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PFE - Q1 2018 Pfizer Inc Earnings Call

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OVERVIEW:

PFE reported 1Q18 revenues of approx. $12.9b and reported diluted EPS of $0.59.

CORPORATE PARTICIPANTS

Albert Bourla *Pfizer Inc. - COO & Director*

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

Frank A. D'Amelio *Pfizer Inc. - Executive VP of Business Operations & CFO*

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

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

CONFERENCE CALL PARTICIPANTS

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

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

Charles Anthony Butler *Guggenheim Securities, LLC, Research Division - MD & Senior Equity 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 Bank PLC, Research Division - MD & 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*

Jason Matthew Gerberry *BofA Merrill Lynch, Research Division - MD in US Equity Research*

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

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

Vamil Kishore Divan *Crédit Suisse AG, Research Division - Senior Analyst*

PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's First Quarter 2018 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.

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

Good morning, and thank you for joining us today to review Pfizer's first quarter 2018 performance. I'm joined today by our Chairman and CEO, Ian Read; Albert Bourla, our Chief Operating Officer; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; and Doug Lankler, General Counsel.

The slides that will be presented on this call can be viewed on our website, pfizer.com/investors.

Before we start, I would 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 release we issued this morning as well as in Pfizer's 2017 annual report on Form 10-K. 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. Reconciliations of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's Form 8-K dated today, May 1, 2018. 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 will 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 & CEO*

Thank you, Chuck, and good morning, everyone. During my remarks, I will discuss the progress and opportunities we are seeing across the business as well as the continued strengthening of our R&D pipeline, which we increasingly believe has a potential to drive significant future growth for Pfizer. In the first quarter, total company revenues declined 2% operationally. This was due primarily to the loss of exclusivity of Viagra in the U.S. in December 2017, biosimilar similar competition for Enbrel in Europe and product supply shortages related to our legacy Hospira products in the U.S. and our production facilities in Puerto Rico. These declines were partially offset by continued strong growth in emerging markets, biosimilars globally and many of our anchor brands.

I'll begin with a few words about each of our businesses starting with Pfizer Innovative Health. This business had another solid quarter growing its top line 3% operationally, thanks to the continued strength of several of our biggest selling medicines. The year-over-year growth rate of the Innovative business was negatively impacted by approximately 1 percentage point due to the reclassification of U.S. Viagra sales to the Essential Health business following its loss of exclusivity at the end of 2017.

In addition, both Ibrance and Xeljanz revenues in the U.S. were impacted by customer buying patterns this quarter, but we expect to remain on track for our full year outlook for both products. In the first quarter, Global Ibrance revenues were up 35% operationally to $933 million, with non-U.S. revenues almost tripling. Ibrance continues to hold a leadership position in first-line hormone receptor-positive/HER2-negative metastatic breast cancer. Since its launch, approximately 12,000 physicians have [been] prescribed Ibrance in the U.S. and more than 120,000 patients have been prescribed the medicine worldwide. The overall CDK class continues to increase penetration within the eligible patient population, and we now see approximately 70% of eligible patients receiving CDK therapy.

Within the CDK category, Ibrance again increased its share from 52% last quarter to 56% this quarter. Xtandi's U.S. alliance revenues were up 21% in the quarter to $159 million. In mid-March, the U.S. FDA granted priority review for the sNDA for Xtandi in nonmetastatic castration-resistant prostate cancer, with a PDUFA date in July 2018. In the EU, the EMA has validated the type-2 variation submission for the same indication and began the new review process on March 5.

Xeljanz revenues increased 29% operationally in the quarter to $326 million. We recently received 2 important regulatory milestones for Xeljanz. The FDA Advisory Committee recently gave us a favorable outcome for moderately to severely active ulcerative colitis, and this indication has a PDUFA date in June 2018. And just last week, the Committee for Medical Products for Human Use of the European Medicines Agency adopted a positive opinion of Xeljanz 5 milligrams twice daily in combination with methotrexate for the treatment of active psoriatic arthritis. We believe the potential for Xeljanz in psoriatic arthritis for which we've already received an FDA approval in December and ulcerative colitis, if approved, could be significant.

