

THOMSON REUTERS STREETEVENETS

EDITED TRANSCRIPT

PFE - Q1 2017 Pfizer Inc Earnings Call

EVENT DATE/TIME: MAY 02, 2017 / 2:00PM GMT

OVERVIEW:

Co. reported 1Q17 revenues of approx. \$12.8b and reported diluted EPS of \$0.51.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

CORPORATE PARTICIPANTS

Albert Bourla *Pfizer Inc. - Group President of Pfizer Innovative Health*

Charles E. Triano *Pfizer Inc. - SVP of IR*

Frank A. D'Amelio *Pfizer Inc. - CFO and EVP of Business Operations*

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

John D. Young *Pfizer Inc. - Group President of Pfizer Essential Health*

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

CONFERENCE CALL PARTICIPANTS

Andrew Simon Baum *Citigroup Inc, Research Division - Global Head of Healthcare Research and MD*

Ardalan Alex Arfaei *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

Charles Anthony Butler *Guggenheim Securities, LLC, Research Division - Senior Analyst*

Christopher Thomas Schott *JP Morgan Chase & Co, Research Division - Senior Analyst*

David Reed Risinger *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

Geoffrey Christopher Meacham *Barclays PLC, Research Division - MD and Senior Research Analyst*

Gregory B. Gilbert *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Jamilu E. Rubin *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Jeffrey Holford *Jefferies LLC, Research Division - Equity Analyst*

John Thomas Boris *SunTrust Robinson Humphrey, Inc., Research Division - MD*

Marc Harold Goodman *UBS Investment Bank, Research Division - MD and United States Healthcare Analyst*

Richard John Purkiss *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

Stephen Michael Scala *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Timothy Minton Anderson *Sanford C. Bernstein & Co., LLC., Research Division - Senior Analyst*

Umer Raffat *Evercore ISI, Research Division - Senior MD and Fundamental Research Analyst*

PRESENTATION

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.

Charles E. Triano - Pfizer Inc. - SVP of IR

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.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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 I - 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 obligations 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. Reconciliations 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 measures at other companies. We will now make prepared remarks, and then we'll move to a question-and-answer session.

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

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

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 1 less domestic and 2 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 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.

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 in 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 2 upcoming significant LOE events, Viagra in the U.S. later this year and Lyrica in the U.S. at the end of 2019.

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 interest of physicians and patients. And with the 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.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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 doublets and triplets are the best areas of greatest potential for patients. We've initiated avelumab combination studies for 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-positive small cell lung cancer and have -- hope to have a filing in the U.S. during the second half of this year. We are also studying it in combination of 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 a factor IX.

In internal medicine, we're advancing our portfolio in NASH, nonalcoholic 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 2 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 determined 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 the 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 6 years. We have built a stronger, more resilient, competitive business with a solid portfolio of market-leading products and a robust R&D pipeline. We have the resources, expertise, talent, acumen and culture required to control our destiny.

In summary, we are looking ahead 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.

MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

Frank A. D'Amelio - Pfizer Inc. - CFO and EVP of Business Operations

Thanks, Ian. Good day, everyone. As always, the charts I'm going to be 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 3 months of legacy Anacor operations, which are immaterial, and 3 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 the first quarter 2017 include approximately 1 month of Legacy HIS domestic operations and 2 months of legacy HIS international operations, while the year-ago quarter reflected 3 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 1 less selling day in the U.S. and 2 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 Plevnar 13 revenues. In the U.S., Plevnar 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 the timing of government purchases for the pediatric indication.

In international markets, Plevnar 13 revenues decreased 4% operationally due to the unfavorable impact of timing of government purchases for the pediatric indication of 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 products -- 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 2017 and a 5% operational decline in legacy established products, all of which were partially offset by 3% operational growth in the sterile injectables portfolio and 62% operational growth of 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. 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 days, product LOEs 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 2 \$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 a year-ago quarter. As you can see, we reaffirmed all components of our 2017 financial guidance.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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.

Charles E. Triano - Pfizer Inc. - SVP of IR

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question comes from Jami Rubin from Goldman Sachs.

Jamilu E. Rubin - Goldman Sachs Group Inc., Research Division - Equity Analyst

Ian, I think you've referenced the Xtandi issue with Patient Assistance Programs, but you can you explain what's going on? Why this is occurring now? Why it 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 been -- 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?

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

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 out an overlay. Thank you, Albert.

