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PFE - Q1 2014 Pfizer Earnings Conference Call

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OVERVIEW:

PFE reported 1Q14 revenue of approx. \$11.4b and reported diluted EPS of \$0.36.
Expects 2014 adjusted revenue to be \$49.2-51.2b.



CORPORATE PARTICIPANTS

Chuck Triano *Pfizer Inc. - SVP of IR*

Ian Read *Pfizer Inc. - Chairman & CEO*

Frank D'Amelio *Pfizer Inc. - CFO*

Geno Germano *Pfizer Inc. - President of Global Innovative Pharma*

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

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

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

Doug Lankler *Pfizer Inc - General Counsel*

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Chris Schott *JPMorgan Chase & Co. - Analyst*

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's first-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 thank you for joining us today to review Pfizer's first-quarter 2014 performance. I'm joined today in New York 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 home page, Pfizer.com, by clicking on the link for Pfizer Quarterly Corporate Performance, First Quarter 2014, located in the investor presentation section in the lower right-hand corner of this page.

Before we start, I would like to remind you that our discussions during this 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 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.

We will now make prepared remarks, and then we will move to a question-and-answer session. As we expect there will be questions related to our proposal to AstraZeneca, and I would also note that there are limitations placed on our responses by the UK Takeover Code, and as such, there will be some questions we are not in a position to answer at this time.

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

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Chuck and good morning, everyone.

During my remarks this morning, we will briefly recap the highlights from the quarter, and provide some observations on how our strategy is progressing. Before discussing the quarter, I'll begin with a few words about the proposal we made to AstraZeneca, to combine our two companies, and the rejection of our proposal by AstraZeneca's Board.

The proposal we announced publicly last Friday represented a substantial premium of 32% for AstraZeneca's shareholders, based on AstraZeneca's closing price of GBP37.82 on the day before speculation began regarding a potential proposal, a 39% premium to the closing price of GBP35.86 on the day before our January proposal, and a 22% premium to the unaffected all-time high closing price since the formation of the Company in 1999. This is an opportunity for AstraZeneca shareholders to realize near-term value creation well in excess of its standalone prospects, as well as the opportunity to effectively trade up their AstraZeneca position for equity in the new combined Company, with far greater potential for value creation.

Up to this point, we've only had access to publicly-available information about AstraZeneca. Based on what we have learned through that information, we believe our revised proposal is compelling, and responds to what we've heard from their shareholders. We are very disappointed with their unwillingness to engage in conversations, and believe it is in the best interest of both companies, and AstraZeneca and Pfizer shareholders, that we pursue a friendly negotiated transaction that can be recommended by both our Boards.

We would like to engage with AstraZeneca to gain a better understanding of their business and prospects. We believe they're an excellent strategic fit for Pfizer, and they have a strong and complementary alignment across and within our product portfolio and research platform. That said, we remain very confident in our go-forward strategy, regardless of a combination. We see this as further enhancing our strategy, and consistent with creating shareholder value.

Regardless of whether we complete this transaction, the main pillars of our strategy remain in place. Namely, focusing on innovation and advancing our pipeline, maximizing the productivity and returns generated within our commercial businesses, and remaining good stewards of our shareholders' capital. We believe that our formidable proposal merits serious consideration. Given our position of strength, we will remain disciplined as we move through this process.

Turning to our performance for the quarter, overall, we continue to perform well in a challenging operating environment. Our financial performance was in line with our expectations. Revenues for the quarter reflected the continuing impact of product loss of exclusivity, and the expiration or near-term termination of some collaborations. A disproportionate amount of about one-third of the anticipated full-year impact was recorded in the first quarter.

If you exclude that impact, we had 1% operational growth. We saw growth from many of our key revenue drivers, including Lyrica, Xalkori, and Inlyta globally, Enbrel outside of the US and Canada, recently-launched products Eliquis and Xeljanz in the US, and from our collaboration with Mylan to market generic drugs in Japan.

I would point out that our business has historically demonstrated seasonality of revenues, and this quarter was no different. In terms of product developments, we reported positive results from Prevnar 13 CAPiTA study in older adults, and announced FDA approvals, including supplementary new drug applications for Xeljanz to include radiographic data in the label, and for Eliquis for prophylaxis of deep vein thrombosis, as well as FDA approval of Nexium 24-Hour, for over-the-counter use, for the treatment of frequent heartburn in adults 18 and older.

There were several positive elements in our pipeline, including positive results from a randomized Phase II study of palbociclib in combination with letrozole, in first line treatment of ER-positive HER2-negative advanced breast cancer, positive results from a randomized Phase II study of bococizumab in the reduction of LDL cholesterol, and a breakthrough therapy designation from the FDA for a meningitis B vaccine for the prevention of invasive meningococcal disease in adolescents and young adults.

For the full year revenue outlook, we anticipate key products will continue exhibiting growth, and that operational growth in emerging markets will be in the mid-single digit range rather than in the 3% range we saw in this quarter. Typically, our sequential annual product revenue pattern exhibits relative strength in the late quarters, compared to our first quarter. For the balance of 2014, we anticipate incremental revenue contributions from Eliquis, Xeljanz, Prevnar 13 adult, Duavee, and the expected launch of over-the-counter Nexium.

As you know, at the beginning of this year, we implemented the new commercial operating structure to position the Company for the future, and to focus on maximizing growth. We have three global operating segments, Global Innovative Pharma; Global Vaccines, Oncology and Consumer Healthcare; and Global Established Product Pharma. These segments are fully functioning and are increasing the focus of management in providing greater transparency to shareholders, and enhancing our ability to drive the business.

As we previously committed to you in today's earnings announcement, we provided the revenues and costs associated with each of these operating segments. In a few minutes, the leaders of each segment, Geno Germano, Albert Bourla, and John Young, will provide you with additional context regarding the performance of their particular segment.

While we have moved to this new operating structure, our overall focus and priorities have not changed. We remain focused on driving future value creation for shareholders by delivering innovative new products, maximizing the potential of our existing products, remaining diligent in terms of capital allocation, and driving a culture that continues to foster a strong ownership environment.

Reflecting on the state of our business, I am pleased with our pipeline progress. We are continuing to see the benefit of the decisions we took over three years ago, when we decided to focus our research and development in the areas where we have the most expertise, and where the greatest unmet medical need exists.

Looking at the compounds we have across all stages of our pipeline, I can confidently say that this part of our strategy is on track and gaining momentum. Similarly, our past and current steadfast focus on the prudent management of our capital is enhancing the overall competitiveness of our businesses.

This quarter, once again, we operationally reduced our adjusted cost of sales, adjusted S&I expenses, and adjusted R&D expense in total. We will continue to build on our solid track record of realizing benefits from cost reductions and productivity initiatives, and as we have done in the past, we will use business development opportunities as an enabler of strategies for creating shareholder value.