Global Eliquis revenues were up 30% operationally in the quarter to $765 million. Eliquis is the #1 new-to-brand novel oral anticoagulant prescribed by cardiologists in 21 markets. In the U.S., it has a 52.1% of the total prescription share for novel oral anticoagulants, 10 percentage points ahead of our primary competitor, Xarelto.

Finally, we continue to review strategic options for our Consumer Healthcare business, which has delivered another solid quarter. We remain disciplined regarding our capital allocation. And at this time, we have not received an acceptable offer for the sale of this business. We will continue to manage this very strong business as we explore other alternatives, which could include everything from a full or partial separation of the business to ultimately deciding to retain the business. We continue to expect to make a decision during 2018. I would like to take a moment to thank all of the consumer health colleagues who have worked so hard in the last quarter to produce a strong 4% growth rate.

Turning now to Pfizer Essential Health. While revenues for the quarter declined due in large part to expected product LOEs and ongoing product supply shortages in the sterile injectables business, we once again saw strong operational growth both in emerging markets and in our biosimilars portfolio. Emerging markets revenue within the Essential Health business grew 12% operationally for the quarter to nearly $2 billion. China led the way, growing 26% operationally. Revenues from our biosimilars business grew 53% operationally in the quarter to $173 million. We expect to broaden our biosimilars portfolio in the U.S. by potentially bringing 5 biosimilars to the market in the next 2 years.

Our sterile injectable shortages are primarily for products from the legacy Hospira portfolio. We expect our sterile injectables sales will be roughly flat year-on-year, and this is incorporated into our financial guidance. We continue with our comprehensive remediation plan to upgrade and modernize these facilities, and we expect additional capacity to be available in 2019.

We continue to strengthen and advance our pipeline, which is, a, is as strong as it's ever been. Let me touch on some of the more promising recent developments.

In oncology, we have a broad range of targeted compounds that represent potential near-term opportunities. The Phase III EMBRACA trial showed that our PARP inhibitor, talazoparib, significantly extended progression-free survival versus standard-of-care chemotherapy in patients with BRCA-positive metastatic breast cancer. We are discussing the results with worldwide health authorities and anticipate filing this quarter. Lorlatinib was recently granted priority review by the U.S. FDA as a potential treatment for patients with ALK-positive metastatic non-small cell lung cancer with a PDUFA date in August of this year. Dacomitinib received the same designation in April for EGFR-positive non-small cell lung cancer with a PDUFA date in September of this year with a potential to broaden our reach in areas of lung cancer where there is a great unmet need.

In I-O, we continue to progress our development program for Bavencio with our partner Merck KGaA, both in monotherapy and combinations with chemo and targeted Pfizer agents, including Inlyta in first-line advanced renal cell carcinoma and talazoparib in multiple tumor types.

In inflammation and immunology, we have built what we believe is a true leadership position with our JAK franchise. We recently started Phase III trials of our once-daily JAK1 in atopic dermatitis. We currently have 10 ongoing selective immunokinase programs.

In vaccines, the Phase III study for our potential C. diff vaccine where we have the potential to be first in class has been enrolling well. Leveraging the success of Prevnar, we're in Phase II with our next-generation pneumococcal vaccine candidate with the potential to cover 20 serotypes. We expect to see the proof of concept data later in the year and expect to begin Phase III in 2019. We also are currently in Phase II of our Staphylococcus aureus vaccine, and we are in discussions with the FDA regarding expanding the study to become a Phase III pivotal study.

In rare diseases, we recently announced a positive Phase III study readout for tafamidis for the treatment of TTR cardiomyopathy, and we expect the Phase III study readout for rivipansel in sickle cell later in the year.

