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PFE - Q3 2014 Pfizer Inc Earnings Call

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OVERVIEW:

PFE reported 3Q14 revenues of approx. \$12.4b and reported diluted EPS of \$0.42. Expects 2014 adjusted revenue to be \$48.7-49.7b, reported diluted EPS to be \$1.50-1.59, and adjusted diluted EPS to be \$2.23-2.27.



CORPORATE PARTICIPANTS

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Frank D'Amelio *Pfizer Inc - CFO*

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's third quarter 2014 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 thanks for joining us today to review Pfizer's third quarter 2014 performance. I'm joined today as usual by our Chairman and CEO, Ian Read, Frank D'Amelio, our CFO, Mikael Dolsten, President of Worldwide Research and Development, Albert Bourla, President of Vaccines, Oncology and Consumer, Geno Germano, President of Global Innovative Pharma, John Young, President of Established Pharma and Doug Lankler, General Counsel. The slides that will be presented on this call can be viewed on our homepage Pfizer.com by clicking on the link for Pfizer Quarterly Corporate Performance Third Quarter 2014, which is located in the Investor Presentations section which is in the lower right-hand corner of this page.



Before we start, I'd like to remind you that our discussion 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 2013 annual report on Form 10-K and in our reports on forms 10-Q and 8-K.

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 28, 2014. We will now make prepared remarks and then we will move to a Q&A session. With that, I'll now turn the call over to Ian Read. Ian?

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Chuck, and thank you all for joining the call this morning. I'll start with a few comments regarding the quarter and then a few words about our strategy, including some remarks on our business development. Starting with the quarter, our performance was well in line with our expectations as the business continues to perform well. In our Innovative Businesses for Global Innovative Pharma, the underlying business grew 9% operationally if you exclude approximately \$425 million, or a negative 13% point impact due to LOEs and the loss of Enbrel alliance revenue.

Operationally, the Vaccines business grew 19%, the Oncology business grew 17% and the Consumer Healthcare grew 4%. For our Established business, GEP revenues for the quarter were down less than 1% if you exclude the approximately \$383 million operational, or 6 percentage points due to the negative impact of recent LOEs and Lipitor in the US and Japan.

We had good operational growth in several of our key products including Lyrica, which grew 16% and the Prevnar franchise which grew 18%. Enbrel remains a solid contributor to markets outside the United States and Canada where we retain marketing exclusivity, and there's good momentum of our newest products including Eliquis, Xeljanz, Xalkori and Inlyta. Specifically for Eliquis, a key leading indicator referred to as new to brand share with cardiologists continues to improve nicely. Since launch, based on the most recent data, Eliquis share has increased from 0% to 44% while our main competitor shares declined from the high of 70s to slightly above ours. For Xeljanz, the inclusion of structural data in the Xeljanz label has served as an inflection point with prescribers. We hope to see further steady share gains aided by the growing attractiveness to physicians of using Xeljanz as an effective monotherapy option.

Again this quarter, we achieved solid companywide performance in emerging markets. Revenues increased 9% operationally compared to the year ago quarter driven by growth in China and Latin America. Overall performance year to date positions us to achieve a strong finish, even after taking into account that we've transitioned to a new commercial model internally, while also adapting to ongoing external market forces.

Looking ahead, the period of high LOE impact will continue through 2016, making it difficult to generate revenue growth on a net basis. We expect the size of the impact to be substantially reduced starting in 2017. Our strategy has not changed; it is anchored upon the following pillars. Making our R&D more productive so we deliver on our pipeline, continuing to make smart and shareholder-friendly decisions on how we allocate our capital, and globally positioning Pfizer to be a market leader through organic and inorganic growth opportunities.

Regarding the pipeline, we recently achieved several regulatory milestones in our late stage vaccines and oncology pipelines. The FDA accepted the biologics license application for our mening-B vaccine with prior review and set a PDUFA date of February 14, 2015. The new drug application for palbociclib was accepted with priority review with an April 13, 2015 PDUFA date. We also had discussions with the European regulatory health authorities and intend to file palbociclib in the EU next year. The FDA approved abuse-deterrent labeling for better extended release capsules, and our investigational C. difficile vaccine was granted Fast Track designation. And the Advisory Committee on Immunization Practices recommended the routine use of Prevnar 13 amongst adults 65 years and above in the United States.

In looking at our late stage pipeline, there are multiple indications for Xeljanz that are progressing. We have completed all four Phase 3 studies in psoriasis, have Phase 3 studies underway in psoriatic arthritis and ulcerative colitis, and there are two phase -- and there are Phase 2 studies in psoriasis for topical use, Crohn's Disease and Ankylosing Spondylitis. And we are exploring the expansion of palbociclib from advanced to recurrent and subsequent early breast cancer. In addition, we are working to advance potentially attractive opportunities that could be commercialized in 2017 and beyond. They include ertugliflozin for the treatment of diabetes, bococizumab for cholesterol lowering in high risk individuals, vaccines



for hospital-acquired infections such as staph aureus and C. difficile and several biosimilars in oncology and inflammation. Given the pipeline progress being made, I believe we have good sight to improve R&D productivity.

In terms of capital allocation, we have a strong, solid track record of taking expenses out of the business, generating strong operating cash flows, and having a sound balance sheet that is a competitive advantage. We have returned significant capital to shareholders through share repurchases and dividends. During the period 2011 through 2013, we returned approximately \$53 billion and expect to return nearly \$12 billion in 2014. All of this positions us well to pursue business development opportunities.

Recently, there has been a lot of attention paid to deals involving redomiciling and the proposed regulations announced by the Treasury Department which make it more complicated and also potentially limits value that could be created by US companies that redomicile. The fact that Treasury has left open their ability to make further changes without notice is of concern. For Pfizer, enhanced financial flexibility from redomiciling is certainly still one potential source for creating value. As we've said previously, will look at any business development opportunities based on strategic fit including operational, portfolio and financial synergies. We continue to evaluate a broad set of potential options on a case-by-case basis to accelerate value creation for shareholders.

Finally, a few words regarding a potential split of our business -- businesses. We have two primary businesses. I want to say that again, because there seems to be some confusion that I may have inadvertently created.

