

Q1 2017 Earnings Call

Company Participants

- Albert Bourla, Group President of Pfizer Innovative Health
- Chuck Triano, Senior Vice President, Investor Relations
- Frank A. D'Amelio, Executive Vice President, Business Operations and Chief Financial Officer
- Ian C. Read, Chairman and Chief Executive Officer
- John Young, Group President, Pfizer Essential Health
- Mikael Dolsten, President, Worldwide Research & Development

Other Participants

- Alex Arfaei, Analyst
- Andrew S. Baum, Analyst
- Christopher Schott, Analyst
- David R. Risinger, Analyst
- Geoffrey Meacham, Analyst
- Gregg Gilbert, Analyst
- Jami Rubin, Analyst
- Jeffrey Holford, Analyst
- John T. Boris, Analyst
- Marc Goodman, Analyst
- Richard J. Purkiss, Analyst
- Steve Scala, Analyst
- Timothy Minton Anderson, Analyst
- Tony Butler, Analyst
- Umer Raffat, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good day, everyone, and welcome to Pfizer's first quarter 2017 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 {BIO 384494} <GO>

Good morning, and thank you for joining us today to review Pfizer's first quarter 2017 performance. I'm joined today by our Chairman and CEO, Ian Read; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Albert Bourla, Group President of Pfizer Innovative Health; John Young, Group President of Pfizer Essential Health; and Doug Lankler, our General Counsel. The slides that will be presented on this call can be viewed on our newly redesigned website, Pfizer.com/investors.

Before we start, I'd like to remind you that our discussion during this conference call will include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. Additional information regarding these factors is discussed under the Disclosure Notice section in the earnings press release we issued this morning, as well as in Pfizer's 2016 Annual Report on Form 10-K, including in Part 1, Item 1A, Risk Factors, that is filed with the Securities and Exchange Commission and available at www.sec.gov and on our website, www.pfizer.com. The forward-looking statements during this conference call speak only as of the original date of this call, and we undertake no obligation to update or revise any of these statements.

Discussions during the call will also include certain financial measures that were not prepared in accordance with U.S. generally accepted accounting principles. Reconciliation of these 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, May 2, 2017. You may obtain a copy of the Form 8-K on our website, pfizer.com/investors. Any non-GAAP measures presented are not, and should not be viewed as, substitutes for financial measures required by U.S. GAAP, have no standardized meaning prescribed by U.S. GAAP, and may not be comparable to the calculations of similar measure at other companies.

We will now make prepared remarks, and then we will move to a question and answer session. With that, I'll now turn the call over to Ian Read. Ian?

Ian C. Read {BIO 3358997 <GO>}

Thank you, Chuck, and good morning, everyone. I'll open with a few brief comments regarding the quarter, our strategy, and the external environment.

2017 is off to a solid start, as we noted in our earnings release. Revenues in the quarter as compared to the prior-year quarter were impacted due to one less domestic and two fewer international selling days, which represents approximately \$300 million of revenue. Additionally, revenues were impacted by the divestiture of Hospira Infusion Systems. We saw strong performance from our core brands, notably Ibrance, Eliquis, Lyrica, and Xeljanz within the Innovative Health business. For the Essential Health business, Sterile Injectables had a strong quarter, and we saw robust operational growth within Emerging Markets and the Biosimilars business. We have reaffirmed our 2017 financial guidance, which at the midpoint represents 4% operational revenue growth and 10% operational adjusted diluted EPS growth on a year-over-year basis, excluding the negative impact of foreign exchange and the divestiture of Hospira Infusion Systems.

FINAL

As we look at the coming year, both of our businesses remain focused on their individual strategies and delivering on their operating objectives. For the Innovative Health business, this means supporting product launches and the late-stage pipeline. And for the Essential Health business, this means continuing to refine and strengthen its portfolio to enable it to ultimately pivot to growth following two upcoming significant LOE events: Viagra in the U.S. later this year and Lyrica in the U.S. at the end of 2018.

Additionally, we are working to improve our growth profile for the overall company by maximizing and focusing on the growth of major inline brands and the growth of new products. The strong performance by key products again this quarter reinforces our view that we have a strong portfolio of meaningful revenue growth contributors. Behind these products is a pipeline of distinct assets that we believe have the potential to become meaningful revenue contributors towards the end of this decade and into the next. We expect Ibrance will continue to perform well even as it faces competition, and we look forward to advancing the recent launches of Eucrisa and Inflectra.

While there has been some displacement in Xtandi revenue relative to demand growth, we expect patient assistance program utilization as a percentage of total demand to stabilize and moderate gradually throughout 2017. While this is a complex reimbursement market, ensuring broad access to these important medicines remains in the best interests of physicians and patients. And with a portfolio well-positioned to compete in Emerging Markets, we see continued growth opportunities for both the Essential Health and Innovative Health businesses in these markets. Of note, about 20% of our total company revenue base comes from Emerging Markets.

Now, turning to the pipeline, our focus remains on advancing assets within core therapeutic areas that address important patient needs. Some of the more noteworthy highlights include: Last month we completed enrollment in EMBRACA, the Phase 3 study of talazoparib in germline BRCA-positive metastatic breast cancer. We expect the study to complete in the upcoming months and to receive top line results by January 2018.

In Immuno-oncology, we continue to believe that doubles and triplets are the best areas of greatest potential for patients. We've initiated avelumab combination studies with chemotherapy and targeted therapies. In 2017, we expect to see early data from a variety of avelumab-based studies, including avelumab plus 4-1BB, avelumab plus OX40, avelumab plus Inlyta. In addition, we have entered the clinic with our first triple combination of avelumab, 4-1BB, and OX40.

In targeted cancer therapies, we are studying lorlatinib as a single agent in second-line ALK+ small-cell lung cancer and hope to have a filing in the U.S. during the second half of this year. We are also studying it in combination with avelumab and expect to have early data in 2017. Also of note, last week lorlatinib was granted breakthrough therapy designation from the FDA for the treatment of patients with anaplastic lymphoma kinase, or ALK, positive metastatic non-small cell lung cancer previously treated with one or more ALK inhibitors.

In Inflammation & Immunology, we submitted a regulatory application for Xeljanz in psoriatic arthritis in February in the U.S. Additionally, we expect to submit a regulatory application for Xeljanz in ulcerative colitis in the U.S. in the first half of the year. We also plan to submit regulatory applications for both of these in the EU in the second half of the year. We have a broad portfolio of investigational next-generation selective kinase inhibitors and see the potential for approximately 10 Phase 2 studies to be in process by the end of 2017, including a potential proof-of-concept readout for our selective JAK1 inhibitor in atopic dermatitis.

In Rare Diseases, along with our partner, Spark Therapeutics, we recently disclosed data from the first 10 patients being treated in our ongoing Phase 1/2 trial in hemophilia B, a gene therapy asset, and we anticipate a potential proof-of-concept in the second half of 2017. This is for factor IX.