Overall, I believe we are performing well in a challenging operating environment. Our pipeline is advancing. We have a strong track record when it comes to using capital to generate value, and we have an engaged and motivated workforce that has embraced the culture of ownership. Collectively, these are the elements of our strategy that are helping to drive our overall business results.

Throughout this year, you will see us taking actions to execute on our plans to advance new therapies for patients, strengthen our commercial businesses, manage our cost structure, and deploy our capital in ways that yield the greatest value to our shareholders. Now, I'll turn it over to Frank.

Frank D'Amelio - Pfizer Inc. - CFO

Thanks, Ian. Good day everyone. As always, the charts we are reviewing today are included in our webcast.

Before I begin, I want to remind everyone that at the beginning of this year, we began operating under our new commercial structure, consisting of three operating segments: Global Innovative Pharmaceuticals; Global Vaccines, Oncology, and Consumer Healthcare; and Global Established Pharmaceuticals. Consequently, we are now reporting our quarterly and annual P&L in accordance with this structure for all periods presented.

I also want to remind everyone that as a result of the full disposition of Zoetis on June 24, 2013, the financial results of the Animal Health business are reported as a discontinued operation in the consolidated statement of income for the first quarter 2013. Now let's move on to the financials.

First quarter of 2014 revenues of approximately \$11.4 billion decreased 9% year-over-year, reflecting a 3% negative impact from foreign exchange, and an operational decline of approximately 6%, driven mainly by the expiration on October 31, 2013 of the co-promotion term of the collaboration agreements for Enbrel in the US and Canada, the ongoing expiration of the Spiriva collaboration in certain countries, continued erosion for branded Lipitor in the US and most other developed markets, the loss of exclusivity and subsequent multi-sourced generic competition for Detrol LA in the US, and other product losses of exclusivity in certain markets.

These were partially offset by the strong operational growth of Lyrica, Xalkori and Inlyta globally; Enbrel outside of the US and Canada; Eliquis and Xeljanz, primarily in the US; the contribution from the collaboration to market generic medicines in Japan, with Mylan. In addition, reported revenues included \$57 million from transitional manufacturing and supply agreements with Zoetis.

Adjusted diluted EPS of \$0.57 increased 12%, primarily due to an aggregate operational decrease of 3% in adjusted cost of sales; adjusted S&A expenses; and adjusted R&D expenses, primarily resulting from cost reduction and productivity initiatives; a lower effective tax rate; and fewer diluted weighted average shares outstanding, due to our ongoing share repurchase program, and the impact of the Zoetis exchange offer. Reported diluted EPS of \$0.36 compared with \$0.38 in the year-ago quarter, was positively impacted by the above-mentioned items and lower restructuring and asset impairment charges, compared with the year-ago quarter.

Reported results were negatively impacted by the previously mentioned year-over-year decrease in revenues, and the non-recurrence of income from discontinued operations associated with our Animal Health business, and the gain associated with the transfer of certain product rights to Pfizer's JV with Hisun in China in the year-ago quarter. Finally, higher legal charges compared with the year-ago quarter.

Foreign exchange negatively impacted first-quarter revenues by 3% to \$364 million, and had a net positive impact of \$195 million on the aggregate of adjusted cost of sales, adjusted S&A expenses, and adjusted R&D expenses. As a result, foreign exchange negatively impacted first-quarter adjusted diluted EPS by approximately \$0.01, compared to the year-ago quarter.

Now moving on to our 2014 financial guidance, historically, our business has demonstrated seasonality of revenues, and this quarter is no different. That said, we are confirming all components of our adjusted 2014 financial guidance ranges, and as such, continue to expect our adjusted revenue to be in the range of \$49.2 billion to \$51.2 billion.

We expect that the continued momentum from our new products, including Prevnar 13 adult, Xeljanz, Eliquis, Inlyta, and Xalkori; the expected launch of over-the-counter Nexium; and the accelerating operational growth in emerging markets will help to mitigate the impact of product LOEs

and losses of alliance revenue. It's important to note that our adjusted financial guidance continues to reflect a full-year contribution from Celebrex in the US. If necessary, we will update our financial guidance when we are in a better position to make an informed judgment about the market exclusivity of Celebrex in the US from May 30 through the end of this year.

With respect to reported diluted EPS, due to the applicability of the UK Takeover Code to our proposed combination with AstraZeneca, we are not currently permitted to confirm or update our 2014 reported diluted EPS guidance, which is our customary quarterly practice. Preparation of certain reports by our reporting accountants and financial advisors in accordance with the UK takeover code are currently under way.

Because Pfizer recorded a number of charges during the first quarter of 2014, relating primarily to the resolution of litigation-related matters, Pfizer's previously-issued 2014 reported diluted EPS guidance is no longer valid. Updated reported diluted EPS guidance will be provided as soon as practical.

As required by the UK takeover code, the Pfizer responsible officers including Ian, Doug Lankler, our General Counsel, and me, confirm that the adjusted financial guidance provided has been properly compiled, based on the same assumptions set out in the adjusted financial guidance issued on January 28, 2014, and prepared in accordance with the accounting policies of Pfizer.

Now, I'll turn it over to the business leads, Geno Germano, Albert Bourla, and John Young, for their respective commentary on their results for the Global Innovative Pharmaceuticals; Global Vaccines, Oncology and Consumer Healthcare; and Global Established Pharma units. Geno?

Geno Germano - Pfizer Inc. - President of Global Innovative Pharma

Thanks, Frank, and hello everyone. The Global Innovative Pharma is our research-driven biopharmaceutical business, focused on developing and commercializing innovative new medicines.

Our current portfolio consists of newly-launched products including Eliquis and Xeljanz, key in-line brands including Lyrica outside of Europe, and Enbrel outside of the United States and Canada, in addition to other products that we generally anticipate will maintain market exclusivity beyond 2015. Our strategy involves making targeted investments to help grow our recently-launched brands and other leading medicines, in order to generate sustainable revenue growth over time, as well as making investments in R&D to support our next wave of innovative products.

Some of these near term investment objectives include continuing to build on our momentum with Eliquis among cardiologists, focusing on the differentiated clinical profile, building on the efficacy profile of Xeljanz in the United States through promotion of the data regarding inhibition of structural damage that's now included in our labeling, and also our monotherapy indication. Leveraging our strong presence in the women's health category to launch Duavee in the United States as a potential new standard of care for moderate to severe vasomotor symptoms associated with menopause, and prevention of post-menopausal osteoporosis. Continuing investment in direct-to-consumer advertising for Lyrica, Chantix and Viagra in the United States, plus investments in growth markets such as Japan, and supporting ongoing Phase III clinical studies for bococizumab, ertugliflozin, and Xeljanz.

Moving to the first-quarter results for the Global Innovative Pharma segment. In the first quarter, revenue declined 4% operationally versus first-quarter 2013, and this was largely due to the expiration of the Enbrel co-promotion term in the United States and Canada.