We have two primary businesses. An innovative R&D driven portfolio, which is managed through our Global Innovative Pharma and Vaccines, Oncology and Consumer segments, and secondly, of Global Established Pharmaceutical business. We have 10 months experience operating in our current commercial model with P&L information. This is providing valuable insights into the strength and challenges of each business.

In 2015, we will maintain a significant effort towards setting up the groundwork required to operationalize a potential split. What we do will eventually depend upon how our commercial business is performing in markets, how our shareholders value these businesses, if the sum of the parts is greater than the whole, and whether there are opportunities to enhance their competitive positioning which could be achieved outside of Pfizer. It is a decision -- it is important to underscore that at this point in time, we have not yet made a decision.

In summary, we have an unrelenting focus on successfully executing on our commitments so that we start 2015 financially and operationally strong and with the flexibility to take the actions that create value in ways that are best for our shareholders, patients and colleagues. Now, I will turn it over to Frank to take you through the financial details for the quarter.

Frank D'Amelio - Pfizer Inc - CFO

Thanks, Ian. Good day, everyone. As always, the charts we are reviewing are included in our webcast. As a reminder, because of the full disposition of Zoetis on June 24, 2013, the financial results of the Animal Health business and the gain associated with its full disposition are reported as a discontinued operation in the consolidated statements of income for the first nine months of 2013. Now, let's move on to the financials.

Third quarter 2014 revenues of approximately \$12.4 billion decreased 2% year-over-year, reflecting an operational decline of approximately \$270 million, or 2%, driven mainly by the expiration on October 31, 2013 of the co-promotion term for Enbrel in the US and Canada, the ongoing termination of the Spiriva collaboration in certain countries, the loss of exclusivity and subsequent multi source generic competition for Detrol LA in the US and other product losses of exclusivity in various markets. In total, LOEs and the decline on alliance revenues had a negative impact of approximately \$750 million in the quarter. These are partially offset by the strong operational growth in developed markets of Lyrica, Plevinar, Eliquis, Xeljanz, Xalkori and Inlyta, as well as Nexium 24HR, primarily in the US, and by 9% operational growth in emerging markets driven by Plevnar as well as Lipitor, primarily in Canada.

Foreign exchange had a negligible impact of \$11 million on reported revenues. Adjusted diluted EPS of \$0.57 decreased 2%, or \$0.01, primarily due to lower revenues and a 2% aggregate operational increase in adjusted cost of sales, adjusted SG&A and adjusted R&D expenses resulting from an unfavorable shift in product mix, upfront payments to Cellectis and MedGenesis, therapeutics associated with recently announced agreements, as well as ongoing Phase 3 programs for bococizumab, ertugliflozin, pablocyclib and certain other new drug candidates.

Adjusted SI&A expenses, however, decreased by 1% operationally because of continued benefits from cost reduction and productivity initiatives, partially offset by product launch investments. Adjusted diluted EPS was favorably impacted by fewer diluted weighted average shares outstanding which declined by 253 million shares versus the year ago quarter, due to ongoing share repurchases and a lower effective tax rate.

We recorded reported diluted EPS of \$0.42 compared with \$0.39 in the year ago quarter, due to the previously mentioned factors and the favorable impact of the non-recurrence of a loss associated with the Teuto option, lower restructuring charges and lower expenses related to cost reduction initiatives which were partially offset by the unfavorable impact of a charge to account for an additional year of the non-tax deductible branded prescription drug fee under the final regulations issued by the IRS during the third quarter 2014. Foreign exchange negatively impacted third quarter revenues by \$11 million and had a net unfavorable impact of \$10 million in the aggregate of adjusted cost of sales, SI&A and R&D. Consequently the impact of foreign exchange on adjusted diluted EPS was negligible compared with the year ago quarter.

Now, moving on to the financial highlights of our business. In the third quarter, Global Innovative Pharmaceuticals revenues decreased 4% operationally year-over-year due to the previously mentioned expiration of the co-promotion term for Enbrel in the US and Canada, partially offset by strong operational growth from Lyrica, primarily in the US and Japan and Eliquis and Xeljanz globally.

Income before taxes declined 8% operationally due to the decrease in revenues, a 12% operational increase in cost of sales, or a 1.9 percentage point increase as a percentage of revenues of which 1.5 percentage points was attributable to the loss of Enbrel alliance revenues. A 6% operational increase in SI&A expenses from increased investment in new products such as Eliquis and Xeljanz and in-line brands such as Lyrica and Viagra as well as the 33% operational increase in R&D expenses due to incremental investment in late-stage pipeline products such as bococizumab, Ertugliflozin, and additional Xeljanz indications. In the third quarter, revenues from our Vaccines, Oncology and Consumer Healthcare business grew 13% operationally year-over-year due to the strong operational growth of Prevnar, Xalkori, Inlyta and Nexium 24HR.

Income before taxes increased 19% operationally due to increased revenues, which were partially offset by a 12% operational increase in cost of sales driven by increased sales volume. As a percentage of revenue, cost of sales decreased by 0.2 percentage points due to a favorable change in product mix, and there was a 13% operational increase in SI&A expenses due to Nexium launch costs and Prevnar adult investment and prelaunch expenses for palbociclib and our meningitis B vaccine candidate. R&D expenses, however, decreased 10% operationally due to lower cost for certain oncology programs, partially offset by increased investment in the palbociclib and mening-B development programs.

In the third quarter, Global Established Pharmaceutical revenues decreased 6% operationally year-over-year due to previously mentioned product launches of exclusivity and the loss of alliance revenues and an operational decrease of Lipitor in US and Japan. Income before taxes declined 4% operationally due to the decrease in revenues, which is partially offset by the decreases in cost of sales, SI&A and R&D expenses which included increased spending on biosimilar development programs.