In Internal Medicine, we're advancing our portfolio in NASH, non-alcoholic steatohepatitis, otherwise known as fatty and inflammatory liver disease. To date, we have positive Phase 1 data for our ACC inhibitor drug and expect to report additional Phase 1 data on two assets, DGAT2 and KHK, later this year.

And in Vaccines, our *C. difficile* vaccine candidate entered Phase 3 in March of this year.

Regarding our views on capital allocation, we continually assess a variety of opportunities to create incremental value for shareholders, whether it be acquisitions, divestitures, direct return of capital, or managing our investments in the business. And we have engaged in all of these opportunities when we determine they are right for creating shareholder value.

Looking ahead to the rest of the year, I believe each of our businesses is well-positioned within their individual markets, with strong portfolios, highly skilled and accomplished leadership, and focused strategies. We are closely monitoring the evolving political landscape and uncertainty coming out of Washington and are keenly aware that tax reform may open up additional avenues of capital deployment to deliver value to our shareholders. We will continue to be alert and flexible to potential policy or legislative changes that could influence decisions we make. And we are continuing to engage with elected officials to educate them on issues relevant to our business.

I am proud of what the people of Pfizer have accomplished over the course of the past six years. We have built a stronger, more resilient, competitive business with solid portfolio of market-leading products and a robust R&D pipeline. We have the resources, expertise, talent, acumen, culture required to control our destiny. In summary, we're looking ahead to the rest of this year. Our businesses are strong. Our pipeline is solid and focused on the areas that address patients' unmet needs. And our financial strength will enable us to deliver sustainable value creation for our shareholders.

Now I'll turn it over to Frank to discuss the quarter in more detail.

Frank A. D'Amelio

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

I want to remind everyone that because we completed the acquisition of Anacor Pharmaceuticals on June 24, 2016, and the acquisition of Medivation on September 28, 2016, Pfizer's financial results for the first quarter 2017 reflect three months of legacy Anacor operations, which were immaterial, and three months of legacy Medivation operations. In addition, Pfizer completed the sale of Hospira Infusion Systems, or HIS, on February 3, 2017. Consequently, our financial results for first quarter 2017 include approximately one month of legacy HIS domestic operations and two months of legacy HIS international operations, while the year-ago quarter reflected three months of legacy HIS global operations.

Now moving on to the financials. First quarter 2017 revenues were approximately \$12.8 billion and reflect the year-over-year operational decline of \$110 million or 1%. It's important to note that first quarter revenues were negatively impacted by one less selling day in the U.S. and two fewer international selling days versus the prior-year quarter, which unfavorably impacted revenues by approximately \$300 million. First quarter 2017 revenues were also unfavorably impacted by foreign exchange, \$116 million or 1%.

Our Innovative Health business recorded 6% operational revenue growth in the first quarter of 2017, driven by Ibrance and Eliquis globally; the addition of Xtandi revenues in the U.S. from the Medivation acquisition September of 2016; and Lyrica and Xeljanz, both primarily in the U.S., all of which were partially offset by a 7% operational decrease in global Prevnar 13 revenues. In the U.S., Prevnar 13 declined 9% due to a continuing decline in revenues for the adult indication because of a smaller remaining catch-up opportunity versus the prior-year quarter, which was somewhat offset by the favorable impact of timing of government purchases for the pediatric indication. In international markets, Prevnar 13 revenues decreased 4% operationally due to the unfavorable impact of timing of government purchases for the pediatric indication in certain emerging markets, partially offset by modest growth of the adult indication in certain developed Europe markets. Fourth quarter Innovative Health operational growth was also negatively impacted by lower revenues for Enbrel in most developed Europe markets, primarily due to continued biosimilar competition and Viagra in the U.S. due to lower market demand.

Revenues for our Essential Health business decreased 9% operationally, driven by a 23% operational decline from peri-LOE products such as Pristiq in the U.S., Lyrica in most developed Europe markets, and Zyvox in developed Europe and the U.S. Essential Health revenues were also negatively impacted by a 68% operational decline in HIS revenues due to the previously mentioned sale in February of 2017 and a 5% operational decline in legacy established products, all of which were partially offset by a 3% operational growth from the Sterile Injectables portfolio and 62% operational growth from Biosimilars, driven by Inflectra in certain developed Europe markets and in the U.S. I want to point out that if you exclude the impact of HIS, fewer selling days, and the LOEs, Essential Health revenues grew 3% operationally.

FINAL

In Emerging Markets, Pfizer's overall Essential Health revenues grew 5% operationally, primarily due to 21% growth from the Sterile Injectables portfolio. First quarter reported diluted EPS was \$0.51, compared with \$0.49 in the year-ago quarter, primarily due to lower legal charges and asset impairment charges, as well as higher net gains on asset disposals, partially offset by a higher effective tax rate, fewer selling days, and lower royalty income. Adjusted diluted EPS for the first quarter was \$0.69 versus \$0.67 in the year-ago quarter. The increase was primarily due to a lower effective tax rate and lower operating expenses, unfavorably impacted primarily by fewer selling (16:14) and lower other income.

I want to point out that diluted weighted average shares outstanding declined by 133 million shares versus the year-ago quarter due to our share repurchase program, reflecting the impact of two \$5 billion accelerated share repurchase agreements, one completed in June of 2016 and the other executed in February of 2017. In the first quarter of 2017, fewer shares outstanding contributed approximately \$0.01 to reported diluted EPS and \$0.015 to adjusted diluted EPS. As I previously mentioned, foreign exchange negatively impacted first quarter 2017 revenues by approximately \$116 million or 1% and positively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate by \$61 million or 1%. As a result, foreign exchange had essentially no impact on first quarter adjusted diluted EPS versus the year-ago quarter. As you can see, we reaffirmed all components of our 2017 financial guidance.

Moving on to key takeaways, our performance in the first quarter 2017 was solid. Excluding HIS revenues in the first quarter and the year-ago quarter, we recorded operational revenue growth despite the \$300 million negative impact of fewer selling days versus the year-ago quarter. We reaffirmed all elements of our 2017 financial guidance. We accomplished several key product and pipeline milestones, and we returned \$6.9 billion to our shareholders through dividends and share repurchases, which includes a \$5 billion accelerated share repurchase agreement executed in February of 2017. Finally, we remain committed to delivering attractive shareholder returns in 2017 and beyond.

Now I'll turn it back to Chuck.

Chuck Triano {BIO 3844941 <GO>}

Thank you, Frank. Operator, can we please poll for questions?

Q&A

Operator

Your first question comes from Jami Rubin from Goldman Sachs.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. Ian, I think you referenced the Xtandi issue with patient assistance programs, but can you explain what's going on? Why this is occurring now? Why this seems to be

only occurring with prostate cancer drugs? And, most importantly, did you plan for this at the time you did your \$14 billion deal? And when do you expect the impact to normalize? And maybe if you could remind us again what the value proposition was of Medivation.