Revenues were also negatively impacted by the loss of exclusivity of Lyrica in Canada in February 2013, as well as some other smaller LOEs from prior periods. If we exclude the impact of Enbrel and these LOEs, our underlying operational revenue growth was 10%, driven primarily by continued growth of Xeljanz, Eliquis, Enbrel, outside of the United States and Canada, and Lyrica outside of Europe.

Now I'd like to review selected financial highlights for the Global Innovative Pharma segment. As a reminder, the revenues and expenses presented are those that were directly attributable to the GIP segment. First-quarter 2014 income before taxes declined 5% operationally to \$1.8 billion versus first quarter 2013.

IBT as a percent of revenues on an operational basis declined modestly to 57.4%. Increased investment in recently-launched brands and key in-line products, partially offset by benefits from cost reduction and productivity initiatives, resulted in a 12% operational increase in SI&A expenses, compared to prior-year quarter. Our first-quarter 2014 R&D expense grew 29% operationally compared to last year, as we initiated Phase III programs for bococizumab, and ertugliflozin, and continued investment in our extensive clinical development program for potential new Xeljanz indications.

Additionally, IBT in the first quarter of 2014 benefited from a significant increase in other income, primarily due to trailing royalties earned on sales of Enbrel in the United States and Canada after October 31, 2013. On that date, the co-promotion term of the collaboration agreement for Enbrel in the United States and Canada expired, and we became entitled to royalties for a 36-month period.

In conclusion, we're excited about the GIP portfolio and our pipeline. We believe our focused investment strategy this year will drive sustained future revenue growth. And now, I'd like to turn it over to Albert Bourla to discuss the global Vaccines, Oncology and Consumer Healthcare segment.

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

Thank you very much, Geno, and hello, everybody.

VOC is comprised of three separate distinct businesses: Vaccines, Oncology and Consumer Healthcare, each poised for organic growth over time. We've had an eventful year so far, and have achieved several significant milestones.

First, with Vaccines, we presented positive results from Prevnar 13's CAPiTA trial at a major conference, which clearly demonstrated that Prevnar 13 can prevent a significant portion of pneumococcal community-acquired pneumonia in adults age 65 and older. Evidence from this study is important for a population in which age-related decline of the immune system makes it difficult to prevent disease.

Hospitalizations due to pneumococcal pneumonia in adults represent a growing burden to public health systems. For example, the annual cost of adult hospitalization in the US alone is estimated at \$8 billion. We look forward to further discussing this data with regulatory authorities and vaccine technical committees to help inform decisions regarding Prevnar 13 label and recommendation updates.

Regarding ACIP, we have had productive interim discussions with the pneumococcal working group. We are prepared for a more formal ACIP presentation in June, should the CDC confirm that topic in their agenda. Second, in vaccines again, the FDA granted breakthrough therapy designation of our vaccine for meningitis B, a disease that is characterized by rapid onset, with high rates of fatality. We intend to file a BLA with the FDA by mid-2014.

Moving to Oncology, we presented positive results from palbociclib's PALOMA-1 trial at a major conference. We are very pleased with the results, which highlight the potential of palbociclib to become a new standard of care for women with ER-positive HER-2 negative advanced breast cancer. This is encouraging information for these women who represent approximately 60% of the advanced breast cancer population. We continue to have productive and ongoing discussions with the FDA about this data, as well as the other necessary supporting data for a New Drug Application.

We continue to envision this potential pathway to filing an NDA based on the PALOMA-1 data, although no decision has been made. Once one has been made, we will communicate it publicly. We also began dosing patients in two additional Phase III trials, one in recurrent advanced breast cancer and one in early breast cancer. And next, we reported positive results for Xalkori compared to chemotherapy, in the first-line setting for ALK-positive non-small cell lung cancer.

Finally, with Consumer Healthcare, we received FDA approval for Nexium 24-Hour, for over-the-counter use. This approval represents the first significant milestone in executing our Rx to OTC strategy. The US launch is set for May 27. We also continued to advance promising candidates to position the next wave of potential innovative launches, including the c-difficile and staph oral vaccines, as well as our small inhibitor for hematologic cancers.

Now, let's go to the first-quarter results. For this quarter, VOC segment delivered revenues of \$2.2 billion, which represents an increase of 1% operationally, versus Q1 2013. Please note that the revenues and expenses presented are those that were directly attributable to the VOC segment.



Revenues for vaccines increased 2% operationally, driven by the US, primarily reflecting government purchasing patterns. Internationally, revenues were flat operationally, with emerging markets growing at 14% rate, driven primarily by China and GAVI purchases, but essentially offset by declines in the UK and Canada. Oncology revenues increased 10% operationally, due to growth from new products, Xalkori and Inlyta, partially offset primarily by changes in certain buying patterns in certain markets.

Consumer healthcare revenues declined 3% operationally, due to a soft cough, cold, flu season in the US and Canada, in comparison with the same period last year, extreme winter weather negatively impacting retail traffic in the US and increased competition for Advil with the return of certain brands to the market. However, it is important to note that as the year progresses, we anticipate revenues to be positively impacted as more healthcare providers appreciate the value of the Prevnar 13 adult indication. Of course, the full potential will depend upon updated labels and recommendation decisions.

Additionally, we expect our revenues to be positively impacted by the launch of Nexium 24-Hour and other consumer products, the timing of certain national immunization programs and continued uptake of recently launched products in oncology, among other factors.

I would like now to walk you through a few additional highlights from the VOC segment financials, specifically regarding our income and our direct, managed expenses. VOC segment income before taxes was \$1.1 billion or 48.6% of our revenue. This represents an improvement of 2.8 percentage points operationally.

Our gross margin was \$1.8 billion or 81.2% of revenue, an improvement of 0.8 percentage points, compared to the year-ago quarter. Due to a greater portion of this year coming from our oncology and vaccines businesses, as well as further cost efficiencies in manufacturing.

SI&A expenses were \$531 million. This represents a 2% increase operationally, primarily due to pre-launch expenses for Nexium. However, as a percentage of revenues, our SI&A spend has remained consistent year-over-year. The VOC R&D expenses were \$184 million, which represents an 18% decrease due to the completion of certain Phase III trials, which more than offset incremental costs related to the expansion of the palbociclib clinical development program.

Thank you, and I will now hand it over to John Young, Group President of the Global Established Pharmaceuticals segment.

John Young - Pfizer Inc. - President of Global Established Pharma

Thank you, Albert, and good morning everyone.

Global Established Pharma, GEP, is a large and highly diverse business, with unique opportunities across portfolios and geographies. It's a significant cash generator, and it's Pfizer's largest business. For the first quarter of 2014, the GEP business accounted for just over half of Pfizer's total revenue, and about two-thirds of Pfizer's total revenue from the emerging markets comes from GEP.

Notably during the first quarter, emerging markets comprised nearly 30% of GEP's segment revenues. Contrary to some perceptions of this business, traditional commodity generic products in developed markets are actually a very small part of the GEP portfolio, and account for only about 5% of GEP revenues. We see our GEP strategic priorities as two-fold: One, is to optimize the financial performance of the declining components in the developed markets. And two, focus on the current and future areas of growth, aimed at reversing the decline trend of not optimizing the business margins over the mid to longer term.