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Thanks, Ian, 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 the 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 '17 and to, over time, resolve. 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, ARTIST, 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.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

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 copay donations which the Health and Human Services Office where 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 all for the early use of Xtandi, this was heavily weighed towards Medicare. A separate part of the government has recently raised questions on 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 for 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 in both globally and in the U.S. for the sector to continually efficiently giving medicine 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, health care policies in 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 valuation process regardless the target size. We'll continue to evaluate deals and we never say never, but I believe the current environment needs to stabilize in order to be in an advantageous market for big deals.

Operator

Your next question comes from Tim Anderson from Bernstein.

Timothy Minton Anderson - Sanford C. Bernstein & Co., LLC., Research Division - Senior Analyst

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. So 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 I/O agreement with Merck KGaA? Just wondering if it's in the realm of possibilities in I/O, where the landscape continues to shift, if you have to remain open-minded when it comes to assessing the best way to try to become a leader in this area. And on that same topic, in the avelumab label there is a mention of a negative effect differentiation that seems like it could be problematic for that product.

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

Okay, Tim, I'm going to -- 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 in the investment. And hopefully, these elections will provide that clarity for that market in its total. As regards to Merck and the I/O 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 raised about the potential differential in the labeling claim is -- or Albert will address that. So go ahead, Mikael.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

Thank you. It's 2.5 years since we initiated alliance with Merck KGaA. And of course, we are pleased that we've been able to initiate more than 30 avelumab programs, and 9 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 '17 all the way to '22 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 in monotherapies. And I think, given the (inaudible) we see in cancer, it's likely to quickly evolve to more of a combination drug play. We are pleased to have 6 I/O 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, 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 I/O 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, lorlatinib, 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 4 chemo combo trials running. So I think you would 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 I/O 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.

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

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

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Yes. I guess the theme that you're referring to injection related, the reactions that they're mentioning in their label. First of all, it is important to note that the adverse reaction rates observed in clinical trials of the 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 1 or 2. Also less than 1% of patients drops -- stopped treatment due to them. And also in our studies, the injection- and infusion-related reactions were managed very successfully with pre-medication. So we think that this is nothing to be worried about.

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

Other than that, we see a very balanced profile of avelumab compared to the other PDL checkpoints.

Operator

Your next question comes from Tony Butler from Guggenheim Securities.

Charles Anthony Butler - Guggenheim Securities, LLC, Research Division - Senior Analyst

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 2 together might have some dramatic effect on the number of solid tumors outside of breast cancer.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

Mikael, if you could answer this, please?

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

Yes. Thank you, Tony, for raising this 2 questions. As Albert alluded to, this 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 raised a real interesting question. There's been some recent data suggesting that combining palbo-like compounds 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.

Operator

Your next question comes from Marc Goodman from UBS.

Marc Harold Goodman - UBS Investment Bank, Research Division - MD and United States Healthcare Analyst

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. In this quarter, it looks a little bit light. I was just curious if maybe there was some inventory that you'd 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. But with respect to I/O, could you talk about some of the other pipeline assets we should be watching for that are non-I/O?

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

Albert, please.

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

We are very happy with the performance of Ibrance this quarter. And, of course, no, there was no material moving inventories. We have revenues of almost \$680 million, which was 59% growth and our internal market shares are around the 50s for the first line and then 40s and 30s in the second line and third line, respectively. We had, this quarter, more than 7,000 new patients that came to the brand and we've 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.

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

Thank you, Albert. Mikael?

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

Yes. 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 year, since 2011, had 21 approvals, 3 to 4 per year. On average, 2 NMEs and we envision in '17 and '18, 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 I/O 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 Ibrance, palbociclib with HER2 active drugs. We have several programs now ongoing to also deal with the growing number of patients



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

that will progress eventually through CDK-like drugs into their systems, 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 with our first-in-class for blood cancers agent, and we're looking to summarize those data, engage with the agency about a possible filing based upon Phase 2 data. There's a readout of talazoparib, the EMBRACA study, that, I think, would 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 penetrance 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 Pevnar 13 vaccine and you're obviously aware that we have initiated Phase 3 with *C. difficile*, which is a 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 JAK drugs. We'll have, later this year, readouts for our JAK1 drug in atopic dermatitis. And I'm very enthusiastic based on a lot of supporting science with that aspect. And our unique JAK1 to 2, the most advanced with its profile in the industry has entered into a platform with numerous trials in ulcer colitis, alopecia, psoriasis, and the drug looks really promising with its unique dual activity. Finally, I'll mention in 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 2 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 a rare disease. In addition to the gene therapy platform, we have now enrolled to the target domagrozumab, our anti-myostatin drug in DMT. And we actually have tafamidis that you may not have kept an eye on, that's going to readout likely next year in polyneuropathy, which, again, could open up a big opportunity for us.