And my second question is - and, I guess, Ian, this again is directed to you. You and the senior management team have for some time now been signaling a desire to go bigger, doing a larger-scale transaction, and I'm just curious to know what's holding you back. It's now May 2, not that I'm impatient, but is it corporate tax reform? Is it something else? Can you remind us what you're looking for exactly, and what are the trigger points for making you decide to pull the trigger? Thanks very much.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Jami. All very good questions, and no one would ever describe you as being impatient. I'll ask Albert to make a few comments on the Xtandi performance, and then I'll put an overlay. Thank you, Albert.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, and thank you, Jami, for your questions. Xtandi net sales performance in the first quarter declined 11%. However, demand grew significantly at 13%. The inconsistency of 24 points observed in demand versus revenue continues to reflect significant increase in utilization of our patient assistance programs. This was likely the result of dislocation in the reimbursement market. However, we believe that the demand for patient assistance as a percentage of total demand will stabilize, moderate gradually through 2017, and over time resolved.

Now to your question if that was expected. The answer is no. This was not anticipated. Today, Xtandi is performing below our expectations in the U.S. That said, the main thesis for Xtandi is broadening both the indications towards earlier, non-metastatic lines of therapy, and the prescriber base, particularly towards urologists. This remains intact, and we remain confident in achieving both of these initiatives going forward. EMBARK, ARCHES, PROSPER - the studies that are focusing on early prostate cancer are progressing well. Also, both demand and monthly urology writers are at all-time high point for the brand. So in summary, at the moment, we continue to see significant upside for Xtandi as a brand going forward.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Albert. Let me just try and unpack a little bit of what is going on in the reimbursement market. There is a guidance, and has been for several years, in place addressing co-pay donations, which the Health and Human Services Office of the Inspector General issued several years ago, which guides companies on how to appropriately provide support through independent third-party foundations to patients who have difficulty paying for their medicines. This, of course, is important in the Medicare population, and most of the early-use Xtandi, this is heavily weighed towards Medicare.

FINAL

A separate part of the government has recently raised questions about these donations with respect to many companies. We have engaged in a dialogue with the government about these issues. The government has expressed a view that they're not looking to shut down these foundations, or stop contributions to them. They just want to provide appropriate safeguards additionally to what the Office of Inspector General had issued. We continue to make donations to independent third-party charities, because we believe they will help ensure that patients can afford medically necessary drugs. Nevertheless, this conversation that's going on between the industry and the government, I believe, had a chilling effect on the amount of assistance patients are getting from the donation programs. We expect this to be resolved during 2017, and the market to normalize after that. This is very important for the access of many patients to these medically necessary products.

Now on BD, we continue to leverage BD as a means of accelerating top and bottom line growth. From a macro standpoint, Jami, I believe the industry will continue to consolidate over time. I believe there is simply too much redundancy and fragmentation, both globally and in the U.S., for the sector to continually efficiently deliver medicines to society. Pfizer has been, and I expect will continue to be, active industry consolidators. However, there is a lack of clarity on potential tax reform, healthcare policies of the U.S., and uncertainties in the European markets both with the French election and the U.K. snap election. And on top of that, certain large companies have significant, almost binary, risks embedded within their business and pipelines, which could meaningfully alter their values.

So we remain prudent in our evaluation process regardless of target size. We will continue to evaluate deals. We never say never, but I believe the current environment needs to stabilize in order to be an advantageous market for big deals. Thank you for your questions.

A - Chuck Triano {BIO 3844941 <GO>}

Thanks, Ian. All right. Next question, please.

Operator

Your next question comes from Tim Anderson from Bernstein.

Q - Timothy Minton Anderson {BIO 3271630 <GO>}

Thank you. A couple of questions. So just going back to M&A, you went after AstraZeneca once. Of course, it didn't happen. It's widely assumed you would not be able to revisit that particular target, but I'm wondering if you could. I know it's a very direct question, but given how open you guys sometimes are to questions like these, just wondering if there's anything you can say here.

And then forgive me for asking the same question I asked last quarter, but can you discuss your level of commitment and enthusiasm for the IO agreement you have with Merck KGaA? Just wondering if it's in the realm of possibilities in IO, where the landscape continues to shift, if you have to remain open-minded when it comes to assessing the best

Bloomberg Transcript

way to try to become a leader in this area. And on that same topic, in the avelumab label, there is a mention of some negative side effect differentiation that seems like it could be problematic for that product.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. Tim. I can't speculate, as you know, on any individual companies. Clearly the U.K. as an area of interest for BD, we need a resolution of the political environment there and the willingness of the government to allow inward investment. And hopefully these elections will provide that clarify for that market in its total.

As regards to Merck, an IO deal, we remain committed to developing avelumab along with, as I mentioned in my opening comments, doublet and triplet therapy. And specifically for avelumab and our development plan, to put that in context, I'd like Mikael to address what is the overall framework of our development plan and data flow, and also this issue you raised about the potential differential in the label where you claim is - well, Albert will address that. So go ahead, Mikael.

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you. It's two and a half years since we initiated an alliance with Merck KGaA. And of course we are pleased that we've been able to initiate more than 30 avelumab programs, and nine are currently registration intent. We were able to get the first registration in Merkel cell carcinoma. We have a second indication under priority review. And when you look at our overall plans for avelumab, we envision that we will have one or more approvals from 2017 all the way to 2022 on an annual basis. So we think there is a really good rhythm in the program.

Of course, the initial emergence of this field was with monotherapies, and I think given the heterogeneity we see in cancer, it's likely to quickly evolve to more of a combination drug play. We are pleased to have six IO combinations in the clinic now, several of them unique and position us for a strong go-forward role, pending of course data readout. That includes avelumab/4-1BB across many tumor types, and we just initiated avelumab/4-1BB/OX40. We have additional studies ongoing with either one that could be of great interest to supplement avelumab, and we also have cancer vaccines now in clinical studies.

Of course, we have learned increasingly that combining IO with targeted therapy is very favorable. We have seen really robust data, as one example, combining avelumab with Inlyta in renal cell carcinoma. Some more data will be shown at ASCO, and with studies ongoing with avelumab combined with Xalkori, volitinib. We plan to initiate additional studies in the EGFR field with proprietary compounds from our pipeline. We're looking at opportunity to combine with talazoparib. And finally, we have four chemo combo trial running. So I think you will see the field unfold with a number of these opportunities, and I think we are quite well-positioned.

In addition to this checkpoint combination platform, we also have additional modalities. In total we have 11 IO compounds in the clinic covering checkpoints by functional

antibodies, cancer vaccines, and also CAR-T program, which I think over this period of a few years will position us for advancement and a really strong platform. Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Mikael. Albert, on the differential profile?

A - Albert Bourla {BIO 18495385 <GO>}

Yes. I guess, Tim, you're referring to injection-related reactions that there is a mention in the label. First of all, it is important to note that adverse reaction rates observed in clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug. And many do not reflect the rates observed in practice. For Bavencio, the vast majority of injection-related reactions were low grade. 97% of them were mild or moderate, grade one or two. Also less than 1% of patients stopped treatment due to them. And also in our studies, the injection- and infusion-related reactions were managed very successfully with premedication. So we think that this is nothing to be worried about.