In gene therapy, we recently dosed our first patient using our investigational mini-dystrophin gene therapy candidate for the treatment of Duchenne muscular dystrophy, and early data for this trial are expected in the first half of 2019.

And in internal medicine, we expect a Phase III readout for tanezumab in osteoarthritis later in the year. If positive, this could be the first and a new class of non-opioid treatment for this disease.

Through 2022, we see the potential for approximately 25 to 30 approvals, of which up to 15 have the potential to be blockbusters, subject to some expected attrition. This presents an unprecedented opportunity to have a life-changing impact on a growing number of patients while creating enhanced value for all our stakeholders.

In summary, we continue to deliver on our strategy and believe we remain well positioned to deliver new medicines to patients and increase value for our investors going forward. Most of our anchor brands are primed for continuous growth. Our pipeline is as deep and focused as it's ever been, our ownership culture remains a key differentiator for us and our strong balance sheet and disciplined approach to capital allocation will ensure we have the resources to invest in future growth opportunities.

Looking ahead, we expect a dramatic reduction of LOE impacts following the upcoming Lyrica LOE in the U.S. will unencumber the potential revenue growth of our key drivers, including expected realization of our pipeline and allow us to achieve an inflection point in our top line growth profile. Coupled with continued strong expense management, we expect this will enable us to continue to drive EPS growth at a rate that exceeds revenue growth.

Now I will turn it over to Frank to provide details on the quarter and our outlook for 2018.

Frank A. D'Amelio - *Pfizer Inc. - Executive VP of Business Operations & CFO*

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

First quarter 2018 revenues were approximately $12.9 billion, which include favorable impact of foreign exchange of $430 million, partially offset by an operational decline of $302 million. Our Innovative Health businesses recorded 3% operational revenue growth in the first quarter of 2018, driven primarily by Ibrance, Eliquis and Xeljanz, which was partially offset by the loss of exclusivity of Viagra in the U.S. in December of 2017 and Enbrel in most developed Europe markets due to continued biosimilar competition. It's important to note that Viagra revenues generated in the U.S. and Canada, which were previously recorded in the Innovative Health business, are now reported in our Essential Health business at the beginning of 2018.

Revenues for our Essential Health business in the first quarter decreased 9% operationally, primarily due to a 15% operational decline in the sterile injectables portfolio, primarily due to continued legacy Hospira product shortages in the U.S.; a 15% operational decrease from Peri-LOE Products, primarily due to the expected declines in Lyrica in developed Europe and Pristiq in the U.S., all of which were partially offset by the inclusion of Viagra revenues in the U.S., 12% operational growth in emerging markets and 53% operational growth in biosimilars, mainly driven by Inflectra in developed Europe as well as certain channels in the U.S. I want to point out that in emerging markets, Pfizer's overall Essential Health revenues grew 12% operationally.

First quarter reported diluted EPS was $0.59 compared with $0.51 in the year ago quarter, primarily due to a lower effective tax rate due to the enactment of the Tax Cuts and Jobs Act, or the TCJA, in late 2017 and higher other income due to increased income from collaborations, out-licensing arrangements and sale of product rights and unrealized net gains on equity securities, reflecting the adoption of a new accounting standard first quarter of 2018, which were partially offset by lower revenues primarily in our Essential Health business.

First quarter reported diluted EPS was also favorably impacted by fewer shares outstanding. Adjusted diluted EPS for the first quarter was $0.77 versus $0.69 in the year ago quarter. The increase was primarily due to the previously mentioned factors. I want to point out that diluted weighted average shares outstanding declined by 35 million shares versus the year ago quarter due primarily to our share repurchase program, reflecting the impact of our $5 billion accelerated share repurchase agreement executed in February of 2017 and completed in May of 2017, to a lesser extent by shares that were repurchased during first quarter 2018, partially offset by dilution related to share-based employee compensation programs.

As I previously mentioned, foreign exchange positively impacted first quarter 2018 revenues by approximately $430 million and negatively impacted adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses in the aggregate by $349 million. As a result, foreign exchange favorably impacted first quarter 2018 adjusted diluted EPS by approximately $0.01 versus the year ago quarter.