Operator

Your next question comes from Andrew Baum from Citi.

Andrew Simon Baum - Citigroup Inc, Research Division - Global Head of Healthcare Research and MD

A couple of questions, please. For Mikael, could you update us on the patent extension for Ibrance? Palbo -- I just saw 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 the 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 in pricing from Novartis' ribociclib on Ibrance, either with a 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 would take 3 years. Do you see any risk that drug pricing becomes more vulnerable given the President's intent to support tax or broader ACA repeal?

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

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

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

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; 2 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 2 years PFS. But also to its manageable safe and tolerability profile with no cardio or liver monitoring required. The last but not least, we have great access for our patients. We price our products appropriately to their value. We have managed to successfully price competition in the past and we will do it in the future.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

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, the net increase, net price increase of branded drugs was about 2.8%. That was in '15. And in '14, it was about 5%. And we don't have '16 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 health care. 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 health care reform, is the fact that the insurers have -- because of the exchanges, have moved to put large copays 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 health care reform ensures access to important medicines, a level playing field so that any subsidies that are given by the government are evenly spread today under the ACA, under the plans, the hospital out-of-pocket for patient is 3%, the out-of-pocket for patient is 15% on drugs. So I think these are the types of things we want to see happen in the health care 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. That, I think, is the line that we need to take, and I think -- I believe the Trump administration will look at, is how to make that market more competitive.

Operator

Your next question comes from Steve Scala from Cowen.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD and Senior Research Analyst

A couple of 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?

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

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

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Yes, absolutely. We continue to believe and expect that Prevnar 13 would be flat to declining this year, slightly declining this year, exactly as we have said in the past. This is 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 had 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 would be partially offset by growth of adult vaccinations in the 18 to 64 age range. And in addition, it's also expected to be partially offset by international adult growth in developed markets. Europe, for example, this quarter, the adult went up 25%. Also, I want to note is that there is -- it is very common to have volatility in overall vaccine sales because they are highly dependent from governmental purchases that the timing could vary quarter-by-quarter.

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

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



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

No change to a slight decline.

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

Mikael, given the rules of embargoed data and everything, what can you say?

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

Thank you, Ian, for adding that perspective. I can only say that the confidence in lbrance is extremely high among us and all the stakeholders. Of course, you're aware that lbrance was recently given full approval, which underlines the strength in data across numerous advanced and metastatic breast cancer segments. And the PFS data has been very robust. Durability is up to almost 2 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 as patients that go off trials can embark on a variety of different treatment. 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.

Operator

Your next question comes from Chris Schott from JPMorgan.

Christopher Thomas Schott - JP Morgan Chase & Co, Research Division - Senior Analyst

I just had 2 questions here. Maybe first, can you, biosimilar questions on 2 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 is coming back to business development and priorities. I appreciate the earlier comments, Ian, but -- and to maybe 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 you still see opportunity? Or are you looking to keep the powder dry in an event when these larger transactions does, in fact, become available?

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

Yes. On the -- I'm going to ask Mikael -- sorry, 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 the deal to do a, what you would call, a mid-sized -- I would say given our market capital, a little less than a mid-sized -- of the type of deals that we've done. But we also believe we have the ability, should the opportunity arise, should the value be there, to do a large deal. So -- but then as I stressed, we are -- we do want to see these uncertainties in the marketplace resolve themselves around tax and the politics, health care reform, French elections, British elections, et cetera, et cetera. Frank, do you want to add anything to that?

Frank A. D'Amelio - Pfizer Inc. - CFO and EVP of Business Operations

Just, our actions suggest we've done it, right? When you look at the last 1.5 years, we've done about almost \$40 billion in mid-sized deals. To the extent we see mid-sized deals, mid-sized deals that we think makes sense, we'll pursue them.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

Right . And then Enbrel in Europe, Albert.

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Yes. This quarter, as you have seen, Enbrel achieved almost \$600 million of revenues, 5 [APA] to be accurate. That was down 18% operationally versus the first quarter of '16 and of course reflects the negative impact from biosimilars in Europe, but they 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 today from 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 update for Benepali, but also we expect introductions of 1 to 2 additional biosimilars likely before the end of the year.

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

Thank you, Albert. John.