A - Ian C. Read {BIO 3358997 <GO>}

Other than that, we see a very balanced profile of avelumab compared to the other PD-L checkpoints. Okay. Next question.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you. Yes, next question.

Operator

Your next question comes from Tony Butler from Guggenheim Securities.

Q - Tony Butler {BIO 1504193 <GO>}

Yes. Thanks very much. Just on the same question with respect to the infusion-related reactions. I was curious of the notion that could it be due to the ADCC activity of avelumab? Would that perhaps explain the difference, if there is one?

And then second, Mikael, I would love to have some thoughts around the potential use of palbo plus avelumab. I actually heard some discussion - maybe it was nothing but chatter - at AACR that suggested maybe those two together might have some dramatic effect on a number of solid tumors outside of breast cancer. Thanks for the time.

A - Ian C. Read {BIO 3358997 <GO>}

Mikael, if you could answer those, please.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you, Tony, for raising these two questions. As Albert alluded to, these infusion-related reactions seems to be mild, transient, and hasn't been clinically an issue. I

don't think there are any reason to assume it's related to a potential ADCC function. The latter, we think, could for some tumors actually be a differentiating factor, and we're exploring the possibility in some tumors to have it as an advantage.

I think you raise a real interesting question. There has been some recent data suggesting that combining palbo-like compound with checkpoints could actually, in some cases, be of additive value. So we're actively looking into it in our broad effort to combine targeted therapy and avelumab. So thank you for shedding light on this, which we think has quite some interest to explore.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you, Mikael. Next question, please, operator?

Operator

Your next question comes from Marc Goodman from UBS.

Q - Marc Goodman {BIO 1853567 <GO>}

Hi. Two questions. One on Ibrance. In the U.S. last quarter, you had a pretty big quarter, and we were asking if there was anything going on with inventories, and you had said no. And this quarter it looks a little bit light. I was just curious if maybe there was some inventory that you picked up later or what's happening. Can you just give us a sense of the number of patients and the share? What's going on there?

And then second of all, Mikael, you talked about a lot of the pipeline stuff with respect to IO. Can you talk about some of the other pipeline assets we should be watching for that are non-IO? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Albert, please?

A - Albert Bourla {BIO 18495385 <GO>}

No, we are very happy with the performance of Ibrance this quarter, and of course - no, there was not material moving inventories. We achieved revenues of almost \$680 million, which was 59% growth. And our internal market shares are around 50s for the first line, and the 40s and 30s in second line and third line, respectively. We had this quarter more than 7,000 new patients that came to the brand. And we had more than 61,000 total scripts this quarter. To remind you, from the beginning of the launch, we have more than 360,000 scripts in total.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Albert. Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

FINAL

Yeah. Thank you. I'm pleased with your interest in our really robust pipeline. We have 96 programs in clinical development. We have over the last years since 2011 had 21 approvals, three to four per year, on average two NMEs. And we envision in 2017 and 2018 up to 10 approvals. So we continue to have a pipeline that can deliver really robust flow of approvals including NMEs.

I'll highlight some compounds outside IO starting in Oncology with the CDK platform. You may have noted that we plan to start a trial for HER2+/ER+ breast cancer, which I think opens up a really interesting field combining lbrance, palbociclib, with HER2-active drugs. We have several programs now ongoing to also deal with a growing number of patients that will progress eventually through CDK-like drugs into resistance, and that's a field where I think we can lead through several ongoing trials in our pipeline.

Targeted NME outside the CDK area, we have had positive data in AML with glasdegib, which is our first in class for blood cancers agent, and we're looking to summarize those data, engage with agency about a possible filing based upon Phase 2 data. There was a readout of talazoparib, the EMBRACA study, that I think could also open up an interesting opportunity for that pipeline asset.

And of course in line, we have numerous trials. Recently we got breakthrough designation for lorlatinib, which I think is the best-in-class ALK inhibitor second generation. Its unique mutation has brain-penetrant activity. And we also have a finalized Phase 3 study with dacomitinib for another segment, EGFR-activated lung cancers, that will be soon reported in a conference. We spoke in the introduction about the Prevnar 13 vaccine, and you're obviously aware that we have initiated Phase 3 with C. difficile, which is very unique designed vaccine. And we expect to early next year put in an RSV vaccine, again with a unique Pfizer leading technology.

Ian spoke about our I&I platform with our inject drugs. We'll have later this year a readout for our inject one drug in atopic dermatitis, and I'm very enthusiastic, based on a lot of supporting science, for that aspect. And our unique JAK1/2, the most advanced with its profile in the industry, has entered into a platform with numerous trials - ulcerative colitis, alopecia, psoriasis - and the drug looks really promising with its unique dual activity.

Finally, mentioning the NASH, as Ian took that into his introduction, we have had a positive Phase 1b readout of our ACC drug in NASH. We have positive proof-of-mechanism data emerging from our KHK drug in NASH, and we have two other NASH drugs that are in or moving into the clinic with quite some promise. So I think that's another platform that you should keep an eye on for Pfizer.

And I'll end with the Rare Disease. In addition to the gene therapy platform, we have now enrolled to the target for domagrozumab, our anti-myostatin drug in DMD, and we actually have tafamidis that you may not have kept an eye on that's going to read out likely next year in cardiomyopathy, which again could open up a big opportunity for us.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you, Mikael. Next question, please, operator.

Bloomberg Transcript

Operator

Your next question comes from Andrew Baum from Citi.

Q - Andrew S. Baum {BIO 1540495 <GO>}

Thank you. Couple of questions, please. For Mikael, could you update us on the patent extension for Ibrance/palbo? I just saw that you filed a second letter following up with the patent authority following initial letter in 2015. Is there any risk that you don't get sought-after patent extension, given the importance of that product? Second, could you comment - I know it's early days - but whether you're seeing any impact of rebates and pricing from Novartis's ribociclib on Ibrance, either at the physician or more importantly at the PBM level?

And then finally a question for Ian. Given Tom Price's comments yesterday about dramatic cuts in drug pricing won't take three years, does he see any risk that drug pricing becomes more vulnerable given the President's intent to support tax or broader ACA repeal?

A - Ian C. Read {BIO 3358997 <GO>}

Okay. Let's look at the patent issue. You know, Andrew, we don't have any significant changes to our patent position or estate with palbo, so we'll look into that and let you know. You may have spotted some filing we did, but the patent estate remains intact and strong, and we have no issues around that.

I'll ask Albert to talk about the incipient competition from Novartis.

A - Albert Bourla {BIO 18495385 <GO>}

Yes. Andrew, we are very confident in the future of Ibrance and its continued growth and leadership. We have established Ibrance as a standard of care in metastatic breast cancer. Two years, 10,000 prescribers, 50,000 pilot patients - 55,000 patients in the U.S. alone. And this is a testament not only to its efficacy with over two years PFS, but also to its manageable safe and tolerability profile, with no cardio or liver monitoring required. Last but not least, we have great access for our patients. We price our products appropriately to their value. We have managed successfully priced competition in the past, and we will do it in the future.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Albert. Really quick general question on pricing. Look, questions around drug pricing have been around since I've been in the industry. The reality is twofold. Number one, drug pricing, pricing of innovative branded medicines, are low - low-single-digit increases in recent years. So in 2016 (sic) [2015], the net price increase of branded drugs was about 2.8%. That was in 2015. And in 2014, it was about 5%. And we don't have 2016's numbers yet. So the cold reality, the facts that policy makers are looking at, is that drug prices, net drug prices, are not a cause of inflation in healthcare.