Before I get into the details of the GEP performance at quarter one, I'd like to give a quick overview of the business, and how it's structured. GEP is comprised of three components that have different market dynamics. Two of these components are in the developed markets:

Firstly, peri-LOE includes major brands that have recently lost or are approaching the loss of exclusivity, such as Celebrex, Lyrica in Europe, Zyvox, Pristiq, and Detrol. Secondly, legacy established products includes mature, off-patent products such as Lipitor and Norvasc, and we also have targeted opportunities that exist in this product grouping.



We expect to see a decline in both of these areas, due to intense erosion from generic competition. However, we will continue to focus on growing the patented brands prior to the loss of market exclusivity, as well as to optimize the transition of brands to the off-patent stage, and extend their life beyond LOE.

The third component is the emerging markets, including the BRIC-MT markets. This includes all GEP products sold in emerging countries and growth opportunities in emerging markets, including the BRIC-MTs. This component is expected to grow steadily, driven by favorable macroeconomic and improving socioeconomic conditions in these countries.

Growth opportunities represents a fourth dynamic of the GEP business, and includes organic and inorganic initiatives such as partnerships, product enhancements, and our biosimilars portfolio, spanning both developed and emerging markets. We anticipate these opportunities will drive revenue growth in our legacy EP developed and emerging markets portfolios over time.

Now let's go to the GEP first-quarter results. For this quarter, GEP delivered revenues of \$6 billion, which represents a 10% decline operationally.

The peri-LOE products in developed markets experienced an overall decline of 17% operationally, due to the loss of exclusivity and subsequent multi-source generic competition for Detrol LA in the US, and for Viagra in most European markets, as well as the termination of the co-promotion agreement for Aricept in Japan, and the decline in our share of revenues, resulting from the wind-down and termination of the Spiriva co-promotion agreement for certain markets. However, it's important to note that certain patent-protected products have shown positive operational growth, including Lyrica in Europe, Pristiq in the US and developed international markets, as well as Inspira in developed international markets.

Our legacy established products in developed markets experienced a 10% operational decline, primarily due to the continued share erosion by generic versions of Lipitor in the US, and most developed international markets. The legacy emerging markets increased 1% operationally. Growth was negatively impacted by certain one-time issues, and removing these, operational growth would have been 4%, driven by our BRIC-MT markets.

The growth opportunities increased 10% operationally, driven primarily by contributions from the collaboration with Mylan to market generic drugs in Japan, and Quillivant XR sales in the US. This growth opportunity's performance is reflected in the previously-mentioned operational results of the legacy established products and emerging markets components. To provide one final metric for how we measure GEP's underlying performance, excluding aligned products, LOEs and Lipitor in developed markets, the operational revenue decline in the first quarter of 2014 for the remaining 92% of GEP's portfolio was 2%, as opposed to 10% for the segment overall.

I'll now walk you through a few additional highlights from the GEP financials, and will explain what is driving some of the ratios, and how I see them evolving. I'll be speaking to our direct managed expenses relative to our revenues.

Income before taxes that is directly attributable to GEP was \$4 billion in the first quarter 2014, or almost 68% of GEP's revenue. This represents an improvement of 1.7 percentage points on an operational basis. Our gross margin was \$5 billion, or 83% of revenue. This is representative of the portfolio profile of the GEP business that is mainly composed of post-LOE and peri-LOE brands, with a smaller contribution from generics. As large brands leave market exclusivity, this gross margin will come under pressure.

GEP SI&A expenses were \$837 million in the quarter. This represents a 20% operational decrease, and is primarily driven by decreased sales force expenses in both developed and emerging markets, as well as resource allocation favoring higher growth opportunities within the emerging markets. This 20% reduction also reflects a favorable one-time item this quarter related to administrative expenses.

We will continue to make SI&A expense discipline a focus of the management of our business. The GEP R&D expenses for the quarter are 2.3% of revenue, and represent a 23% operational decline. This is the result of focused reductions in operational expenses, partially offset by higher spending for clinical trials associated with the development of our biosimilars portfolio. Moving forward, we expect to increase investment in those assets that have entered and will enter Phase III.

In summary, while GEP is expected to go through a period of revenue decline over the next few years, primarily due to the LOEs of major brands in developed markets, we are focused on building our revenue base and stabilizing margins over the mid to longer term, and following the period

of anticipated LOEs, we expect revenue growth to return as our growth opportunities become a more substantial piece of the GEP business in the future.

Thank you. And I'd now like to hand it back to Frank.

Frank D'Amelio - Pfizer Inc. - CFO

Thanks, John.

Now moving on to key take-aways, our first-quarter 2014 results were in line with our expectations, and reflect the loss of exclusivity of certain products, the expiration and near term termination of certain collaboration agreements, and the continued challenging operating environment. We confirmed all components of our 2014 adjusted financial guidance, which continues to reflect the full-year contribution from Celebrex in the US. We're now operating under our new commercial structure, and the presentation of our financial results for the new structure provides transparency into each of our global segments.

With respect to our late-stage R&D pipeline, we achieved the statistically significant primary endpoint results in our PALOMA-1 Phase II breast cancer study of palbociclib, and began dosing patients for two Phase III breast cancer trials. And we presented positive results of our CAPiTA trial, which demonstrated that Prevna 13 prevented a first episode of vaccine-type community-acquired pneumonia in adults 65 years or older.

We continue to create shareholder value through prudent capital allocation. To date in 2014, we've repurchased \$1.7 billion, or approximately 54.3 million shares, and we continue to expect to repurchase \$5 billion of our common stock this year.

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

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Frank.

And I want to thank the audience for listening. I know the prepared remarks were longer than typical, but given it was the first quarter with the new financials for the segments, we wanted to give our business leaders some time to walk through their segments in the financials. We'll get ready for the Q&A session, and I think I would just reiterate once more related to questions regarding AstraZeneca, we will have limitations placed on our responses by the UK Takeover Code.

With that, operator, if we could please poll for questions. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Your first question comes from Mark Schoenebaum from ISI Group.



Mark Schoenebaum - ISI Group - Analyst

If I could just throw one at you. I'm sure you've gotten this in all kind of one-on-one meetings, and it might be good just to address it again. The big concern I guess about the AZ deal or proposed deal is that you obviously think there's something wrong with Pfizer, if Pfizer wasn't able to acquire AstraZeneca. I was just wondering, Ian or Frank, if I could just get a general reaction to that.

Number two, the Street, as I understand it, is currently modeling pretty dramatic revenue decreases for GEP, as well as more modest decreases for GIP over the long term. I heard in the prepared remarks you talked about a return to growth in GEP. I was just wondering if you could expand on that a little bit, and help us out. I know you did a little bit, but I'd appreciate some more color if possible.