John D. Young - Pfizer Inc. - Group President of Pfizer Essential Health

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. Inflectra is now available through both national and regional wholesalers and multiple GPO contractor in place. We've seen increased access to Inflectra and we estimate that over half of commercial lives and about 100% of Medicare, Medicaid lives are covered. So far, this kind of thing has been aligned with our expectations and we remain confident that our contracting status is offering appropriate pricing flexibility. And as we have 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 switched 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.

Operator

Your next question comes from Umer Raffat from Evercore ISI.

Umer Raffat - Evercore ISI, Research Division - Senior MD and Fundamental Research Analyst

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 breakup fee if you were ever to 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 do you reasonably expect it could enter a potential pivotal trial?

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

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, if any, that any type of breakup fee would be material compared to the size of a large deal. So -- but as I would say, we said we're committed to this partnership and we have a lot of trials ongoing there.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

Yes. Thank you, Umer, for noticing our pneumococcal next-generation vaccine with 20-valent approach, which is likely the most comprehensive vaccines 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 in immunogenicity and how to design clinical studies, to move very swiftly after finalizing proper regulatory dialogues.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you, Mikael.

Operator

Your next question comes from Richard Purkiss from Piper Jaffray.

Richard John Purkiss - Piper Jaffray Companies, Research Division - MD and Senior Research Analyst

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?

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

Okay, so I don't think, Albert -- you became a bit low over the speaker. So, Albert, it's the, 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?

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Yes, thank you very much. The -- we are very enthusiastic about Xeljanz. We're very enthusiastic because we are expanding geographically with Xeljanz. We are going to Europe and other places and to also expanding therapeutically with potential new indicators -- new indications in psoriatic arthritis and ulcerative colitis. Now as regards to 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 for 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 a return to much higher growth next quarter.

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

Yes, 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, used in combination with a Trexate or monotherapy. So -- and this, 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?



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

Yes, yes. I'm happy to comment that we really appreciate your interest in Ibrance studies that are indicative on its large potential in early breast cancer. And of course, Ibrance has been recruiting and showing 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 event, which would be quite an issue for patient in that type of very early disease. And it doesn't have a lot of gastrointestinal adverse events, which also would mean the ease-of-use in drug. But that has been all great experiences we have, PALLET studies using early breast cancer and using a new adjuvant approach to get insights 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 potentially in the future for early breast cancer.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you, Mikael.

Operator

Your next question comes from Gregg Gilbert from Deutsche Bank.

Gregory B. Gilbert - Deutsche Bank AG, Research Division - MD and Senior Analyst

Three quick ones. First, do you see a rationale for looking at continues dosing for Ibrance? And if you don't, is that because of the 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 insisted that it would 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 I/O space?

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

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

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

Continuous dosing.

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

Dosing.

Albert Bourla - Pfizer Inc. - Group President of Pfizer Innovative Health

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 dose 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 3 weeks on, 1 week off may be preferable to patients. But many of them, they like this break. So I don't think that there is anything in continuous dosing.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

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

John D. Young - Pfizer Inc. - Group President of Pfizer Essential Health

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

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

Yes, I would just add to that, to what John said. The actual inspections were recently of Hospira. They were within, I believe the first 9 months of our acquisition, so the data is -- the data in the 483s are based on a view of the plan as 1.5 years ago or 1 year ago. So we've made progress. We continue to make progress, and we believe that our plans to rectify these observations are well under way. I think that was it.

Frank A. D'Amelio - Pfizer Inc. - CFO and EVP of Business Operations

The IP?

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

IP. We have no -- I have no reason to have concerns about our IP estate on avelumab.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you, Ian.

Operator

Your next question comes from John Boris from SunTrust.

John Thomas Boris - SunTrust Robinson Humphrey, Inc., Research Division - MD

Just have a couple. Just back to the original question on Medivation, Ian. As -- when we did our original analysis, it seemed to get a return on this investment, and it was heavily weighted on the pipeline. In light of some of the issues related to -- 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, to bundle together some products. Can you give some information around those products and the operating margin around these products and timing for divestiture? And then lastly, Mikael, you indicated in '17 and '18, there would be 10 approvals. How many of those would be NMEs? And what are the NME's that you're being graded for approval?



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

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

John D. Young - Pfizer Inc. - Group President of Pfizer Essential Health

Yes, so thanks for the question, John. So yes, we've been very clear that one of the things we've done 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 set opportunities to create value for our shareholders as the opportunity presents itself. I'll 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 divestments.

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

Thank you. Mikael?