FINAL

On the other hand, they produce huge value both for the industry, for the GDP, and also for patients. What we're seeing, I believe, is that - and this may be part of any type of healthcare reform, is the fact that the insurers have, because of the exchanges, have moved to put large co-pays and large total deductibles into their business model, which includes first dollar on pharmaceuticals. So individuals are now suffering in absence of good insurance on pharmaceuticals because they have to burn through sometimes a \$6,000 deductible before they get any real relief.

So I think those are the type of issues that need to be looked at to ensure that any healthcare reform ensures access to important medicines, a level playing field so that as any subsidies that are given by the government are evenly spread today under the ACA, under the plans, the hospital out-of-pocket for patients is 3%; the out-of-pocket for patients is 15% on drugs. So I think these are the type of things we want to see happen in healthcare reform. Reforms in the way that we can be more competitive in the generic market, where we can be more competitive in offering programs to hospitals and managed care, and that I think is the line that we need to take and I think - I believe - the Trump administration will look at, how is to make their market more competitive. Thank you.

A - Chuck Triano {BIO 3844941 <GO>}

Thanks, Ian. Next question, please, operator?

Operator

Your next question comes from Steve Scala from Cowen.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. A couple questions. Pfizer guidance for Prevnar in 2017 is flat to slightly down. With Q1 down 7% to 8%, presumably the franchise will need to grow at some point in 2017 to get to the full-year guidance. So is that your expectation, a return to growth in 2017? And should we expect that to continue in 2018?

And then second question, final OS data for palbo plus letrozole will be presented at OS from the Phase 2 study. The interim was not statistically significant. Could you help us set an expectation relative to your ability of hitting OS when we see the data at ASCO? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Albert, would you like to talk about the first question on Prevnar, please?

A - Albert Bourla {BIO 18495385 <GO>}

Yes, absolutely. We continue to believe and expect that Prevnar 13 will be flat to declining this year. Slightly declining this year, exactly as we have said it in the past. With the first quarter, the 7% decline in the U.S. is driven by the U.S. adult that went down 32%. As previously discussed, we have already vaccinated approximately 50% of the 65-plus

population, and we were expecting that because we are comparing it to a very, very strong quarter of last year. We expect that this decline in adult will continue but will be partially offset by growth of adult vaccinations in the 18 to 64 age range, and in addition is also expected to be partially offset by international adult growth in developed markets. In Europe, for example, this quarter the adult went up 25%.

Also, I want to note that it is very common to have volatility in overall vaccines sales because they are highly dependent from governmental purchases that the timing can vary quarter by quarter.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you. So net-net, we expect to meet our original guidance on Pevnar.

A - Frank A. D'Amelio

No change.

A - Albert Bourla {BIO 18495385 <GO>}

No change. Flat to slight decline.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you. Mikael, within the rules of embargoed data and everything, what can you say?

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you, Ian, for adding that perspective. I can only say that the confidence in Ibrance is extremely high among us and all stakeholders. Of course you're aware that Ibrance was recently given full approval, which underlines the strength in data across numerous advances in metastatic breast cancer segments. And the PFS data has been very robust. Durability is up to almost two years of use of the drugs and a delta of 10 months. OS data in these type of indications, in general, are something that you always need to be aware is difficult to interpret it as patients that go off trial can embark on a variety of different treatments. That's why we think the PFS data has been the strong indicator of the performance of this drug. But we look forward, of course, to share the entire profile and OS data at ASCO.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you.

A - Chuck Triano {BIO 3844941 <GO>}

Next question, please, operator.

Operator

Your next question comes from Chris Schott from JPMorgan.

Q - Christopher Schott {BIO 6299911 <GO>}

Great. Thanks very much. Just had two questions here. Maybe first can you – a biosimilar question on two sides here. So maybe first talk about what you're seeing in Europe with Enbrel and how that has been playing out relative to your expectations? And on the flip side can you maybe talk about Inflectra and how you're thinking about the U.S. launch as we go through this year?

My second question was coming back to business development and priorities. Appreciate the earlier comments, Ian, but – and maybe to paraphrase it sounds like the environment for larger deals might not be ideal today given some of these uncertainties around tax and binary events for certain targets, but that could change over time. I guess my question is how does that dynamic impact your thoughts on mid-sized transactions? Let's just say Medivation or larger. Is that an area where you still see opportunity? Or are you looking to keep powder dry in the event one of these larger transactions does in fact become available? Thanks very much.

A - Ian C. Read {BIO 3358997 <GO>}

Yes, I'm going to ask Albert to deal with the European situation on Enbrel, and then Inflectra, John. And I'll deal with the BD.

Look, we in BD we don't see it as an or, but we see it as an and. We think we have the capability if there is value in a deal to do what you would call a mid-size. I would say given our market cap, probably a little less than a mid-size, of the type of deals that we've done. But we also believe we have the ability, should the opportunity arise and should the value be there, to do a large deal. But as I stressed, we do want to see these uncertainties in the marketplace resolve themselves around tax and the politics, healthcare reform, French elections, British elections, et cetera, et cetera.

Frank, Do you want to add anything to that?

A - Frank A. D'Amelio

Just – and our actions suggest we've done that, right?

A - Ian C. Read {BIO 3358997 <GO>}

Yeah.

A - Frank A. D'Amelio

When you look at the last year and a half, we've done about almost \$40 billion in mid-size deals. To the extent that we see mid-size deals that we think make sense, we'll pursue them.

A - Ian C. Read {BIO 3358997 <GO>}

Right. And Enbrel in Europe, Albert?

FINAL

Bloomberg Transcript

FINAL

A - Albert Bourla {BIO 18495385 <GO>}

Yes, Chris, this quarter, as you have seen, Enbrel achieved almost \$600 million of revenues, \$588 million to be accurate. That was down 18% operationally versus the first quarter of 2016 and of course reflects the negative impact from Biosimilars in Europe that were launched late in last year, in 2016. Also, this decline reflects some mandated price reductions that we had to take in a few countries. So far, from the limited pricing we have seen to date for Benepali, the discount levels are in line with our expectations and we expect Enbrel's pricing to be competitive. This year we expect continued modest uptake for Benepali, but also we expect introductions of one to two additional biosimilars, likely before the end of the year.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Albert. John?