And finally, an easy one for Frank, since you have 2013 segment information, as least for the 1Q of 2013 in the press release, is there any chance that those numbers could be audited? Such that would become year one? Thank you very much.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Mark, for your one question. I think we've gone out of our way to say that this -- I see this AZ deal as a way to accelerating an already good strategy. I think we've gone at pains in this release to point out the exciting developments in our pipeline, the evolution of fixing of any core, the way we return value to shareholders, and so I definitely feel that we did this out of a position of strength.

In fact, we, having approached AZ in December, and having received a negative from them in confidential conversations, decided to wait until we had results of palbociclib and adult vaccine, so that if we came back into the market it would be seen as we're coming back from a position of strength. So we will continue to operate our business, continue to drive shareholder value, and feel very confident about our standalone strategies.

I'm going to ask John to talk a little bit about GEP, and I believe interesting enough, GEP when you took out the loss of exclusivity, or loss of the deal with Amgen and other smaller LOEs, it was 10% growth, which is a really good growth in that area, solid in that area. John, regarding GEP?

John Young - Pfizer Inc. - President of Global Established Pharma

Thanks for your question, Mark. So I think we've -- certainly in my prepared remarks, and the meetings we've had with the analyst community, one of the things we've been very clear on is that we know in the short to medium term, we will see pressure on revenues as we experience losses of exclusivity from some of the major brands in our portfolio that are either already post LOE and are still coming under pressure. Brands would include Lipitor falling into that bucket, or some of the major brands that we have in our portfolio, that have yet to lose exclusivity, but will do so over the next coming few months and years, so brands like Lyrica in the EU, like Celebrex in the US, like Zyvox, and so on.

So to be clear, we certainly know that this is a business portfolio which will come under revenue pressure in the short to medium term. But in the medium to longer term, we certainly see our revenues plateauing and having the opportunity to return to growth. And the underlying drivers for that opportunity that we see in the medium term would include our biosimilars portfolio. We believe we're going to have a strong biosimilars portfolio, or we hope, ultimately five biosimilars that we will aim to bring to market.

Clearly, the landscape for that type of portfolio and the regulatory environment is still evolving, but we have regulators that have clarified the regulatory pathway. We actually believe that is a very positive opportunity for growth.

Additionally, we see the opportunities for growth with this portfolio in some of the emerging markets, including China as an example, but not limited to China, remain very positive. Our China business continues to perform well, and additionally, we see additional opportunities for growth with certain key partnerships such as Hisun in China, and our Teuto partnership.

When we put all those things together, whilst in the short to medium term we certainly will see continued pressures on revenues, in the medium to long term, we do believe this business has a number of underlying factors which will enable us to return to growth in the medium to longer term. Hopefully that answers your question.



Frank D'Amelio - Pfizer Inc. - CFO

Thank you, it's Frank. Mark, no change from what I have said previously. 2014 year one, three years prospective audited financials. I think the key here is to remember audited financials require more than an income statement.

They require a balance sheet, a cash flow statement, another comprehensive income statement, and a shareholders equity statement. So no change from what I've said previously.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Frank. Next question, please.

Operator

Your next question comes from David Risinger from Morgan Stanley.

David Risinger - Morgan Stanley - Analyst

I just had two questions. First, with respect to Xeljanz, obviously the competitive landscape will evolve down the line, but you've talked about driving greater uptake. Could you just comment on why you wouldn't consider discounting more to drive greater share?

Obviously, the plans are using safety concerns to limit formulary adoption in an attractive Tier 2 status position. But really, the plans obviously get tremendous rebates on Humira and Enbrel. So I'm just wondering how we should think about the pricing strategy for Xeljanz, and if pricing can be a greater lever to drive greater uptake.

The follow-on to that is, since you've asked for just one question, could you just update us on the once-a-day formulation development and filing timing? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Dave. Geno, could you take those questions?

Geno Germano - Pfizer Inc. - President of Global Innovative Pharma

Obviously, Dave, we're keenly aware of the pricing and access and reimbursement environment for Xeljanz, and frankly, in the whole class of biologics for RA, and have run all the scenarios. And frankly, at this point in time, we think the best thing to do is to continue to build on the positive profile that we're seeing with Xeljanz. In the data from our Phase III studies, from our long-term extension, now we have the structured data in our label, we had positive outcomes from patient-reported outcomes analyses, and we think that will give us the strength that we need with physicians and with payers, to continue to grow the business.

We saw a nice increase from fourth quarter of 2013 to first quarter of this year, with the 16% uptick in prescriptions, and we continue to gather momentum. So we're feeling pretty good about that. With regard to the once-a-day, we are putting the data together, and I believe we're planning to file next year.



Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Geno. Next question, please, operator.

Operator

Your next question comes from Chris Schott from JPMorgan.

Chris Schott - JPMorgan Chase & Co. - Analyst

I appreciate all the business unit details. It's very helpful to understand the Company here. So two questions. The first was, if you actually split your business into three standalone entities, can you quantify how much more operating expense or dissynergy the Company would incur? I think it would just be a helpful data point, as the Street looks to value your various business units.

My second question was just on managing the Company in this business unit structure, I guess it's been about four months. Maybe the business unit leaders could talk about what they're finding in terms of the strategy and expense structure of the business.

I guess my question is, should we think about either incremental cost cutting or updated strategic priorities for one or more of these units over time, as the new management teams further review their franchises, or is everybody pretty comfortable in terms of how the businesses are positioned today, and how they're being managed? Thanks very much.

Ian Read - Pfizer Inc. - Chairman & CEO

Chris, on this idea of three segments, I think I would draw the market to the view that there are actually two major segments inside the Company. There is an innovative core and there is an established products.

And as we look to the future optionality, I would be more focused on that than looking at multiple businesses with multiple dissynergies. So we don't really think there's any material dissynergies, if these businesses were to be standalone, or these two segments. In fact, we think that management focus overcomes those type of dissynergies.

And on getting to this stage, given we've taken so long with prepared remarks, I'm really going to say I think we feel we've laid out for you by our opening comments the major strategies of these businesses, and during the year, will be ample time, I think, for the business unit leaders to have conversations with you. Frank, do you want to add something to that?

Frank D'Amelio - Pfizer Inc. - CFO

Just a couple quick things on the first point, on the standalone, to respond to Chris. Chris, we gave you all the detail we could relative to the direct managed and then the allocated piece, with the big chunks of the allocated piece being research and development through POC, medical, and then corporate centers. Finance, IT, those kinds of functions.

In terms of hypothetically, if they were separate companies, there would be some incremental cost, right? There's one CFO in the Company today. They'd each need their own CFO, and they'd each need their own general counsel, so there'd be those kind of incremental costs.

We didn't assign any of the interest expense or the interest income to the businesses, either. We left it out of the allocation. So there's some items, clearly, that would be incremental, if they were to be standalone. To Ian's point, I don't think there's anything that would be really material to those being standalone businesses.

Chuck Triano - Pfizer Inc. - SVP of IR

Next question, please.