As you can see, we reaffirmed all components of our full year 2018 financial guidance.

Moving on to key takeaways. We delivered solid financial results in the first quarter of 2018 with a 12% increase in adjusted diluted EPS versus the prior year quarter. We reaffirmed all components of our 2018 financial guidance. We accomplished several key product and pipeline milestones, and we returned $8.1 billion to shareholders in the first quarter of 2018 through dividends and share repurchases. Finally, we remain committed to delivering attractive shareholder returns in 2018 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) Your first question comes from Jami Rubin from Goldman Sachs.

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

Ian, this is for you as well as Frank. You've talked about an inflection point and growth post the Lyrica LOE, I think, starting after 2019. While I'm not asking you for specific guidance, can you give us a sense for the magnitude of that change? Are you talking about sales going from sort of flattish where it had been for quite some time to sort of mid-single-digit growth and earnings which have been sort of mid-single-digit growth to where can that go? And Frank, assuming you don't do a large transaction, can you still drive bottom line leverage? Ian mentioned that you can, but your margins are already 40%. Can they get to 45% without a large deal? And then just lastly, to you, Ian, every CEO before you has done a major transaction to accelerate revenue and earnings growth. Just curious because your messaging has shifted a lot on a quarter-by-quarter basis. What would your legacy be before you retire? I mean, at one time, you had said you aspire to get back to the Innovative core, and other times you've talked about wanting to do a large transaction. So just was wondering if you can kind of share with us what you expect your legacy to be.

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

Thank you for that. Let me, first of all, address the exciting growth question, and then I'll come back to the more mundane facts of legacy. We continue to believe that the combination of our late-stage pipeline, as you mentioned, the significant tapering of LOEs post the impact of Lyrica, plus the growth drivers of our pipeline will give us a substantial inflection point, I believe, moving our growth rates and revenue to mid to high-single digits, and obviously, our revenue being at least equal to that. If you look at our Innovative Health growth drivers today, we have Ibrance, Xtandi, Xeljanz, Eliquis. And we're participating -- those products that continue to perform well, they have significant patent lives and they have significant extension of data readouts coming on those products. Our Essential Health business, we'll expect to be growing at that period, having passed through major impacts of the LOEs. We have our emerging market business. We have our biosimilars business. And plus, we have our sterile injectables business, which we think will put past us any of the issues of manufacturing from the Hospira plants. So all in all, I'm really looking forward to the growth rates that we will produce. And if you look over the 4 years, we have projected the potential for approximately 20 to 30 approvals, of which 15 have the potential to be blockbusters. I mean, we put out a list of those products. I mean, I don't want to extend the answer too far, but it is an exciting list. We have, in vaccines, Clostridium difficile, we have staph aureus, we have pneumococcal next gen. In rare diseases, we have products in Duchenne's, we have rivipansel, we have tafamidis and tanezumab in pain. I probably think tafamidis was the most risky of those alternatives, and we are extremely pleased with the data from tafamidis. Inflammation, we have JAK1, atopic dermatitis; JAK3; TYK2/JAK1; Xeljanz in psoriatic arthritis and ulcerative colitis. I think we have about 10 potential therapies in our JAK kinase franchise. So I mean, really exciting stuff. In oncology, we continue to look at targeted cancer agents, Ibrance, intermediate, high-risk breast cancer; Xtandi in nonmetastatic. We've

got PROSPER, EMBARK and ARCHER. So I think that is what will drive a really robust top line growth. Now turning to this issue of legacy. I don't really think a lot about that. I think deals are done on -- based on value to shareholders. As you say, we've looked at different strategies over the years. Our decision-making changes when the facts change. Right now, I think -- I would like to think that the legacy that when I do retire that I will leave to patients and to Pfizer is that of an extremely robust pipeline that's beginning to deliver and a really strong culture of ownership and doing the right thing for patients. With that, I'll hand it over to Frank.

