, Japan, and several other smaller markets. Sales are continuing to grow as adoption of molecular testing continues to expand. We started out with about a 10% testing rate. Now the testing rate is over 60%. We think in the past year, we captured about a quarter of the potential patients in the US. We're also seeing an expansion in duration of treatment as we're identifying patients earlier in their disease. We're happy with the progress of Xalkori and looking forward to expansion in new markets around the world.

Inlyta has also gotten off to a very strong start in the US, where it's already established the leading share in second-line. In Japan, it's the second-most prescribed drug for metastatic renal cell carcinoma and with a 10% share and 40% in the second-line setting. In general, we're seeing good growth of Inlyta, continued progress with Xalkori, and now we're just getting started with Bosulif.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you. Olivier.

Olivier Brandicourt - Pfizer Inc - President and General Manager, Emerging Markets and Established Products

Right. For emerging markets, definitely they represent an important growth opportunity. So we have been investing quite significantly in this market in recent years. We continue to invest to remain competitive. However, we are putting transformation programs to ensure that we are optimizing sales force and we have the best potential deployment, especially in support of the new products, which are going to be very important for emerging market, and the new launches, in addition to putting in place go-to-market models when it comes to brand marketing. So while we are investing, we are also beginning to get positive leverage from those investments.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Olivier.

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

We have a very exciting Phase 2 cohort, reading out more than 10 studies in the next 12 months. I'll share a couple with you. Immunology, we have our best-in-class IL-6 antibody with data coming in Lupus and also in Crohn's disease. We have an anti-mad cam antibody for Crohn's disease, a small-molecule P38 highly selective inhibitor for COPD. In diabetes, we have a pancreatic Glucokinase activator with a really unique profile reading out in diabetes and glucose control. We also have a novel PDE5 inhibitor for Diabetic Neuropathy. In vaccines, we're expecting data from staphylococcus aureus. Our F14 biosimilar are starting to move very nicely. We recently had positive data on Trastuzumab, which is exploring plans to go into Phase 3, while this year, we expect data from our second bio-similar, Rituximab, after completion of Phase 2. In some small areas, we're strengthening our portfolio in rare diseases and have a readout on our GMI-1070 in sickle cell crisis. Also, PCSK9 had a positive readout that we reported last year, and we have Phase 2b data coming, which underpins then our path forward to Phase 3.



Operator

Tony Butler, Barclays.

Tony Butler - Barclays Capital - Analyst

Thanks very much. Sticking with the pipeline, Dr. Dolsten, if possible, will we actually get the readout of the Phase 3 study ARCHER with Dacomitinib this year? Second, I guess for Geno, going back to Xeljanz, some docs' feedback to us -- and again, it's limited -- has suggested that patients do not actually know about the drug. Is patient awareness important at this early in the launch and is a DTC campaign actually in the cards? Thanks very much.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you. Mikael, are you going to talk to the pipeline?

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

I can mention we are very excited about Dacomitinib. As you know, it's a pan-HER inhibitor, irreversible binding, and did very well in our Phase 2 data against tarceva. The ARCHER trial, if you referred to is event driven, we expect the data probably more during first half of 2014 to have accrued the number of events required to close the trial. In addition to that trial, where we go against tosivas within our Phase 2, we also have another partner trial against refractory non-small cell lung cancer. It's run by the National Cancer Institute of Canada. It's a nice study set behind Dacomitinib, and we look very much forward to see that data come for possibly a new generation of pan-HER inhibitors.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you. Geno.

Geno Germano - Pfizer Inc - President and General Manager, Specialty Care and Oncology

With regard to awareness on Xeljanz, fortunately, within the first few weeks of launch, we have near 100% awareness among the prescribing community, which is terrific. And as I mentioned before, a lot of enthusiasm for the drug. Patient awareness is much lower, and we haven't done a lot of work with consumers, but we expect to roll out a consumer program around the middle of this year in keeping with the pharmaceutical guidelines to hold off on direct-to-consumer advertising for the first six months of launch. But we do think that consumer communication will be an important driver. We know that consumers are excited about idea of having an oral option and also excited about the potential to have an effective therapy without the need for methotrexate.

Operator

Seamus Fernandez, Leerink Swann.