Operator

Your next question comes from Jami Rubin from Goldman Sachs.

Jami Rubin - Goldman Sachs - Analyst

Just a couple. On Prevnar 13, you had mentioned that the next ACIP meeting is in June. What are the potential outcomes of that meeting? I would assume that the most realistic outcome, given results of CAPiTA, would be that Prevnar 13 would be included in the 65 and older mandated vaccination schedule, if you could confirm that.

Just one other question, rather two other questions on the new business structure. Ian, how does the business development process work in the context of the new structure? If VOC wants to make an acquisition of GIP or GEP, I may have gotten those wrong, want to make acquisitions, are they competing with each other for capital? How do you assess which of the three groups get capital to make acquisitions.

Finally, Frank, I noticed when you broke down the three businesses that there is a very large R&D expense, \$896 million allocated under other. How do we think about that other business, and how do we allocate that across three businesses? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

Thanks for the questions. I'm going to just answer the Prevnar 13 because I think we're -- as I said, we took a long time with prepared remarks. They will consider in June.

Normally the usual practice is for ACIP to have two meetings, one to debate, and the second meeting they will vote on. They may decide to short step that in June and both discuss and vote, but the normal pattern would be a discussion in June, and then a vote in October. Albert, do you want to add anything to that? Is that fine?

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

That's fine. It's not unprecedented that they have done it one meeting.

Ian Read - Pfizer Inc. - Chairman & CEO

It's not unprecedented. We're working with them. The data was really good. But we're working with the agencies as hard as we can to get excited about this data.

On BD, how it works is that there is a corporate cost of capital, and BD is run corporately. In essence, each business unit will have projects that they bring forward to the corporation. Competition for capital is not necessarily -- we're not necessarily limited in capital.

There's competition for good ideas and best returns, and I think the most important thing of this structure is that it puts the business leaders on the accountability side of the projects they want to get funding for. So I think it clears up and makes it very, very -- it's good governance that inside the Company now, a BU leader says I want to do this project, I stand by it and I'm a champion by it and accountability attaches, which I think brings a great judgment and a great discipline to capital allocation. Frank, you want to add anything to that?



Frank D'Amelio - Pfizer Inc. - CFO

I was going to answer Jami's third question. I don't have anything to add on the biz-dev line. Jami, I think, the best way for me to explain this is to point you to certain pages of the release, and just quickly walk you through it, if that's okay.

If you go to chart number 18, you'll see up on the top, the quarter ended March 30, 2014, and then there's a column called Other, and in that column called Other there's an R&D expense line, which amounts to \$896 million, which is the number you quoted. If you go to the next page and you go to the tables on the bottom but the one higher up on page 19, you'll see the \$896 million off to the right, the far right column, and then you'll see the breakdown of that between the different organizations.

And then if you go to the next page and you go to the table again, but the bottom three numbers, you'll see in the last number there, research and development expenses, and you see how we give percentage ranges to drive it to each of the BUs. We try to provide drill down for you all, so you could see how we take the numbers and then how we drill them down, and we gave you ranges of allocation to enable you to do that by business unit.

Chuck Triano - Pfizer Inc. - SVP of IR

Very helpful, Frank. Next question, please.

Operator

Your next question comes from Jeff Holford from Jefferies.

Jeff Holford - Jefferies & Company - Analyst

I don't know to what extent you'll be able to answer this, obviously AstraZeneca in terms of its statements has pushed back around valuation, the mix of cash and equity, and also execution risk. Would you characterize conversations you've had with shareholders voicing similar concerns, or perhaps is it slightly different reception as you go around asking about that?

And just another side question, just on GEP. I wonder if you could just break down the current R&D spend, in terms of what would be on newer projects such as biosimilars, and what may be associated with sort of older based business products. Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

We listen to the shareholders and we made a -- we thought was a compelling offer, which fully valued AZ, and we're awaiting commentary back, or further commentary back from AZ. On the R&D, we've given you quite a lot of statistics in the back-up pages for you to allocate R&D. Perhaps John, you want to make a couple comments on the main spending gap.

John Young - Pfizer Inc. - President of Global Established Pharma

As a precedent we don't sort of go into detail on the sort of breakdown of R&D expenses overall. I think what I mentioned, Jeff, in my opening comments, is that obviously includes operational expenses for the business unit as a whole, and also includes the expenses for the development of the biosimilars portfolio. And I think at this point, that's probably as much detail as I can give.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, John. Next question, operator. Thank you.

Operator

Your next question comes from Seamus Fernandez from Leerink.

Seamus Fernandez - Leerink Partners - Analyst

So first question for Frank, and then the second question is actually on Prevnar 13. Frank, can you just talk about your cash and borrowing capacity, and remind us what your current rating is, and what the difference in the borrowing costs might be from the current rating to a single step-down in the rating.

And then separately, as we think about Prevnar 13 and the adult indication, obviously, there's been quite a bit of impressive data already accrued, in terms of the herd immunity that we've already seen presented to the ACIP. Just wonder if you could help us understand that in terms of the evaluation of Prevnar 13, particularly in international markets, and the willingness for national immunization programs to pay for the adult indication?

And then just a last question on Prevnar 13. The ACIP also reviewed a possibility of a three-dose schedule for Prevnar 13. Can you just update us quickly on how a three-dose schedule might actually evolve, or if that's a very unlikely situation, or if the product is already being used mostly at a three-dose schedule? Thanks so much.

Ian Read - Pfizer Inc. - Chairman & CEO

Okay. So I'll ask Frank to answer the cash and borrowing and costs, and then we'll ask Albert to take the Prevnar adult, and the ACIP three-dose question.

Frank D'Amelio - Pfizer Inc. - CFO

So Seamus, let me start with on the current ratings. With S&P -- I'll do long-term ratings first. S&P we're at AA, Moody's we're A1, Fitch we're an A-plus. On the short term ratings with S&P we're at A1-plus, with Moody's we're at P1, with Fitch, we're an F1.

In terms of cash and borrowing capacity, the end of last (technical difficulty) dollars. Obviously given that, given our ratings, we have a significant amount of borrowing capacity.

And in terms of a change in rating, what would that do to our borrowing cost? You got to make assumptions about notches, but I don't think there would be any material notch change, so whatever changes there were, would not be material. And quite frankly, if you look at the capital markets these days and investment grade paper, it's a very favorable market.

Ian Read - Pfizer Inc. - Chairman & CEO

Albert?

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

Let me start first with a side effect, and then I will speak about the dosing schedule. While Prevnar 13 has led to substantial reduction in the incidence of pneumococcal disease, the residual disease pattern in the US and globally is still significant. Even if it decayed after the introduction in the infant

program, in the US alone there are 440,000 cases of known bacterial pneumococcal pneumonia. They account for 300,000 hospitalizations, 200,000 emergency room visits, and unfortunately, 90,000 deaths.