A - John Young {BIO 16960082 <GO>}

Okay. Thanks for the question, Chris. So obviously we remain very positive about the opportunity for Inflectra in the U.S. Just as a reminder, the U.S. launch of Inflectra represented the first launch of biosimilar infliximab in the United States. Based on the size of the originator business, we see significant potential for Inflectra as the first biosimilar in the U.S. to Remicade. While the launch is in the early stages, customer reception has been very positive, and Inflectra is now available through both national and regional wholesalers, and multiple GPO contracts are in place. We've seen increased access to Inflectra. And we estimate that over half of commercial lives and about 100% of Medicare and Medicaid lives are covered.

So far, discounting has been in line with our expectations, and we remain confident that our contracting status is offering appropriate pricing flexibility. And, as we've always said, we expect that biosimilar adoption will be gradual at first but accelerate as physicians build their own clinical experience with both new patients and switch patients. We saw the same with Inflectra in Europe, and in the third year of launch in Europe, infliximab biosimilars have now reached something like 41% of total infliximab volume. So we'll see a slow but steady uptake in the U.S., which is in line with our expectations. And we remain very confident that we have the right strategies in place to bring Inflectra to patients in the U.S.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, John.

A - Chuck Triano {BIO 3844941 <GO>}

Thanks, John. We'd like to on to the next questioner, please.

Operator

Your next question comes from Umer Raffat from Evercore ISI.

Bloomberg Transcript

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my question. Ian, you guys have clearly made a lot of progress on initiating a bunch of Phase 3 trials for avelumab. My question is specifically on the contract you have with Merck KGaA. And there's been some feedback that there's a multibillion-dollar breakup fee if you were to ever consider walking away. Can you help clarify that, number one?

And then perhaps one for Mikael. Mikael, there's a program we're trying to look into, Prevnar 20. Just trying to understand what the current status is, any gating factors, and when you reasonably expect it could enter a potential pivotal trial. Thank you very much.

A - Ian C. Read {BIO 3358997 <GO>}

Well, our contract with Merck is confidential, but we remain focused on developing avelumab, and I really think that's all I would say on that. I don't think that any type of breakup fee would be material compared to the size of a large deal. So - but as I always say, we said we're committed to this partnership, and we have a lot of trials ongoing there.

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you, Umar, for noticing our pneumococcal next-generation vaccine with 20-valent approach, which is likely the most comprehensive vaccine developed. And we are very pleased with the progress we have made. We have concluded a comprehensive Phase 1 trial. We think data emerging is encouraging, and we're preparing our plans and regulatory dialogues how to move swiftly - move it forward to subsequent trials. And I think we will be able, given our tremendous expertise in analytics of these complex vaccines, immunogenicity, and how to design clinical studies, to move very swiftly after finalizing proper regulatory dialogues.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you, Mikael. Next question, please?

Operator

Your next question comes from Richard Purkiss from Piper Jaffray.

Q - Richard J. Purkiss {BIO 16073464 <GO>}

Well, thanks, guys. Could Albert maybe give us a perspective on how he sees the RA market outside the U.S. developing, just given the increasing complexity there with TNF, brands, biosimilars, other biologics, now JAKs? And then just a quick one on Ibrance. Can you just update us on when we might see data from the PALLET study? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. So I don't think Albert - you came a bit low over the speaker. So, Albert, it's how do you see the RA development given the multiplicity of TNF factors in there and the fact that

we'll be the only company with a JAK in that marketplace orally, the only oral treatment really beyond - a modern oral treatment. What's your view of that marketplace?

A - Albert Bourla {BIO 18495385 <GO>}

Yes. Thank you very much. We are very enthusiastic about Xeljanz. We are very enthusiastic because we are expanding geographically with Xeljanz. We are going to Europe and other places, and we're also expanding therapeutically with potential new indications in psoriatic arthritis and ulcerative colitis.

Now, as regards to the rheumatoid arthritis that you spoke, we had 27% growth overall for Xeljanz. 21% was in the U.S. The scripts were a little bit higher at 25%. This growth was mainly driven by increased confidence as an effective agent. Also, inclusion in the ACR guidelines of Xeljanz, that played an important role. We are growing brand awareness among patients. And last but not least, we are improving access with Xeljanz in rheumatoid arthritis.

As I said, growth of revenues although high at 21% were lower than the scripts, and this was negatively impacted by some timing of purchases but also unfavorable channel mix in this quarter because we had a little bit more Medicaid than we were expecting and some rebates higher. But we expect to return to much higher growth next quarter.

A - Ian C. Read {BIO 3358997 <GO>}

Yeah, we're very enthusiastic on Xeljanz, as Albert said. Look, we have an opportunity to be the JAK in the marketplace for rheumatoid arthritis, oral, twice-a-day use in combination with trexate or monotherapy. So we see this position existing for some time in the U.S. So really strongly behind the development of this product that is very efficacious.

Now on the PALLET, Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, I'm happy to comment that - we really appreciate your interest in Ibrance studies that are indicative on large potential in early breast cancer. And of course Ibrance has been recruiting and showing a great interest from all participants in this space because of its fabulous profile, very well-tolerated. There is no need for monitoring of liver or cardiac events, which would be quite an issue for patients in that type of very early disease. And it doesn't have a lot of gastrointestinal adverse events, which also would limit the ease of use in drugs. So that has been all great experiences we have.

PALLET studies using early breast cancer and using a neoadjuvant approach to get insight into the efficacy. We had earlier a trial by Washington University in a very similar setting that showed very robust effects on Ibrance in this setting on tumor size and also on biomarkers for tumor proliferation. The PALLET study primary completion day will be early fall this year, and you will, at proper conference, hear the data. And I'm quite encouraged given the previous performance that this would add further confidence about the great

opportunity for Ibrance across many breast cancer segments and potential in the future for early breast cancer.

A - Chuck Triano {BIO 3844941 <GO>}

Thanks, Mikael. Next question, please.

Operator

Your next question comes from Gregg Gilbert from Deutsche Bank.

Q - Gregg Gilbert {BIO 3565226 <GO>}

Thank you. Three quick ones. First, do you see a rationale for looking at continuous dosing for Ibrance? And if you don't, is that because of side effect profile or you just don't believe that it brings anything to the table from an efficacy standpoint? Secondly, for John. I think in light of the EpiPen recall and the generic Copaxone delay and some other recalls of injectables, can you update us on the progress in rectifying some of the legacy quality issues?

And lastly for Ian, Bristol has hinted that it will go after PD-1 and PD-L1 therapies based on its IP portfolio, as it did with Merck in extracting that large settlement. Can you comment on your confidence in your freedom to operate in the IO space? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. I'll ask Albert to address the...

A - Albert Bourla {BIO 18495385 <GO>}

Continuous dosing.

A - Ian C. Read {BIO 3358997 <GO>}

...dosing.

A - Albert Bourla {BIO 18495385 <GO>}

Yes. There is no evidence currently to suggest that continuous dosing leads to better efficacy. Ultimately, Phase 3 results will demonstrate the extent of efficacy improvement, and of course relatively to the impact of continuous dosing on the safety profile of a given CDK inhibitor. Now, from the patient experience perspective, we need to take into account those interruptions and reductions. For example, abemaciclib is taken twice daily, whereas Ibrance is taken only once daily, which may be more convenient for patients. In addition, a dosing schedule of three weeks on, one week off may be preferable to patients. Many of them, they like this break. So I don't think that there is anything in continuous dosing.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Albert. John, on the McPherson position.