Frank A. D'Amelio - *Pfizer Inc. - Executive VP of Business Operations & CFO*

And Jami, on operating leverage, let me just run some numbers for this year and then I'll answer the question. So if you look at the midpoint of our revenue guidance for this year, if you look at the midpoint of our EPS guidance, compare that to last year, revenues up 4%, EPS -- adjusted EPS is up 11%, so clearly the ability to continue to demonstrate operating leverage in terms of revenue in the top line to the bottom line. Going forward, I would leave our margins relatively where they are. If you look at our gross margin, look at operating margin, they're very strong, top quartile in the industry. I think for modeling purposes, we'd leave them where they are.

Operator

Your next question comes from Tim Anderson from Bernstein.

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

If I could just go back to the pipeline and your level of excitement. You guys have a long list of products and it's almost a laundry list. Some of those invariably will be smaller commercial opportunities, like PARP, maybe dacomitinib, maybe the new ALK inhibitor. I'm hoping you can narrow the discussion down to maybe 2 or 3 of those products that you think will be the most commercially significant drivers of future growth as you look forward over the next, call it, 5 years. And second question, kind of bringing up this old topic of splitting up the company. You talked about robustness in the business and how both divisions, Innovative and Essential, are increasingly in better shape. I know some companies have further digested the tax reform rules that came out before, and they've had a different view of what that means for them going forward. So my question to you on this is, is there any possibility of reconsidering splitting up the company over the next few years?

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

Tim, thank you for the question. I don't think it's a laundry list. I think all of those products we mentioned either individually or group, like the targeted oncology therapies, have potentials to be blockbusters. It's difficult to pick out one specific product. But I would say when you look at the totality, I would focus on our vaccine franchise, especially C. difficile. I would look at the huge potential of tafamidis. I would look at tanezumab in pain. And then frankly, I think the inflammation and immunology franchise taken as a whole is probably the best in the industry, and we could get into all of the different indications and products there. But if you look at the depth and strength of our science in that area, I'm really excited about our ability to drive meaningful growth from that franchise. Vis-à-vis the tax law and the split potential, I'll ask Frank to make a few comments on that.

Frank A. D'Amelio - *Pfizer Inc. - Executive VP of Business Operations & CFO*

Yes. So on the tax law, obviously, we've had more time to digest and analyze the new tax laws, tax reform. We're even more comfortable with the guidance we provided for the year, which is approximately 17% on the tax rate. On the split, what we've said previously on optionality is that we were taking it off the table for the foreseeable future. So from our perspective, no change. We never say never to anything. But right now, for the foreseeable future, we're all about executing on the business.

Operator

Your next question comes from Geoff Meacham from Barclays.

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

I just have a few. Ian, with the recent win for tafamidis and the technology deals in the space, I just wanted to see if rare disease is elevated at all on your strategic priority list? It's a good category, but Pfizer would have to add scale to have it really move the needle. And then just on the products side, just wondering if you guys have an update on the progress of Xtandi moving upstream to the M0 population. I know that was a big part of the original value proposition with the Medivation deal. I just wanted to check on the progress thus far.

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

Well, thank you. I think we have critical mass in rare diseases. We've committed capital to that. We've committed capital to production. We have not only 2 possibilities in Duchenne's. We have sickle cell. We have tafamidis. We have tanezumab. We have gene therapy. I'm confident that we have the critical mass. And if assets become available that could be added to that as a bolt-on that add significant value, we would act on that. But once again, we've always been, I think, very disciplined in our allocation, and we haven't seen those opportunities as yet. I would ask Albert to talk about Xtandi and its movement into the early population.