Seamus Fernandez - Leerink Swann & Company - Analyst

Thanks for the question. First for Ian, Ian, can you clarify your comments in terms of the separation of the management? Are you planning to actually tighten down the management from the multi-tiered organizations to now officially providing reporting at some point around the structure of the two businesses as you described them, the innovative core and the value business? Separately, Geno, can you help us understand, back when

Pprevnar 7 -- there was a decision at Wyeth way back when to not continue forward with Pprevnar 7 in the adult setting, in large part because of herd immunity that is created by dosing infants. How do you see herd immunity influencing the adult indication for Pprevnar 13? Is it just really more a timing-related issue as we think about herd immunity with Pprevnar 13? Thanks a lot.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Seamus. What you were really talking about was segment reporting. Right now, we have the management split and the responsibility split in the developed markets. We don't have that split in the emerging markets. So it's really, I think, premature at this stage to look at segment reporting, but we'll continue to review that so as to give shareholders the transparency they need. With that, --

Geno Germano - Pfizer Inc - President and General Manager, Specialty Care and Oncology

Seamus, regarding Pprevnar, my recollection is that we chose not to go forward with the adult indication on 7 because we were so focused on advancing the -- and broadening the serotype coverage and getting to a 13 ahead of our competition. Once we achieved the formulation for 13, we were anxious to proceed to the adult vaccine. With regard to herd immunity, we know there is some herd immunity with the vaccination of children. There are a variety of epidemiologic studies that show different rates of herd effect. There are surveillance programs as well underway to identify the herd effect. What we see is that there is a residual disease burden that we think that the adult vaccine will help prevent in the adult patient population, and the opportunity remains significant.

Operator

David Risinger, Morgan Stanley.

David Risinger - Morgan Stanley - Analyst

Thanks very much. I have some questions on Xeljanz and then on emerging markets, the future growth prospects. With respect to Xeljanz, we're going to try to benchmark the prescription trend ramp. I wanted to understand your sampling program, because on the one hand, I understand that you're giving 30-day samples, but on the other hand, for virtually all drug launches, drug companies give samples. I don't know if your sampling program is unusually strong relative to other product launches such that we should expect unusually low reported prescriptions? Then with respect to the once-daily Xeljanz, which is entering Phase 2 in 2013, could you help us understand whether Pfizer plans to run bridging studies to shorten the timeline to filing, and when do you plan to file that once-daily for approval?

Changing gears to Emerging Markets, the operating performance growth was 12% in 2012, including a huge fourth quarter, which seemed to be driven by some anomalies. I know that you're sticking to your high-single-digit growth target operationally for Emerging Markets, but is that too conservative? Because you reported 12% in 2012, and it looks like high-single-digits growth going forward would be below market growth. Or should we think about potential upside to that target for high-single-digit Emerging Market growth going forward? Thank you.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you. Geno, could you answer the Xeljanz issues?

Geno Germano - Pfizer Inc - President and General Manager, Specialty Care and Oncology

With regard to the sampling program on Xeljanz, there's really two components. One is we have a patient-support program to help patients access reimbursement and to go through that process, which is very similar to any of the other drugs that they would be using in Rheumatology. There's a 14-day supply that we make available to patients to ensure that they can start therapy as soon as possible while they're going through that



reimbursement process. In addition to that, we identified a group of rheumatologist's who we wanted to have access to drug right away so that they'd gain experience immediately. And we gave 30-day supply bottles to that identified population of rheumatologist's to use to again that early experience. Now, whether we'll continue that program into the future or not is unknown at this point, but the very initial impact of these two sampling programs will range from a fairly short period of time.

With regard to the once-a-day program, we're going to want to have the once-a-day have adequate labeling to enable use across all of the indications that we're pursuing. The program is a robust program, and we are still in discussion, actually, with the Agency on the exact protocol.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you. David, on the Emerging Markets, I would agree with you that most multi-nationals are growing at slower than the overall market rate, as these markets are very local in their health care delivery, and there are strong local competitors who, given the lack of intellectual property in the last 25 years, have broad portfolios and add to those portfolios very fast. So I don't think it's reasonable to expect that multi-national will outgrow the marketplace. That being said, we have had accelerating growth. I was very pleased with the growth in the fourth quarter. However, I still believe that it's appropriate and aggressive to maintain a high-single-digit growth rate in Emerging Markets.

Operator

Catherine Arnold, Credit Suisse.

Catherine Arnold - Credit Suisse - Analyst

Thanks very much. I wanted to ask you a few things. First of all, could you comment on your strategic interest on the eye business for the right price and also tell us when we're going to hear about your dry AMD program? And on the CDK I don't think we got to is if the Part 2 study comes out as positive or directionally the same as we've seen for Part 1 of your ER-negative -- ER-positive HER-negative study, would you presumably go to FDA for an accelerated approval path? Thanks.