A - John Young {BIO 16960082 <GO>}

Okay. So thanks for the question, Gregg. So allow me to say we're obviously disappointed with the outcome of recent regulatory inspections at some of our manufacturing facilities, including McPherson. Pfizer takes these matters extremely seriously. We've implemented corrective and preventive actions to address issues identified by the FDA. We are making all the investments necessary to satisfy the items identified during the recent inspections, and our goal is to have these issues remediated in a timely fashion.

This includes both capital investments as well as obviously exchanging experiences and capabilities across the whole of the Pfizer network. So we remain confident that we will be able to remediate these issues, and we're working closely with the FDA in order to be able to do so.

A - Ian C. Read {BIO 3358997 <GO>}

Yeah. I would just add to what John said. The actual inspections were recently of Hospira. They were within, I believe, the first nine months of our acquisition. So the data in the 483s are based on a view of the plant as a year and a half ago or year ago. So we have made progress. We continue to make progress. And we believe that our plans to rectify those observations are well underway. I think that was it.

A - Chuck Triano {BIO 3844941 <GO>}

The IP.

A - Ian C. Read {BIO 3358997 <GO>}

IP. Look, I have no reason to have concerns about our IP estate on avelumab.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you, Ian. Next question, please, operator?

Operator

Your next question comes from John Boris from SunTrust.

Q - John T. Boris {BIO 2563403 <GO>}

Thanks for taking the questions. Just have a couple. Just back to the original question on Medivation, Ian, is - when we did our original analysis, it seemed to get a return on this investment that was heavily weighted on the pipeline. In light of some of the issues related to (1:02:22) prescribing going forward, do you continue to believe you can generate a return on this that's above your weighted average cost of capital?

The second question on the established health products group. We saw some information come across, Frank, that you're looking to divest or bundle together some products. Can

you give some information around those products and the operating margin around those products and the timing for divestiture?

And then lastly, Mikael, you indicated in 2017 and 2018 there'd be 10 approvals. How many of those would be NMEs, and what are the NMEs that you're being graded for approval? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. Why don't I ask John to deal with your question, and then Mikael can talk about the NMEs and the approvals, and I'll come back on the Medivation.

A - John Young {BIO 16960082 <GO>}

Yeah, so thanks for the question, John. So we've been very clear that one of the things - that as part of our active portfolio management strategy, we want to be very focused on - is with core segments of our business, such as our portfolio in Emerging Markets, such as our Sterile Injectable business and Biosimilars. We will be very invested in making sure that we can grow those portfolios. But to the point of your question, we're obviously clear that across what is a very broad portfolio of products, not all of those products are necessarily core to our business. And some of them are declining because they're in a position where they're post-LOE. And so we've been very clear that one of the things that we will assess is whether there are opportunities for some products or portfolios to create greater shareholder value outside of Pfizer than inside of Pfizer. So that process is ongoing. We have identified some portfolios that are noncore to our business, and we will assess opportunities to create value for our shareholders as the opportunity presents itself.

I would just add that one example of that strategy at work was the divestment of the Hospira infusion Systems business, as Frank said, we completed in the first quarter. And we will remain very vigilant and active in seeking to create value across this business, both by growing core portfolios, as well as by assessing the opportunities for value creation through divestment.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you. Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes. So we see up to 10 potential key approvals in 2017 and 2018, and we see a rhythm continuing in 2019, 2020, and 2021 where we have some really large opportunities in our pipeline. In the 2017 and 2018, about two-thirds will be in Oncology. The remaining likely Immunology, Biosimilars, Internal Medicine. I'll mention, of course you're projecting what can happen in the future, so I will just give example of assets that are in the peri-registration phase. The outcome of those assets is of course pending the regulatory review.

But you have assets such as elotuzumab, which has priority review. You have our partnership with Merck on ertugliflozin alone and combined with metformin, as well as Januvia. You have our recent breakthrough designated drug, lorlatinib, for patients with progression on ALK+. It also has activity on ROS tumors, and you have example of the Biosimilar portfolio as well as some really interesting salient indications that are in this registration phase, psoriatic arthritis. You have Sutent as the first drug to conclude an adjuvant trial. So it's a nice mix of assets with a various profile, and I think some of them represent really novel modalities, like elotuzumab antibody-drug conjugate; some represent our stronghold in targeted agents. And I think a nice mix of agents here.

A - Ian C. Read {BIO 3358997 <GO>}

And to the extent that it's a combo product with a 4-1BB or OX40, it's new entity coming into the marketplace. Okay. On Xtandi, Frank, why don't you answer that question, as you're the guru capital of returns?

A - Frank A. D'Amelio

Sure. So, John, I'll start by saying that we continue to expect our return on capital for that transaction to exceed our cost of capital. Now, the performance to date is less than we had planned for. Ian and Albert have explained why that is on the call. But, as we've said all along, the real critical pivot point for that deal is the non-metastatic, the earlier stage prostate cancer. We remain confident in our ability to get approval for those indications. That's the pivotal point relative to that.

A - Ian C. Read {BIO 3358997 <GO>}

And I do believe at this time that this dislocation in the reimbursement market is temporary in nature.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you. Next question, please.

Operator

Your next question comes from David Risinger from Morgan Stanley.

Q - David R. Risinger {BIO 1504228 <GO>}

Thanks very much. So I have two questions for Frank, please. The first is, could you comment on the outlook for margins beyond 2017? Obviously you are not providing guidance, but just wanted a framework for how to think about it with respect to how you plan to offset negative mix shift when U.S. Viagra and U.S. Lyrica expire? Obviously there'll be more of a mix shift towards other franchises, including emerging markets that are lower margin. And then, second, if you could just update us on the total cash and ex U.S. cash at Pfizer, and if you don't have the end of March, just remind us where you were at the end of December? Thank you.

A - Frank A. D'Amelio

FINAL

Sure. So, Dave, on U.S. cash, I'll go through the end of December. At the end of the year, we had \$25 billion in cash, short-term investments, and long-term investments. And what we always say is, at any point in time, no more than \$10 billion of that is in the U.S., and obviously the majority of it being outside the U.S. We'll give an update on the balance sheet when we issue our 10-Q this quarter.

In terms of the outlook for margins, beyond 2017 - let me talk about 2017 first, and then I would talk about a rhythm beyond 2018, which is if you look at 2017, we have significant LOEs in 2017. Call it almost \$2.5 billion. Yet I've looked at our margins; our margins are still very good relative to last year. For example, our gross margin is actually improving. Our cost of sales is lower than last year. And it gets to the mix of business, which you alluded to.

So think about, even though we're losing some of the high-octane margin products from LOEs, things like alliance revenues, where we're getting significant growth in Eliquis, significant growth in Xtandi, those have no associated costs, so they have a really significant positive impact on our margins, and you see that in our 2017 guidance. Net-net, beyond 2017, as of now, we don't see any major changes in our margin profile.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you, Frank. Next question, please.