Now, moving on to our 2014 financial guidance. We're updating certain components of our 2014 financial guidance based on our year-to-date performance, recent changes in foreign exchange rates in our outlook for the remainder of the year. It's important to note that this guidance does not include an adjustment for the potential devaluation of the Venezuelan Bolivar or any other currency. We are narrowing our adjusted revenue range to \$48.7 billion to \$49.7 billion from \$48.7 billion to \$50.7 billion. We are narrowing and lowering our adjusted cost of sales as a percentage of adjusted revenues range to 18.5% to 19% from 19% to 20%. We are narrowing our adjusted SI&A expenses range to \$13.5 billion of \$14 billion from \$13.3 billion to \$14.3 billion. We are narrowing our adjusted R&D expense range to \$6.9 billion to \$7.2 billion from \$6.7 billion to \$7.2 billion. We now expect other income to be approximately \$400 million versus our previous expectation of about \$200 million. We continue to expect our adjusted effective tax rate to be approximately 27%, which does not assume the renewal of the US R&D tax credit. If renewed, the effect would not be material and we would not anticipate any impact on our 2014 adjusted effective tax rate guidance.

We are narrowing our reported diluted EPS range to \$1.50 to \$1.59 from \$1.47 to \$1.62, and we are narrowing our adjusted diluted EPS range to \$2.23 to \$2.27 versus \$2.20 to \$2.30.

Now, moving on to key takeaways. We narrowed our guidance ranges for adjusted revenues and adjusted diluted EPS. We recently achieved several key R&D milestones related to palbociclib, our meningitis B vaccine candidate, Prevnar 13, and our investigational C. diff vaccine. We continue to create shareholder value through prudent capital allocation.



To date in 2014, we've returned approximately \$5 billion in dividends to shareholders and repurchased \$4.2 billion, or approximately 140.4 million shares, and we continue to expect to repurchase approximately 5 billion of our common stock this year. These repurchases and planned repurchases for the remainder of the year are expected to reduce total shares outstanding year-over-year by a total of approximately 100 million shares by the end of 2014 after considering actual and projected dilution related to employee compensation programs. In total, we expect to return nearly \$12 billion via share repurchases and dividends to shareholders this year. In addition, last week the Board of Directors authorized a new \$11 billion share repurchase program to be used over time.

Finally, we remain committed to delivering attractive shareholder returns in 2014 and beyond. With that, I'll turn it back to Chuck.

Chuck Triano - *Pfizer Inc - SVP of IR*

Thank you, Frank and Ian, for your comments. At this point, operator, can we please poll for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Chris Schott from JPMorgan.

Chris Schott - *JPMorgan - Analyst*

Just a few here on bus. dev. First, I just want to make sure I'm clear on your comments. Do you still see meaningful value to Pfizer from inversion? Or should we be thinking about larger deals having to be much more driven by operating synergies and pipeline opportunities relative to 6 or 12 months ago? The second question is, how does potential for future Treasury action factor into that analysis, in terms of -- can -- do you really know what Treasury ultimately does, and does that affect how you are thinking about this? And then the final one is a broader one, which is relatively to a year ago, it seems like Pfizer is much more focused on business development. This question for -- what has changed over the last year that it seems like you are just trying to be a big value creating event for shareholders that didn't exist maybe one or two years ago? Thanks very much.

Ian Read - *Pfizer Inc - Chairman & CEO*

I appreciate the questions on BD. I just want to make the point that BD is not a strategy, it's an enabler of the strategy. I don't want to get us totally focused on BD and not on the strength of our underlying business, the development of our pipeline, and I think both our prepared remarks have gone through that. I won't repeat it here, but I do want to stress that we feel the strategies we put in place on improving our innovative core and getting capital allocation right are working and working well. The rules -- our proposed rule changes on inversions have not stopped inversions. If you are between the 80% and the 60%, I think it's fair to say they have made it more difficult and perhaps changed the timing on realization of the value. But we still believe on a case-by-case basis, there is meaningful value to be had from inversions. And probably the most significant is the liberation of a substantial proportion of your future cash flows outside of the US tax system into a territorial system.

The next question, I believe was future Treasury actions. I can't predict what they are going to do, so no one can. It's worrying that we are put in this -- the US businesses are put in this uncertain situation and that US companies are put at such a competitive disadvantage because of the foreign competitors, both on the tax rate and also the uncertainty of the rules. But that's where we are today, and that's what we have to live with.

I think what it means is as you look at an inversion, you need to thoroughly understand case-by-case what the inversion target is, what your capabilities are and how you intend to realize the values. And there should be multiple ways of realizing such value because you can't anticipate the rule changes the Treasury may put in place. So, all of that will be factored in, I think by anybody who intends to do an inversion deal.



And then I think from your question about why more focus from Pfizer now on BD, I think you've got to look that in the context of when this team took over the Company back in late 2010, we were really focused on fixing our innovative core, working with Michael to make sure that our science organization was best in class, advancing our pipeline, getting our capital allocation right, getting our expense base rate, getting our culture where we want it to be. And I think through 2011, 2012 and parts of 2013, we got where we wanted to be and we felt very confident about our ability to take on a BD or a bolt-on or a large size and ensure we maximize the value of any such BDs. So, I think that explains the timing. Thank you for the questions.

Chuck Triano - *Pfizer Inc - SVP of IR*

Operator, next question, please.

Operator

Gregg Gilbert from Deutsche Bank.

Gregg Gilbert - *Deutsche Bank - Analyst*

Ian, what have been the key learnings since the decision to separate your businesses internally? I realize it's only 10 months, but I'm sure you've learned some goods and bads. And maybe part B of that question is a hypothetical. If someone were to offer you a price for the EP business and could run it in a more cost and tax efficient manner and that Pfizer shareholders could benefit from that, would it even be possible at this point, or soon, from an operational standpoint? In other words, has enough separation work occurred to enable that type of hypothetical to be a reality? Thanks.

Ian Read - *Pfizer Inc - Chairman & CEO*

Okay. I'll deal with the learnings and I will ask Frank to talk about the hypothetical of this more immediate separation. I think the learnings are what we basically expected, it's the power of focus. It's the power of having a leader and the team focused on established products with John Young leading that. With crafting strategies that address the specific issues of the EP business, of driving that business in those countries without losing focus on what the strategies are for that business. It's about having John working on growth opportunities, his team looking for growth opportunities. I think it's back to the whole area of give a team an objective, make it clear, make it focused and let them go at it. And if you've got good people, they will come up with extraordinary results.