And the global WHO has also similar estimations, 600,000 to 800,000 adult annual deaths due to streptococcus pneumonia which is the leading cause of COPD. We need to understand that the scientific community and us of course do not regard the effect as an alternative to direct vaccination. So in summary, we believe that the vaccination with Prevnar 13 represents a compelling value proposition for healthcare systems around the world.

Moving now on the dose schedule. First of all, we support the continued scientific exchange on the top, but having said that, we have a vaccine schedule in the US, which has demonstrated success. And we believe that this clinically-proven, FDA-approved, CDC recommended four-dose schedule is the optimal way to protect US infants and young children from pneumococcal disease. Also, we believe there are no data in the US populations to make a decision to divest from this four-dose schedule, that it has proven to be so successful.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, Albert, and from my point of view, and I think from society's point of view, the Prevnar 13 vaccination schedule delivers considerable value, and we see that value to society in the overall treatment, and don't necessarily really look at it as a per dose cost, it's more an overall value delivered by the protection. Mikael, do you want to add a little about the herd effect?

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

Albert described it very well. I could just comment one clinical aspect which we learned in Netherlands, is that when we type the serotypes the immune IPD cases which was possible by a proprietary asset that we have developed, it was nicely shown that significant a fraction, about a quarter of the cases refers to serotypes from the original Prevnar, the 7 valent, which clearly shows that although there has been immunization, there is residual serotypes remaining in the population, and herd effect is not sufficient to protect.

And finally, I also want to add a medical aspect, that with increasing age, you're more susceptible to severe outcomes and increased fatality occurs by age, underlining the importance that Albert alluded to, to get the campaign rather earlier rather than later in adults for protection.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you. Next question, please, operator.

Operator

Next question comes from John Boris from SunTrust.

John Boris - SunTrust Robinson Humphrey - Analyst

First question is for Frank. When we look retrospectively at the last big breakup that we had which was Abbott spinning off Abbvie, when we look back at that transaction, there was some dilution that was associated with it. By our math, the breakup of the two companies was about 15% dilutive in retrospect to what the separate companies would have earned, if they had stayed as one. In this instance, you're breaking up into three. What is the potential dilutive effect operationally, and potentially from any tax leakage, by breaking the entity up into three different businesses?

Second question, just for Ian. You indicated in your opening comments that once you had the palbo data and the Prevnar data, that positioned you at least from a position of strength, to be able to go back to AZN. Is your assumption then on palbo that you'll be able to file in 2014 and then launch in 2015? Are you assuming you're going to get a universal vaccination recommendation on Prevnar going forward? Is that the position of strength that you're coming at this from? Thanks.

Ian Read - Pfizer Inc. - Chairman & CEO

On this whole issue of Abbott and Abbvie, we really can't comment on how they went about restructuring, or what expenses they incurred, and what dilution they incurred. I do believe, though, just from memory, that I think if you took their value of the two separate companies, after they did this, and you stripped out general market movement, they still created many billions of dollars of value. So I think that's a more important issue than the dilution or the small incremental cost of the separate companies.

By the way, as I tried to emphasize, John, we're not talking about -- there's no decision been taken regardless of separating these companies, and certainly we're not talking about a three or four-way split. We're talking about two major segments, just to emphasize that.

And on this question of yours on position of strength, I was not trying to assume any action on the part of the FDA or the ACIP panel. I was just talking about the strength of the data and the data's compelling and one would expect the marketplace to follow the data. So thank you for the question.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Ian. Move to the next question, please, operator.

Operator

Your next question comes from Tim Anderson from Sanford Bernstein.

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

Couple of questions that are both merger-related. What things do you think that a merged Pfizer and Astra can do better than Astra alone? In other words, what do you see as potential weaknesses of Astra's standalone business, either in terms of product mix or R&D ability, through geographic positioning or anything else?

I want to go back to a question I asked on the call you did last week. Just to confirm or reconfirm Pfizer's intentions, assuming it acquires Astra, is it again most likely that you would take the post-merger entity and eventually split it up completely into separate publicly-traded companies? Because it's kind of a different story if the answer to that is no. So I guess I'm just looking for some continued assurances here, not promises, but rather what's most likely, or is there something about inversion and redomiciling in the UK that would make a full split-up like that more difficult?

Ian Read - Pfizer Inc. - Chairman & CEO

I think if you look from our point of view, if you look at AZ, and it's my view, not their view, so I'm talking my view of their strategy, not their view of their strategy, that they've had a strategy of -- confronted with massive LOEs, they've gone out and they have licensed in and brought in the lots of products from other companies. In fact, most of their pipeline is licensed-in products, with very few developed nationally.

But so we look at that and we look at the fit with our portfolio, especially in the immune oncology area, where they have assets which, standalone, are probably coming late to the market, but if they were combined with our portfolio, I think it strengthens their portfolio substantially. And then when you look at their products, they fit into our categories. So we believe that with our marketing presence and our ability in those categories, we can make more out of those products than they can standalone.

But the power of this deal for us is these three components. It's the fit on the portfolio, it's the nice fit with the early pipeline, but it's not a pipeline story, per se. It's also a removing of overlaps, and making the organization more efficient.



And I do believe you're seeing -- you'll continue to see a trend in the industry towards, as governments pressurize on access and pricing, they're really telling the industry you need to get more efficient. You need to bring to market higher-value products at a lower cost and there are ways -- different ways of doing that. There's internal improvements in your efficiencies, which Pfizer has done, and been very effective at.

There's asset swaps, which you saw going on between GSK and Novartis, which also gets to getting companies to remove overlaps. Or there is industry consolidation, which this would be an example of that. And then the third component of value here, which is really important for Pfizer, is this ability to free the balance sheet up, and get our tax rate down, which would enable a lot of different strategies.

And so all three of these elements are important. I've been asked, would you do it if you didn't have this part, you didn't have that part. I think the answer is I'm doing it because I have all three parts, and it strengthens our strategy right now, and creates, I believe, compelling shareholder value.

I would say on your other question that we are interested in preserving optionality that we've set up. We would see the integration of AstraZeneca with Pfizer along the way that we are organized.

We would preserve that optionality. We would focus on managing those businesses as efficiently as possible. And no decision has been taken about the future, as there's been no decision taken about our businesses at this moment in time, but we would conserve that optionality.

Chuck Triano - Pfizer Inc. - SVP of IR

Thank you, Ian. Next question, please.

Operator

Your next question comes from Marc Goodman from UBS.

Marc Goodman - UBS - Analyst

Couple things. First, you had mentioned last time on the call about palbo that you were going to be meeting with the FDA. Just wanted to know if that meeting actually had taken place, if you have it scheduled yet. I was a little unclear about your comments on palbo there.

Second, the meningitis B vaccine, when will we see the data? Three, on biosimilars, can you just remind us of when we will start to see data from the studies there, these pivotal Phase IIIs and filings start to occur.

Ian Read - Pfizer Inc. - Chairman & CEO

On palbo it is scheduled. It is extremely imminent. And once we've had that meeting, and once we have any confirmation from the FDA, we will let you know. We're still in discussions with the FDA. On meningitis B, I don't know who is the best, Mikael, do you have the data?