Albert Bourla - *Pfizer Inc. - COO & Director*

Absolutely. And also just to add in the rare disease that it is a multibillion-dollar business right now. We have 4 assets that they are in Phase III. We are expecting readouts as we speak. Cardiomyopathy, it is the one that Ian spoke, but we have also rivipansel and we have a gene therapy platform that we have already in clinic 3 different modality, hemophilia A, hemophilia B, and Duchenne muscle dystrophy all in rare disease. Now let me speak about Xtandi and your question about earlier treatments. And I do believe -- we do believe that moving Xtandi into earlier treatment settings represents a potential significant opportunity. In the short term, we are focused on with the nonmetastatic castrate-resistant prostate cancer indication, which is based on the positive results and filing acceptance that we got over the PROSPER study. As you know, we have priority review for that. We have a PDUFA date in July. And hopefully, we will see this medicine brought to patients in the near term. Now in the medium term, we believe growth will potentially come from expanding the Xtandi indication into hormone-sensitive prostate cancer. We have the EMBARK trial, but it is not in nonmetastatic hormone sensitive. And we have the ARTIST trial, which is in metastatic hormone sensitive. So both studies are progressing very, very nicely. They are definitely on their time line, and we are very optimistic about their success.

Operator

The next question comes from Gregg Gilbert from Deutsche Bank.

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

First, Ian, on consumer. If timing is not right for whatever set of circumstances, you can't get a fair price for consumer in the near term, how interested are you in doing something external to Pfizer like a spin or a JV as opposed to retaining and likely needing to invest in it? And then perhaps, Albert, you can talk about the competitive threat to the Prevnar franchise that you see from Merck. When could you get your next-gen Prevnar to market versus Merck's? And what's next on the legal front?

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

Thank you, Gregg. On the consumer business, it's a good asset. We said we were looking at strategic alternatives to see if there's a better owner. As I've commented, we don't, at this moment, see value in the sale. We'll focus on running the business. We had a very good quarter. I'm very

pleased with the way our consumer colleagues have reacted and are working hard. We'll look during the year at potential spins or joint ventures. But frankly, the business is a good business. And if we can't get value, we'll retain it, we'll invest in it. And it continues to be important to us in that sense. Albert?

Albert Bourla - *Pfizer Inc. - COO & Director*

Thank you, Gregg. From what we know, Merck's pediatric program for a 50-valent pneumococcal vaccine in Phase II, and the adult program is awaiting start of Phase III. This is what they have said, so far, Merck officials. So let me talk to you about our program. We have entered the clinic with a next-generation 20-valent pneumococcal vaccine. And this is expected to include 7 additional serotypes, in addition to those covered by Prevnar 13. All 7 significantly improve the coverage in the current situations. Our result for Phase I trial demonstrated that the vaccine was safe, it's well tolerable, but more importantly, demonstrated that induced functional immune responses that could kill all 20 serotypes. So these results supported advancement into Phase II that was initiated last year. And right now, it is fully enrolled. So if everything goes as planned, we could start our Phase III trials in '19. All in all, assuming regulatory success for both vaccines and not accounting for patent protection issues that we mentioned, we would anticipate launching in a competitive time frame to Merck a much broader spectrum of coverage product.

Operator

Your next question comes from Umer Raffat from Evercore.

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

I had 2 on R&D and 1 for Ian. Maybe starting out on R&D. On Bavencio, so it's my understanding that the half-life is materially less than the competitor PD-1. So it's about 3 days for Bavencio. It's about 14 to 21 days for competitor's. However, the dosing frequency of Bavencio is comparable to Opdivo. So my question is just wanted to understand the thought process behind that dosing frequency given the half-life difference as well as whether you think that's played any role on efficacy in some of the trials we've seen lately. Secondly, on tafamidis, congrats on the data. And my question is, how do you see the competitive landscape versus Alnylam's patisiran, especially in light of the recent post hoc analysis that Alnylam showed on cardiac outcomes and about a 45% reductions that they were seeing on a post hoc basis? And then finally, Ian, there's been some investor commentary lately on whether your recent comments on not looking for transformative M&A is mainly aimed at controlling the price of the potential target so that it meets the valuation threshold when you do actually potentially revisit it in 3 to 6 months. How do you react to that?