So, I think that's the learning on that, and we continue to be pleased with the way John's approaching his, the way Albert is doing it with VOC and the way Geno is doing it with GIP. These growth rates in Eliquis and Xeljanz and Lyrica are a result of a great management team working, and Albert also, with the growth in the Vaccines Oncology. So, I'm very pleased with the focus we are achieving. With that, I will hand it over to you.

Frank D'Amelio - *Pfizer Inc - CFO*

Gregg, in terms of the timing, the way I'll answer the question relative to, for example, our Established Products business, the way to think about this is, is it a public transaction or a private transaction? If it's a public transaction -- by the way, I know your example is a private, one, I'll get to it. If it's a public transaction, so a reverse Morris trust, a partial spin, a complete spin, a partial IPO, a partial IPO followed by a split, three years of ordered financials required. Then that would be three years of prospective orders of financials. Think about that as 2017.

If it's a private transaction -- by the way, your example was a private transaction. So, we sell an entire segment to someone or we're going to sell a partial element of a segment or a joint venture with a minority interest or a joint venture with a majority interest, then it's subject to what's called a significance test. And then there's three tests within the significance test. There's an asset test, an income test and an investment test. The asset



test is the target's assets as a percentage of the acquirer's assets. The income test is the acquirer's income as a percentage of the acquirer's income, and then the investment test is the acquirer's investment in the target as a percentage of the acquirer's assets.

If all three tests are below 20%, no ordered financials are required. If any one test is between 20% and 40%, one year of ordered financials is required. If any one test is between 40% and 50%, two years of ordered financials are required, and if anyone test is greater than 50%, two years of balance sheet, three years of income statement, cash flow, comprehensive income and shareholders equity are required. Given the size of our Established Products business, it's very likely one of the tests, if not all, would be greater than 50%.

Ian Read - Pfizer Inc - Chairman & CEO

Gregg, you can see that we've given this some considerable thought and continue to be working on this and leaving no stone unturned in ways of trying to achieve our objective here. Thank you.

Chuck Triano - Pfizer Inc - SVP of IR

Next question, please, operator.

Operator

Mark Schoenebaum from ISI Group.

Vlad Nikolenko - ISI Group - Analyst

Actually Vlad Nikolenko sitting in for Mark. Again, congratulations with a great quarter. I have a couple of questions about the R&D update. Wondering if you can provide more color on the level of confidence for the ongoing palbociclib filing, which is -- our understanding it's based on Phase 2 data and the plans how to use the Phase 3 data. Also, I want to know if you can give more highlights about the ongoing PCSK9 program. And finally, just to give more sense about the state of the pipeline because currently, published pipeline has more than 80 programs at different stages of development, some of the my label extensions. What do investors have to focus on besides palbociclib and PCSK9 and vaccines that you've already mentioned?

Ian Read - Pfizer Inc - Chairman & CEO

Good questions, which we welcome answering. I'll ask Albert to deal with the palbo issue. Geno with the bococizumab, and we will ask Michael to give you a succinct description of the portfolio on what we are excited about.

Albert Bourla - Pfizer Inc - President of Vaccines, Oncology and Consumer

Thank you, Vlad. For palbo, as you're aware, we've submitted our filing and FDA has accepted the NDA and gave us priority review. And we have a PDUFA date which is on April 13. This filing was based on Phase 2 data. To date, FDA has not placed any conditions related to submission of Phase 3 data results during the NDA review. In fact, we do not expect to have any Phase 3 data before the PDUFA date. There is an interim review built into the protocol, which is event driven, and so I cannot speculate when that will happen. But this interim review will not happen before the PDUFA date. So, we are looking forward to continue working with the FDA so we can bring this product to patients as soon as possible.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you. Geno?



Geno Germano - Pfizer Inc - President of Global Innovative Pharma

The palbociclib, the PCSK9 program is progressing. We are in Phase 3. We've been enrolling for about a year, now. We have a fairly extensive Phase 3 program with five LDL trials and two cardiovascular outcomes trials. This differentiates our program from others in the category. I believe we are the only one with a cardiovascular outcomes trials in the high risk patients who are unable to get their LDL levels below 100 on maximum doses of statins.

This is a patient population where we are likely to show a benefit. And in the event that reductions in LDL levels to very low levels don't show the linearity that we are looking for, we think this patient population will still show the benefit. We have a second cardiovascular outcomes trial in a broader patient population, testing whether reducing LDL levels below the current recommended levels will confer an additional morbidity and mortality benefit. It's a robust program. We're moving quickly to enroll patients and we are on track.

Ian Read - Pfizer Inc - Chairman & CEO

Mikael some comments on the other products outside of those near term?

Mikael Dolsten - Pfizer Inc - President of Worldwide Research and Development

Absolutely. The way to look upon the pipeline is, as you said, we have more than 80 projects across Phase 1 to registration. And when you look at the late stage, I would encourage you to see there's four potential (inaudible) franchises supporting GEP, VOC and GEP. And you are aware of palbo for VOC, for GIP boco and Xeljanz lifecycle management. As you've heard, Xeljanz is really picking up pace already, and there are multiple indications that the following, psoriasis, oral ulcerative colitis, psoriatic arthritis and a QD foray. And then finally for GEP, the biosimilars which are moving to 4, soon in Phase 3 and one additional in (inaudible) starting.

There is also an upside that we haven't discussed a lot, and that is progress that we're making on tanezumab in preclinical safety in dialogue with the agency. And we look forward to concluding this data with a potential opportunity to get back on a dialogue to restart that program, pending, of course, good data and so on agency dialogues. You already mentioned vaccines, and I expect that we'll see in the middle of next year that we will have six different programs in addition to staph C. diff. We also have therapeutic vaccines now coming that includes (inaudible) cancer vaccine, and I encourage you to see that as a whole technology platform that we have built. In immunology inflammation, in addition to the tofacitinib oral program, there are now additional opportunity in psoriasis, we have recently seen encouraging data for our topical version of tofacitinib in both dermatitis and psoriasis, and we are designing a new generation of JAK inhibitors for psoriasis, as well as for IBD.