Ian Read - Pfizer Inc - Chairman and CEO

Eye interest -- I don't believe that the eye is a stated strategic disease area for us, so that would probably answer that one. On the Macular Degeneration, could you comment on that?

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

We have more opportunistic efforts in ophthalmology based on scientific spin-off opportunity. The particular program we have, RN6G, is an antibody against amyloid that we made some findings seem to in the models play a role in dry MD. The study's up and running, but we'll not have any data coming this year.

Ian Read - Pfizer Inc - Chairman and CEO

On palbociclib, which is the CDK 4/6, look, I think Geno's comment on this, I'll just reinforce it. We have great data in the first trial. We have a second trial running, which is a different cohort of patients. We expect to be able to give you the results of that trial in the second half of this year. And as the data revolves, we will continue to work with the FDA and other agencies. We will clearly try and work with the regulators to bring this product to patients as fast as is appropriate given the data we have.



Chuck Triano - Pfizer Inc - SVP of IR

All right. Thanks. Thanks for the context, Ian. Next question, please.

Operator

Steve Scala, Cowen.

Steve Scala - Cowen and Company - Analyst

A couple of follow-ups. First, has the strong flu season increased the event rate in CAPiTA, and has it changed the timing from the Q3 conclusion, which I think is what the Company had said previously? Secondly, has the decision by many payers to pay for Xeljanz post-TNF failures been mostly dictated by price, by lack of real-world experience, or by some other factor? Thank you.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Steve. Geno.

Geno Germano - Pfizer Inc - President and General Manager, Specialty Care and Oncology

It has been a robust flu season this year, and generally, that is associated with a higher number of events. I can't confirm or deny whether or not there has been an acceleration of events in the trial. Clearly, the sooner the events accumulate to the target, the sooner we'll have results. So we'll let you know as soon as we know something there. With regard to reimbursement for Xeljanz, actually the reimbursement rates -- reimbursement coverage has been very favorable. Most of the plans are reimbursing out of the gate, and we'll conduct category reviews over time.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you, Geno.

Operator

Michael Tong, Wells Fargo Securities.

Michael Tong - Wells Fargo Securities, LLC - Analyst

Hi, just a quick question with regard to your biosimilar strategy. When do you expect your first biosimilar product to get onto market? Within 18 months of that, how many more would you think you would be able to get through?

Ian Read - Pfizer Inc - Chairman and CEO

Michael, we have a -- I think we're focusing on five molecules initially. We have two in active development and three that we're -- it's -- are further back. I really can't give you the -- we don't give timings, but the lead candidate biosimilar is in Phase -- Mikael, as you indicated, Phase -- (multiple speakers)



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

We just completed successfully with our first biosimilar. I briefly mentioned earlier Trastuzumab, which is the name for Herceptin, completed Phase 2 and are exploring plans for Phase 3 opportunity this year. The second that Ian alluded to, Rituximab, is going to complete in this year a Phase 2 study. You can see it's good momentum. We're using the deep skills seen in bio-pharmaceuticals and manufacturing to provide quality data.

Ian Read - Pfizer Inc - Chairman and CEO

So far, we're very encouraged by the Phase 2 data and our ability in this area.

Operator

Kim Vukhac, CLSA.

Kim Vukhac - Credit Agricole Securities - Analyst

Thank you. Just a quick question. With regard to the guidance, can you talk about what your share repurchase assumptions are for the year? In addition, speak to the timing of the buy-backs, if it weighted more the first half versus second or more that we should assume evenly spread out throughout the year?

Ian Read - Pfizer Inc - Chairman and CEO

Thank you. I think Frank can give you the numbers on that.

Frank D'Amelio - Pfizer Inc - CFO

Kim, the assumption is mid-teen billions relative to buy back's. In terms of the rhythm, I think the way to think about that is throughout the year. So no heavy waiting one area or another, just kind of throughout the year, and mid-teen billions.

Chuck Triano - Pfizer Inc - SVP of IR

Thank you, Frank. Thank you, everybody, for your attention this morning.

Ian Read - Pfizer Inc - Chairman and CEO

Thank you. Have a good day.

Operator

Ladies and gentlemen, this does conclude the Pfizer's fourth-quarter earnings conference call. You may now disconnect.



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