Operator

Your next question comes from Jeff Holford from Jefferies.

Q - Jeffrey Holford {BIO 4872636 <GO>}

Hi. Thanks very much for taking my question. I just wondered if you can go into the alliance revenues just in a little bit more detail for us. They're obviously quite difficult for us to model and follow. I wonder if you can break it down a little bit more, just in terms of the drivers and dynamics within that number. Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Go ahead, Frank.

A - Frank A. D'Amelio

So - by the way, what we did this quarter is, if you look on page 28 of our product tables and the attachments to the release, we've actually broken it out now. So you can see, if you look up at the top of the page, "Eliquis alliance revenues and direct sales," and obviously the bulk of that is alliance revenues, \$564 million. You go down a little bit further, you'll see "Xtandi alliance revenues," \$130 million. And then if you go down below, you see "Total Alliance revenues" at the very bottom of the page, which is \$656 million. So you can easily reverse-engineer what the Eliquis direct sales were. I mean, it's very simple to do. Just take the alliance revenue, subtract Xtandi, and it'll give you the

residual, which is essentially Eliquis alliance revenue. So we've broken that out for you. We've given you additional detail on that starting this quarter.

A - Chuck Triano {BIO 3844941 <GO>}

Great. Thanks for the clarity, Frank. Next question, please.

Operator

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

Q - Alex Arfaei {BIO 15433937 <GO>}

Good morning, folks. Thank you for taking the questions. Most of my questions have been answered. Ian, a higher level question on R&D productivity: While I appreciate the earlier comments on your pipeline, as I look at the Street expectations for what will be the key growth drivers, most of them come from acquisitions. It seems as though the focus is always more on what you're going to buy as opposed to what's coming out from your pipeline. So just wondering, what are your thoughts on your R&D productivity? Is it meaningful enough to drive growth, and is there anything you can do structurally to improve it? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Alex, thank you. Normally most big pharmaceutical companies have a component of their growth from business development, and I don't think ours is out of weight with the rest of the industry. I do think we have very productive R&D with potentially very large products coming. You've got the whole line extensions of Ibrance, which was internally discovered and developed. We have our C. difficile vaccine, which is internally developed. We have a Staph aureus vaccine, which is internally developed. We have a lot of substrate coming out of Immunology & Inflammation. So - and our cancer, we have most of our productivity there is coming from the - what we believe is coming from the doublets and the triplets (1:12:24)

So I think our R&D productivity is good. It can always be better. I think every conversation I have with Mikael is more, faster. We have robust mechanisms, and we continue to improve them to measure productivity, to understand from Phase 1 to Phase 2, from Phase 2 to Phase 3, from time lags between those. There is a constant push in this organization to improve productivity. But overall I'm pleased with the strength of our internal development, and I'm pleased with our external acquisitions, and I think the mix is appropriate. Thank you.

A - Chuck Triano {BIO 3844941 <GO>}

Thanks, Ian. And if we can take our last question, please, operator.

Operator

Your final question comes from Geoff Meacham from Barclays.

Q - Geoffrey Meacham {BIO 21252662 <GO>}

Hey, guys. Thanks for the question. Just wanted to revisit Xtandi a little bit. When you look at the opportunity among urologists, have you guys seen script volume per doc or number of urologists writing a script increase? And what would be your view as a tipping point? Is it data and M-zero? And one for Ian. When you look at the P&L impact of a deal, the law of large numbers always comes into play for Pfizer. So would you expect to revisit a split or a larger-scale spinout at some point if the deal opportunities aren't a fit? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Albert?

A - Albert Bourla {BIO 18495385 <GO>}

Yeah, so basically you're speaking about the growth potential of Xtandi in the metastatic setting, which is currently the current indication, because as we discussed, we have great expectations for the upcoming early non-metastatic.

So we believe that there is a lot of room to grow here. The novel form of therapies are about 55% of the total market, so there is room for expansion, and we believe that will continue showing growth. The total demand was up 13%, as I say, in the first quarter, despite the fact that was affected, the total demand, by the lack of assistance for some patients that they cannot afford their co-pays, and they are not eligible for free drug that we are provide. The number of urologists prescribing has reached a all-time high. We have 1,500 urologists prescribing right now the brand. And a recent market research saw the significant increase in prescribing intent by both oncologists and urologists that were aware of the TERRAIN data versus those that were not aware. I want to remind you that the TERRAIN data that came out recently and have been already incorporated in our label saw a reduction of risk of radiographic progression or death by 40% compared to Casodex, which is the main product that urologists are prescribing today.

And also we are taking several actions to make sure that this is happening. We are engaging with payers and implementing successful strategies to ensure optimal access to Xtandi. For example, effective, we believe, next quarter, in second quarter, we have regained full access of Xtandi with two large payers, PBMs. Also the commercial team now is focused on leveraging the Pfizer scale, and portfolio synergies to drive growth. And that includes leveraging existing Pfizer urologist sales representatives that have current relationships with urologists, and now they will support also Xtandi. And of course also we expect to accelerate Xtandi growth by focusing on educating physicians, and particularly urologists, on the updated label, positive experience with Xtandi in the metastatic prostate cancer market.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you. Regarding your question on size and the size of the company and the need for deals to make a difference, we have always said that we continue to review on an ongoing basis our total portfolio. We look at what are the ways to maximize shareholder value, and we look at all the large segments of our business to ensure that their value inside Pfizer is

greater than what we believe their value outside of Pfizer would be. So that is an ongoing effort.

So there would need to be a triggering event for us to relook at the Essential business being separated. Now, remember, our four questions were: Is it functioning well inside the company; is it maximizing inside? Do we believe it could do a better job outside of the company? Is there trapped value? Can it be released in a tax-efficient manner? So those are still relevant questions. So a triggering event, major tax reform or a major change in the way we allocate our resources, would of course cause us to review all of our portfolio with that same lens. Thank you.

A - Chuck Triano {BIO 3844941 <GO>}

Thanks, Ian, and thanks, everybody, for your attention on the call.

Operator

Ladies and gentlemen, this does conclude Pfizer's first quarter 2017 earnings conference call. Thank you for your participation. You may now disconnect.

This transcript may not be 100 percent accurate and may contain misspellings and other inaccuracies. This transcript is provided "as is", without express or implied warranties of any kind. Bloomberg retains all rights to this transcript and provides it solely for your personal, non-commercial use. Bloomberg, its suppliers and third-party agents shall have no liability for errors in this transcript or for lost profits, losses, or direct, indirect, incidental, consequential, special or punitive damages in connection with the furnishing, performance or use of such transcript. Neither the information nor any opinion expressed in this transcript constitutes a solicitation of the purchase or sale of securities or commodities. Any opinion expressed in the transcript does not necessarily reflect the views of Bloomberg LP. © COPYRIGHT 2021, BLOOMBERG LP. All rights reserved. Any reproduction, redistribution or retransmission is expressly prohibited.