In cardiovascular metabolic, we have generated encouraging data on a novel PD5 inhibitor for diabetic neuropathy. And we have another drug, CS-25 that is reading out in the next one or two months. Oncology, there is a very nice midstage pipeline with GSI drug for genetical altered triple-negative breast broad program around slow and hematology, and we have recently seen encouraging Phase 1 data for our ALK follow on drug 3922. As you are aware, we are building an increasingly robust immuno-oncology second wave program and we are now, for example, dosing 41BB on top of PD1 in partnership with Merck. Recently, we moved our fifth antibody drug conjugate into the clinic and are addressing multiple solid tumors. These were just a couple of things that I think will deliver a lot of momentum over the next two years.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Mikael.

Chuck Triano - Pfizer Inc - SVP of IR

Next question, operator.

Operator

Marc Goodman from UBS.

Marc Goodman - UBS - Analyst

Yes, I'm not sure if Geno is on the line, but if he could talk about the oncology business and maybe specifically some of the products. Inlyta, Xalkori, some of these products look that they are slowing down a little bit, so I was curious what's happening there. And then I believe we got into the oncology just at the end there about how you are positioning yourself for the future, but I'm curious how you are thinking about immuno-oncology and the products that you are working on. And then on biosimilars, could you tell us, the four Phase 3s, has anything moved forward? When should we be expecting the Phase 3s to finish?

Ian Read - Pfizer Inc - Chairman & CEO

Okay. I will ask Albert, who has responsibility for oncology business, to make some comments on SUTENT and Inlyta and (multiple speakers) Xalkori. Basically our late -- our inline products. And then on the positioning, perhaps, of the -- for immuno-oncology, I would ask Mikael to make a comment on that. And then on biosimilars, John can make a comment. Thank you.

Albert Bourla - Pfizer Inc - President of Vaccines, Oncology and Consumer

For the Inlyta, we said for the quarter, 23% growth, operationally. US was 9%. In US we had a strong uptake in the academic setting. What we are working now is to make sure that we have a strong uptake also in the community. We have numerous programs that are in place to achieve that.

In EU, Inlyta was quite impressive, 32% growth for the quarter. Over there, the results are driven basically by positive ESMO guidelines, but now are endorsing Inlyta as a standard second line treatment option. And also, we saw this year improvement in our reinvestment status. Right now, we have basically all 16 EU countries reimbursing Inlyta.

If I go to Xalkori, Xalkori, we were very pleased with the performance, we have 55% growth operationally for the quarter, US, 33%. It's driven by clearly an increase, testing for the ALK gene mutation. Right now, we are at 74% testing. To remind you, we started the launch at 11% and a year ago, it was 60%. A significant improvement. In the EU, the growth was even more impressive, 74% for the quarter. That again is driven by ESMO treatment guidance, but also we had positive data from the PROFILE 1014 study which we released, and that is driving a lot of these results in Europe. And finally in Japan, Xalkori had 43% growth and is driven by, again, the new data of PROFILE 1014 that have compared Xalkori to the standard chemotherapy.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you very much. So, if we go to the positioning on immuno-oncology?

Mikael Dolsten - Pfizer Inc - President of Worldwide Research and Development

Yes, we are enthusiastic about immuno-oncology rising as a new modality in oncology. And as you know, it has been durable, but many are partial responses. We see the next level of immuno-oncology to go to deeper and more complete responses, and that's where we really are focusing our current efforts strongly to be a leader. I mentioned briefly that our 41BB is now dosing on top of PD1 in a partnership with Merck. We have partnership to study 41BB on top of CCR4 with KHK, and we are moving additional checkpoint modulators into human studies, export early late next year, late next year, I want PD1.



In addition to the checkpoint drugs, a think you will see not only IO plus IO combos, but IO plus targeted agents. And we are working in a partnership with Merck studying PD1 plus Inlyta and planning to study PD1 plus Xalkori together. A second modality beyond the IO checkpoints are cancer vaccines where we are planning during next year to start our first out of a series of cancer vaccine clinical studies. We also have our own platform of bifunctional antibodies that will start delivering human agents in 2016. And as you know, we did select this partnership around core T-cells. So, we are playing very broadly with the leading technologies and assets, and our goal is to move one to two immuno-oncology agents in the class, as I described, every year for the coming period into human studies, mainly focusing on combination, which we think will deliver the utmost value of deep, more durable responses.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Mikael. John?

John Young - Pfizer Inc - President of Established Pharma

Just as a reminder, in our first wave, we have five monoclonals in our biosimilar portfolio, primarily in oncology and inflammation indications. There's three biosimilars that are already in Phase 3 studies that are ongoing or enrolling our biosimilar for rituximab, biosimilar for trastuzumab and a biosimilar for infliximab. So, those Phase 3 studies are ongoing already. As Mikael mentioned earlier on, bevacizumab, biosimilar bevacizumab has just recently completed, successfully completed Phase 1 study. The next milestone for that in development would be the initiation of Phase 3, and we have adalimumab biosimilar which is currently in Phase 1. Those studies are progressing well, and we anticipate bringing this portfolio to the market in the 2017, 2018 timeframe.

Chuck Triano - Pfizer Inc - SVP of IR

Moving to the next question, please, operator.

Operator

Steve Scala from Cowen.

Steve Scala - Cowen and Company - Analyst

A few questions. You stated, I think, that you would file palbociclib in the EU in 2015. Is that based on the same Phase 2 data that you submitted to the FDA so the filing could be early in 2015? Or is it based on some look at Phase 3 as well, which would probably push the filing to later in the year?

And two questions for Ian, and I apologize in advance for both. But why the very deliberate comment on two businesses rather than three when the Company is giving financials on three businesses and has been talking about three businesses for several years? I know you've been talking about two companies or two businesses in recent calls, but why the need to emphasize it now? Secondly, I'm not clear on the benefit to Pfizer of saying an inversion is still possible. Is it, for instance, to prompt further Treasury clarification or for some other reason? Thank you.

Ian Read - Pfizer Inc - Chairman & CEO

I'll ask -- on the -- on saying -- I was answering a question about whether we still thought that inversion was a viable strategic component of any deal. We still believe it is. I was answering a question. So, I think that explains why answered it that way. There was no ulterior motive beyond that of reassuring investors that while the rules have changed, we still believe in the appropriate circumstances that inversions can be part of the value



mix of a deal. And -- although we can do deals and we do see value in deals with that inversion as it still remains part of our overall mix. So, I hope explains that, Steve.