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

I can just mention that we are in the process of sharing data at conferences. It includes experiences from our Phase I, Phase II and dosing schedules, and also very encouraging data, strong data on combining meningitis B with vaccines that are used in these age groups, such as Gardasil or the typical adolescent vaccines, different schedules in Europe and the US. Hence, we will present soon at European Society For Pediatric Infectious Disease, and later in this fall, a corresponding US presentation too.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, John. Biosimilars?

John Young - Pfizer Inc. - President of Global Established Pharma

So I'll get back to you with some specifics on our plans for presentation of the data. Just to remind you, we have two of our portfolios which are in Phase III. We have rituximab, which initiated Phase III or initiated Phase III in the second half of this year.

We have trastuzumab, where Phase III has already been initiated. Rituximab will go into Phase III in the second half of the year, trastuzumab is already there. There will be some time before we see the readout of those studies. We'll get back to you separately, in regard to your question about any plans to present any other of our Phase I data.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you. I would say internally that Mikael is very satisfied with the profile that we're exhibiting, and the ability to say that it is biosimilar, and we're very pleased with the science we have and the capabilities around this development area.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks. We can move to the next question.

Operator

Your next question comes from Steve Scala from Cowen.

Steve Scala - Cowen and Company - Analyst

Thank you. I have three brief ones. First, why is early stage R&D such a high percent of the total? 56% of R&D is unallocated to any division, which seems high versus your peers.

Second, why is there still uncertainty around Celebrex US sales from May 30 to the end of the year, given the settlements? And then lastly, Ian, are you willing to give any assurances of limited R&D cuts in the US, like you did in the UK? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

Thank you, could we do first of all the early stage and the allocation algorithm there, and then Doug, will you answer the uncertainty?

Frank D'Amelio - Pfizer Inc. - CFO

So I think the best way to answer this, Steve, is the way we manage the organization which is all of the post POC R&D spend is in the business units, the new operating segments. The pre-POC R&D spend, so all the discovery, the research up and through inclusive of POC is in Mikael Dolsten's organization, WRD.

That's what you are seeing in the other column. That's really what's driving that. That's why you get the split that we currently have.

Doug Lankler - Pfizer Inc. - General Counsel

So on Celebrex, both Mylan and Actavis have sued the FDA, having concluded that FDA will give Teva 180 days exclusivity. They believe unless the courts overseeing those suits rule in Mylan and Actavis' favor, and change FDA's ruling, that Teva is going to have exclusivity. We previously settled with Teva, and as part of that settlement the earliest date Teva can launch is December 2014, and their exclusivity would begin then.

Ian Read - Pfizer Inc. - Chairman & CEO

Frank, you want to add to that answer?

Frank D'Amelio - Pfizer Inc. - CFO

I should have mentioned partner alliance too. Regulatory, toxicology, all those kinds of things, pharm sci are all in that other column as well.

Ian Read - Pfizer Inc. - Chairman & CEO

So on your question about the integration of the two companies, I think we've made some commitments to the combined Company's presence in the UK, and we clearly will stay with a massive presence in the US, as a combined Company.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, Ian. Next question, please.

Operator

Next question comes from Vamil Divan from Credit Suisse.

Vamil Divan - Credit Suisse - Analyst

On the VOC unit, Albert, you mentioned these are really three different businesses, blended into one. Can you just talk about that one, specifically in terms of synergies or overlaps, you see that make it worthwhile to keep them all as one unit, as opposed to being structured maybe differently?

On the consumer side, you obviously highlighted the news around Nexium 24-Hour. We saw some disappointing news for Singulair potentially being an OTC product. Given you've been generally bullish on the Rx-OTC switch opportunity. How important do you see it to have a consumer business internally, to be able to profit from that opportunity, as opposed to maybe alliances with other companies that might have consumer, if you didn't have one yourself?

Ian Read - Pfizer Inc. - Chairman & CEO

Vamil, thank you for the questions. First question, remind me again was on --?

Frank D'Amelio - Pfizer Inc. - CFO

The three separate units.



Ian Read - Pfizer Inc. - Chairman & CEO

These units are independent global units that are run basically separately. I think any type of -- and Albert is a very experienced business leader and has three division heads reporting to him. Any type of synergies between those businesses are more of the nature of managerial talent and leveraging strategies across great leaders, and not really addressed towards synergizing operational infrastructure of those businesses as they are distinct, they are global, and they have their own culture and their own focus, which is part of the reason why we've made them global businesses.

On the other side, from the point of view of the corporation, the business is an important business for us. We see it as a great storer of value. We've made acquisitions in that business, and the OTC strategy is a component of the value of that business.

But we're not just managing that business only because we have an OTC strategy. We see acquisitions as part of that strategy, and switches and organic growth and the freshness index in the business and continuing to make sure that business grows. Thank you for the question.

Chuck Triano - Pfizer Inc. - SVP of IR

We have time for our last question, please, operator.

Operator

Your final question comes from Alex Arfaei from BMO Capital Markets.

Alex Arfaei - BMO Capital Markets - Analyst

Ian, at what point would you consider going directly to AstraZeneca shareholders? You mentioned a premium that you're offering, plus your disappointment by the Company's lack of engagement.

On the pipeline, and approaching AstraZeneca from a position of strength, other than palbo and Plevnar 13 in adults, what are the other key assets that you think may not be adequately appreciated by the Street? Thank you.

Ian Read - Pfizer Inc. - Chairman & CEO

We've made public our offer to the Board. We remain considering all our options on how we progress these discussions.

And I think on our -- you're talking about our pipeline. I think you've got PCSK9 which is -- we will arrive at the market, we expect roughly the same time as the other major competitors in that, with outcomes data.

We have palbo, we have all the trials around palbo, Plevnar 13 in adult, we've got a meningitis B, we've got the ertugliflozin with Merck. We have the Xeljanz license extensions around that, continuing growth in Eliquis, continuing growth in Xeljanz, continuing growth in our oncology portfolio, and Inlyta, and Xalkori. Some very good fast filing products in oncology, that could come to market, given we think they are very differentiated.

Frankly, opportunities abound inside our Company, both from the in-line portfolio, the emerging markets opportunities, the pipeline, recent launches, and to be launched, and then if you look at the -- across vaccines, oncology, and get a very nice portfolio of unique opportunities. So as I say, this is -- we're doing this because we see an opportunity to create additional value from this acquisition or combination, not because we feel any negativity towards our present strategy, which we feel is very strong.

Okay. Thank you.



Frank D'Amelio - Pfizer Inc. - CFO

Thank you, everybody. For your time today.

Chuck Triano - Pfizer Inc. - SVP of IR

Thanks, everybody.

Operator

Ladies and gentlemen, this does conclude today's Pfizer First-Quarter 2014 earnings conference call. Thank you for participating. You may now disconnect.

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