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

Yes, so we see up to 10 potential key approvals, '17 and '18. And we see a rhythm continue in '19, '20 and '21, where we have some really large opportunities in our pipeline. In the '17 and '18, about 2/3 would be in oncology. The remaining likely in immunology, biosimilars, internal medicine. And mentioned, 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 inotuzumab, 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 patient with progression on ALK-positive, it also has activity on ROS tumors. And you have example of the biosimilar portfolio as well have some really interesting salience indications that are in its registration phase, psoriatic arthritis. You have Sutent. That's the first drug to conclude an adjuvant trial. So it's a nice mix of assets with various profiles. And I think some of them represent really novel modalities, like inotuzumab antibody drug conjugate. Some represent our stronghold in targeted agents, and there are, I think, a nice mix of agents here.

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

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

Frank A. D'Amelio - Pfizer Inc. - CFO and EVP of Business Operations

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 said all along, the real critical pivot point to that deal is the nonmetastatic, 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.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

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

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you.

Operator

Your next question comes from David Risinger from Morgan Stanley.

David Reed Risinger - Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst

So I have 2 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 franchisees, 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.

Frank A. D'Amelio - Pfizer Inc. - CFO and EVP of Business Operations

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'll talk about our rhythm beyond 2018, which is, if you look at 2017, we have significant LOEs in 2017, call it almost \$2.5 billion. And yet, look 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 and now 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.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thank you, Frank.

Operator

Your next question comes from Jeff Holford from Jefferies.

Jeffrey Holford - Jefferies LLC, Research Division - Equity Analyst

I just wondered if you can go into the alliance revenues just in a little bit more detail for it was obviously quite difficult for us to model and follow. If you can break it down a little bit more just in terms of the drivers and dynamics within that number.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

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

Go ahead, Frank.

Frank A. D'Amelio - Pfizer Inc. - CFO and EVP of Business Operations

So by the way, what we did this quarter is, if you looked on Page 28 about our product tables in 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 write -- take the alliance revenues, subtract Xtandi and it'll give you the residual, which is essentially Eliquis alliance revenue. So we've broken that out for you. We'll give you additional details on that starting this quarter.

Charles E. Triano - Pfizer Inc. - SVP of IR

Great. Thanks for the clarity, Frank.

Operator

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

Ardalan Alex Arfaei - BMO Capital Markets Equity Research - Pharmaceuticals Analyst

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 looked at Street expectations for what would 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?

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

Alex, thank you. Well, normally, most big pharmaceutical companies have a component of their growth from business development, and I don't think ours was 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 and 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 triplets and the IDOs. 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.

Charles E. Triano - Pfizer Inc. - SVP of IR

Thanks, Ian.



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings Call

Operator

Your final question comes from Geoff Meacham from Barclays.

Geoffrey Christopher Meacham - *Barclays PLC, Research Division - MD and Senior Research Analyst*

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 the tipping point? Is it data and 0? And then 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 larger-scale spin-out at some point if the deal opportunities aren't a fit?

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

Albert.

Albert Bourla - *Pfizer Inc. - Group President of Pfizer Innovative Health*

Yes, so basically, you are speaking about the growth potential of Xtandi in the metastatic setting, which is currently the current indication, because as we already discussed, we have great expectations for the upcoming early nonmetastatic. So we believe that there is a lot of room to grow here. The novel hormone therapies are about 55% of the total market, so there's 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 it was affected, the total demand, by the lack of assistance for some patients, that they cannot get -- they cannot afford their co-pays, and they are not eligible for free drugs that we are providing. The number of urologists prescribing has reached all-time high. We have 1,500 urologists prescribing right now of 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 they 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 have taken 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 2 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 urology 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 or the experience with Xtandi in the metastatic prostate cancer market.

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

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 will -- 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 large segments of our business to ensure that their value inside Pfizer is greater than what we believe their value outside Pfizer would be. So there is ongoing effort. So there would need to be a triggering event for us to relook at the essential business being separated. I remember our 4 questions were: Is it functioning well inside the company? Is it maximizing inside? Do we believe it could do a better job outside the company? Is there trapped value, and can it be released in a tax-efficient manner? So those are still relevant questions. So a triggering event, major tax reform, a major change in the way we allocate our resources, would, of course, force us to review all of our portfolio through that same lens. Thank you.

Charles E. Triano - *Pfizer Inc. - SVP of IR*

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



MAY 02, 2017 / 2:00PM, PFE - Q1 2017 Pfizer Inc Earnings 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.

DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2017, Thomson Reuters. All Rights Reserved.