On the two businesses, the reason I was so -- I've been talking to investors, and I believe there is a confusion out there. We have two businesses. We report one of the businesses in several -- in two segments. We have our business which is Innovative business, which relies on our core research and our core capabilities and which I see is an integral business is made up of Oncology and Vaccines and Consumer and what I would call traditional Innovative. That is, as I see it, one business. And the fact that we report it separately is really an artifact of the SEC rules on segment reporting and depending on your management construct and who reports to the CEO. I think that's led to some confusion in the investment community that we see the Company as made up of more than two business segments. So, I see two business segments, one that's Innovative, using those resources as Innovative, and one that is Established using -- and those are the ones that John runs. I just wanted to make that clear. And most of the work we're doing on optionality is around those two businesses, not around more than those two businesses. Palbo in the EU?

Albert Bourla - Pfizer Inc - President of Vaccines, Oncology and Consumer

We have had discussions with European regulatory health authorities on the (inaudible) date. And it is our intention to file in the EU, and that filing will happen in 2015. I don't want to be more specific, if it's going to be beginning or the end of 2015, it's going to be 2015. Now, the anticipated the filing packets will likely look similar to what was submitted in US to the FDA.

Ian Read - Pfizer Inc - Chairman & CEO

Okay.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Albert. Next question, please.

Operator

Colin Bristow from BofA Merrill Lynch.

Colin Bristow - BofA Merrill Lynch - Analyst

On BD, immuno-oncology part, it seems to continue to grow as potential indications continue to grow, making it arguably more attractive for those who aren't first to market. How are you thinking about this space with regards to your business development priorities? And then just on Xeljanz, there's obviously a couple of competitor JAKs on the horizon. How do you view the competitive threat and Xeljanz's positioning? And you said on track for a filing in the first half of 2015, for your once daily formulation. Thanks.

Ian Read - Pfizer Inc - Chairman & CEO

Albert can -- sorry, Geno could talk about the Xeljanz situation, and then I'll come back on the BD.

Geno Germano - Pfizer Inc - President of Global Innovative Pharma

I think we are very pleased with the progress we're making with Xeljanz. We see continued adoption by the rheumatology community. We have about a 10%, now, share of new-to-brand patients from rheumatology, which is a nice leading indicator where that business is going. Obviously, the rheumatology community is getting more and more comfortable with Xeljanz. A majority of the use of Xeljanz is used in what I call

methotrexate-free regimens where patients who have difficulty with methotrexate are finding adequate therapy with Xeljanz, which is great. So, it's becoming entrenched, it's becoming established, and we think that's going to speak well for its competitive position in the future. We are still on track for first half filing for the once a day.

Ian Read - Pfizer Inc - Chairman & CEO

On our immuno-oncology BD activity, I agree with you that I think the value is in combinations. You've all seen the results with PD1. There are some durable responses in monotherapy, but our belief is the true power of the immuno-oncology will be from combinations, perhaps on two or three combinations. And so we are focused in developing our second wave immuno-oncology and our vaccines and the CART technology and are clearly open to any type of business development which would give us access earlier to a PD1-type portfolio that we could more easily integrate and combine with our second wave.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Ian. Next question, please, operator.

Operator

David Risinger from Morgan Stanley.

David Risinger - Morgan Stanley - Analyst

I have two questions. First, regarding the net cost outlook. Frank, could you just talk about how investors should think about cost trends going forward? And maybe you could weave in some comments about the potential for some increased cost if you are building up two business segments from the one that currently exists globally? And then with respect to palbo, I'm just curious, what should investors focus on in terms of timing of next key palbociclib readouts in case the FDA does not improve palbociclib on the first cycle review next spring? Thank you.

Ian Read - Pfizer Inc - Chairman & CEO

Okay Frank, do want to go into net cost and then Albert can look at the --

Frank D'Amelio - Pfizer Inc - CFO

Dave, the way I think about cost trends going forward is kind of by starting with, where are we? And I think where we are now, and I've said this before, is we are in the late innings, I think, on cost reduction. There's always more opportunity to be more efficient in everything that we do, but I think the big ticket items are behind us. We've basically gotten those identified, we've gotten those implemented, we've gotten those executed and they are obviously in our results. So, I think going forward, there'll be some opportunities, but the big-ticket opportunities, from my perspective, are behind us.

The one thing I always say, through, about just managing cost is, I'm making every statement based on the hand we currently have. To the extent that we expand that hand through whatever, collaborations, partnerships, business development, then that gives us opportunities once again to be efficient on a going forward basis. I think late innings, we've taken a bunch out. Still some more we can take out, but the big-ticket items are primarily behind us. In terms of frank increased cost going forward, I think the way I'll answer that is if we look at this year to last year, so 2014 to 2013, the one area where you see a fairly sizable increase is in our R&D spend.



If you look at our guidance for the year now, we just tightened it to \$6.9 billion to \$7.2 billion. If you take midpoint of that range, just for analytical purposes, compare it to last year, our R&D spend year-over-year is up \$0.5 billion. It's the late stage assets that we talked about plus the business transactions we did with Cellectis and MedGenesis. You see some pressure on the R&D spend, at least in 2014 versus 2013. Beyond 2014 going into 2015, we'll obviously give guidance on every line item when we get on our next earning calls where we close out 2014 and provide guidance for 2015.

Ian Read - Pfizer Inc - Chairman & CEO

Frank, I think you want to comment on -- I think the comment was, was there any ongoing expenses of setting up the two businesses?

Frank D'Amelio - Pfizer Inc - CFO

In terms of optionality, the short answer is, there are. They haven't been material on a year-to-date basis, but we are clearly incurring expenses, give or take about \$50 million this quarter, roughly twice that year to date. That will ramp up as we go into 2015 and obviously, I'll call that out on a going forward basis.

Ian Read - Pfizer Inc - Chairman & CEO

There are two types of expenses, of course. One is just the ongoing, which I think are very modest structural expenses of running and collecting information for two businesses and the other, which is more one-off and one-time as you set up your structures and your tax planning, et cetera, et cetera.

Frank D'Amelio - Pfizer Inc - CFO

Okay. Albert, on the?

Albert Bourla - Pfizer Inc - President of Vaccines, Oncology and Consumer

Palbociclib. David, right now we are focused on getting in US registration, based on our Phase 2 submission. FDA has accepted the submission, has given us priority review, we have a PDUFA date of February 13. We are looking forward to bring in the product to US based on this submission to the US patients as soon as possible. In Europe, as we just said, we also plan to submit in 2015, with a similar packet.

I can tell you that there are several studies that we are moving on. We had PALOMA-2, which is a Phase 3 study. But is expected to come to completion at the end of 2016, so the report sometime in March 2016. This is a replica of our Phase 2 study. We have two additional studies that will give us additional registration indications which are recurrent, and one of them is expected to come to completion, again, next year. And then we have one registration study, one Phase 3 study, which is recurrent advanced, in early stage with high risk of recurrence. And this is expected to come into completion sometime in the 2019 timeframe. As I said, our focus right now is to bring the first indication, which is first-line advancement of study in US based on our submission in -- that happened this August and had a PDUFA date of April 2015.

Ian Read - Pfizer Inc - Chairman & CEO

I suppose, David, to your question, that while we are working with the FDA to get approval in the April time frame of palbo, if they decide not to approve on that, then we have the replica, which we will report out towards the end of the year with interim look at some point in the year when the -- if they hit the number of events. I think the more important thing is that we have already started the trials to expand beyond advanced breast cancer in intermediate and early. And that lead is not a lead that will be eroded by the decision on when we get approval for advanced breast cancer. Because the fact that we started those trials now and our competitors are not in the position to start those trials because they don't have



the data, if you look at it from a competitive point of view, there is competition for advanced breast cancer, which may become more intense if our approval is delayed until the end of our Phase 3 trial. But I don't see that having and the implications on the competitive position on the intermediate or early breast cancer, which is a far larger percentage of the market longer-term. I hope that explains how we see the dynamics of that market.

Chuck Triano - Pfizer Inc - SVP of IR

Next question, please.

Operator

Jami Rubin from Goldman Sachs.

Jami Rubin - Goldman Sachs - Analyst

Ian, a want to go back to capital allocation. I think the market is saying that you need to do something bold and just wondering if you agree with that? And if so, how would you -- what would you define as bold? And what is your timeline? We've been talking about capital allocation and doing something bold now for several quarters. How we thinking, in terms of timing? Thirdly, I think that the AstraZeneca deal was thought of as a potential carveout opportunity. Would you consider -- I think the GEP business as a business that really has limited longer-term growth visibility whereas the Innovative business, we see pipeline assets that would drive future growth. Can you describe your options, options available to you in the GEP business? I think you've described incremental options. But is there something you could do in that business that's on the bolder side? Thanks very much.

Ian Read - Pfizer Inc - Chairman & CEO

Your characterization of something bold -- going back to the issue, we have a great sense of urgency inside Pfizer to continue to accelerate returns to shareholders. So, to the extent that BD will allow us to do that, then I am willing to take bold actions. And I believe that the initial approach to AZ was a bold action, one that we couldn't get to the right value equation and so the deal didn't progress. Certainly, I feel a sense of urgency on utilizing our balance sheet and our capital to do deals that are incremental, add incremental value and certainly add revenue growth in the innovative space. We are looking at all alternatives, and we are aggressively looking at all alternatives.

Now, in the GEP space, I think we said that -- I think the GEP business is somewhat difficult to analyze. I understand that. But, it's made up of what is really a great emerging markets business, which today represents about 30% to 35% of the total GEP business and is growing. That business is based on brands and quality and out-of-pocket, and I would model it more like I would model a consumer business, frankly. Then the rest of it is around peri-LOEs, which are highly profitable, and managing a pipeline that's mature in the developed markets. We are looking at ways to add additional growth levers to that business such as biosimilars, which we are investing in. And we are also looking at other types of acquisitions where we can use offshore cash, so it's highly efficient, or even where I'll we would do acquisitions that are in specific areas such as sterile injectables. I believe there are lots of opportunities to do BD in that area so as to add growth.

I thank you for your encouragement to be bold. We are looking at bold ideas. We are looking aggressively at using BD and we have a sense of urgency. Thank you for your question.

Chuck Triano - Pfizer Inc - SVP of IR

Thanks, Ian. Next question, operator.

Operator

Alex Arfaei from BMO.

Alex Arfaei - *BMO Capital Markets - Analyst*

Just a follow-up on the biosimilar comments earlier. Just at a higher level, could you comment more specifically at the commercial opportunity? I think it's fair to say that expectations for biosimilars have come down recently. How should we think about the process, the commercial process for your meningitis B vaccine? Thank you.

Ian Read - *Pfizer Inc - Chairman & CEO*

I will ask John to talk about biosimilars, and then Albert can talk about the mening-B. Thank you.

John Young - *Pfizer Inc - President of Established Pharma*

Thanks for the question, Alex. First thing to say if obviously, the biosimilars market is really one that is still evolving. We are still seeing regulators around the world put into place their guidance around biosimilarity and the development pathway for biosimilars. That's the first comment to make, is that marketplace is still in evolution. That said, it's estimated by independent analysts as being a market that is around about \$100 billion globally. The biotherapeutics marketplace overall, that biotherapeutics marketplace is going to grow to about \$250 billion by 2020. So, the market for biosimilars in that context potentially could grow as a market opportunity from around about \$1 billion today to about \$18 billion by 2020. Those are the general ranges that you actually see from independent analysts about the potential for this marketplace.

So, I think beyond saying that we see it as being a significant opportunity and saying that we believe we are well placed with our first wave of biosimilar assets, which as I commented already, we are progressing as expeditiously as we can. And we believe we'll be well placed in that marketplace. I think the general comment would be that, clearly, there's much water to flow under that bridge, but we are continuing to be very actively engaged in both monitoring and also engaging with regulators in the space.

Ian Read - *Pfizer Inc - Chairman & CEO*

Albert?

Albert Bourla - *Pfizer Inc - President of Vaccines, Oncology and Consumer*

From the mening-B vaccine, look, mening-B disease, is devastating, is characterized by rapid onset. Has very high rates of fatality, up to 20% of the people that get mening-B die from it. Usually within 24 hours. Many that survive will have permanent long-term (inaudible). This introduction, it is an important product for the patients to start with, and addresses the high unmet medical need. On the commensurate front, we believe that will give us a modest contribution to our revenue line, given the magnitude of our vaccines business.

Chuck Triano - *Pfizer Inc - SVP of IR*

Thanks, Albert. Next question, please.

Operator

Jeff Holford from Jefferies.

Jeff Holford - *Jefferies & Company - Analyst*

Just going back to the capital allocation, timing of business development. For Ian, really, just wondering around what your thoughts are about a potential for tax reform now that this has become such a focus for everybody. Do you potentially get paid to wait on doing business development? It depends on what your view is around the likelihood of that happening into next year. Just wondering if you could talk about some of that. Thank you.

Ian Read - *Pfizer Inc - Chairman & CEO*

Jeff, I think it's an interesting question. Clearly, there is that dynamic going on about what you are willing to pay for inversions vis-a-vis what you believe is the opportunity for fundamental reform in the US. I think we will know a little bit more after the midterm elections. But historically, you don't get tax reform unless the President of the United States puts a lot of his credibility and weight behind it. There are just too many factions and too many ways of dividing the cake and you need -- you really need the White House to take the lead in that.

And so if you are a betting man, you would suspect that fundamental tax reform would not occur until post the 2016 presidential elections. But, in politics, you never know. It's day to day. We will look at that after the November 4 and continue to factor in the elements you comment in what we think the value and inversion is worth. Thank you for the question.

Chuck Triano - *Pfizer Inc - SVP of IR*

Thanks, Ian. Next question, please.

Operator

Vamil Divan, Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

My first question is on the BD side. You touched on a couple of things like sterile injectables and maybe immuno-oncology. Are there any other areas that you highlight in terms of where you are looking to do more investing in? Do you really have a preference between investing on the Innovative side of your business as opposed to the more Established side? My second question, just following up on your comments around Xeljanz, earlier. You mentioned as being more now in methotrexate-free regimens, I believe. So, have these patients actually tried TNFs, or is it before TNFs? And anything you can update on your latest timelines around resubmitting into EU? Thanks.

Ian Read - *Pfizer Inc - Chairman & CEO*

Okay. On the business development, I think in the GEP business, there's a wide range of opportunities that stem from local investments using offshore cash to larger type investments to have capabilities in how to make generics. We just did a small acquisition in that area on Innopharma. So, there are a multitude of opportunities, and that's what John is looking at and going through in trying to isolate with the best opportunities would be.

From a point of view of, do we have a preference between GEP or Innovative? Everything is driven by value and portfolio balance. You would expect the larger scale acquisition to potentially cover both businesses. It may not do. Those are all the things we factor in. And then there was a question on Xeljanz (multiple speakers).



Geno Germano - Pfizer Inc - President of Global Innovative Pharma

On Xeljanz, about half the patients on Xeljanz have gone from methotrexate to Xeljanz, and about half have them been on a biologic -- one or more biologics. So, it's a mix. And then in terms of resubmitting in Europe, we intend to resubmit late in 2015 to the Europeans.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Geno.

Chuck Triano - Pfizer Inc - SVP of IR

In the interest of everybody's time, operator, if we could take one more question, please.

Operator

Your final question from Seamus Fernandez from Leerink.

Seamus Fernandez - Leerink Partners - Analyst

Just wondering if Mikael could talk to us a little bit about the differences in the bococizumab clinical trial design versus competitors and your views on the -- on how that is differentiated from competitors and why you think bococizumab is going to be a competitive offering in that space.

Ian Read - Pfizer Inc - Chairman & CEO

Okay, Seamus, Geno tried to do it, I will give Mikael a chance to make it clearer this time around. And Geno should feel free to add anything if he thinks Mikael hasn't covered it.

Mikael Dolsten - Pfizer Inc - President of Worldwide Research and Development

I'll build on Geno's excellent description why we think that the way we are developing bococizumab and importantly, the learnings we did in place to be that it was very extensive that allowed us to design what we think is a very comprehensive, broad Phase 3 program. A couple of key takeaway messages. One, our Phase 3 program includes population for both primary and secondary prevention. We think there will be a growing opportunity for patients that are at high risk in primary prevention such as diabetics with a high risk equivalent of cardiovascular disease. And to the best of our knowledge, we had only seen the outcome trial program that includes primary prevention.

Number two, we structured it in two different trials. One addressing individuals that cannot get down to 100 or below, and that allows is to show most likely a substantial risk reduction in cardiovascular disease since this is the segment where we expect a strong correlation between lowering cholesterol and lowering risk for CV events. The second trial really focusing on bringing patients in the 70 to 100 segment with high risk, both primary and secondary prevention patients, down really low in cholesterol. And we think that will allow us to open up unmet need in that area further by generating data.

I should say that the dose regiment that we developed in Phase 2b is really crucial for this study design, and we developed the dosing regimens that allows us to start with a high dose and get immediately down patients to low levels. And only if necessary do a dose titration with lower dose of bococizumab. We do think bococizumab is one of the most potent antibodies that showed really pronounced lowering of cholesterol. It performs well in every two weeks, and we have said earlier that through a partnership with Halozyme, we have a longer lifecycle management plan exploration of once a month after first ensuring generating good data in the current regimen.



Ian Read - Pfizer Inc - Chairman & CEO

That Halozyme is unique to us, I think we have exclusivity on that technology.

Mikael Dolsten - Pfizer Inc - President of Worldwide Research and Development

Correct. Thanks, Ian.

Ian Read - Pfizer Inc - Chairman & CEO

Thank you, Mikael. Good answer.

Chuck Triano - Pfizer Inc - SVP of IR

Thank you, and thank you, everybody, this morning, for your time.

Frank D'Amelio - Pfizer Inc - CFO

Thanks for your time, everybody. Bye-bye.

Operator

Ladies and gentlemen, thank you for participating in today's Pfizer's third-quarter 2014 earnings conference call. This does conclude the call. You may now disconnect.

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