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

Let me deal with that last question first. We continually look at all deals, as I've said. We look for value for shareholders. I don't think we're that smart enough to be gaming anything to that extent. Frankly, we don't -- I don't see that we need a transformative deal nor do I see one at appropriate values right now in the marketplace. We'll continue to use our capital wisely. I believe at this moment in time -- although things can always change, marketplaces can change, I believe the best investment we have now is in our own pipeline. So with that, I'll turn it over to Mikael to answer the half-life question and then probably take the tafamidis question as well as it's still in research phase.

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

Thank you for that. Yes, we did, together with our partner, Merck KGaA, substantial pharmacokinetic and pharmacodynamic studies and the current dose, 10 mg/kg intravenously every 2 weeks will -- should cover the PD-L1 target for blocking that receptor. You may have noted that we are -- also have an aspect that the antibody has ADCC, which could be a unique property. And we have one study that tried to address whether it can be a positive differentiated property with an even more intense dosing regimen. Concerning tafamidis, we are, as Ian alluded to, extremely enthusiastic to share the positive results that was in cardiomyopathy population. And as you know, the endpoint was all-cause mortality and cardiovascular hospitalization. The study includes wild-type TTR and mutant TTR. For cardiomyopathy, it is to a major extent, the wild type; and to a minor extent, patients having the mutant. So this is quite different from the other biotech companies using injectable that primarily were focused

on polyneuropathy. Some of those polyneuropathy patients that have the mutant form may also have later in life cardiac symptoms. To the best of my knowledge, those were measured with more functional data and there were no hard endpoint related to cardiovascular hospitalization or even more, of course, mortality data related to cardiac patients. And finally, to the best of my knowledge, there are no pivotal studies on wild-type patients outside of tafamidis, which is, again, the major patients in the United States and the Western world suffering from this difficult fatal disease. So we believe we are, to the best of our knowledge, years ahead of anyone else to have such interesting dataset. And we also believe it's a disease that is not well diagnosed and has substantial potential.

Operator

Your next question comes from Jason Gerberry with Bank of America.

Jason Matthew Gerberry - *BofA Merrill Lynch, Research Division - MD in US Equity Research*

Just a quick question on Ibrance.

As the share of growth shifts in the near- to medium-term to the ex U.S. markets, just wondering if you can kind of talk us through the progression in those markets of sales uptick given that you now have reimbursement in EU established and Japan is coming online. So can you talk us through the progression there? Do you think that ex U.S. markets can ultimately one day be as big as the U.S.? And then just secondly, just on EUCRISA. I understand there's still maybe a fair amount of free product in the channel, so difficult to really gauge the product at this point, but could you provide a little bit of direction or commentary just around when we could start to see a bigger uptick in revenue-generating scripts?

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

Thank you, Jason. I'll ask Albert to answer both of those good questions.

Albert Bourla - *Pfizer Inc. - COO & Director*

Yes. Thank you, Jason, and I'm sure you've noticed, we are very, very pleased with the progression of Ibrance in the international markets. We have very strong growth. It was in the excess of 170%. Growth of sales almost tripled. Volume has been higher than that. As of December, Ibrance made up 98% of the total plus packs sold in the EU 5 and also we did progress a lot with reimbursement. Right now, Ibrance is reimbursed in all of EU 5 finally and in Japan, as you mentioned. And in total, we have 25 markets that Ibrance is reimbursed right now outside of the U.S. So we expect to have significant progress and growth acceleration in that part of the world. Coming back to your question on the U.S., I think, first of all, let me make some comments on the U.S. and then I will compare it with the European markets, the ex U.S. side of the market. But in the U.S., we have seen everything that we predicted, CDK class there in the first-line new starts, continues to steadily grow as we had predicted. It is now 69% from 58% at the end of last quarter. And Ibrance continues to hold the leadership position in first-line, again, as we also had predicted. It grew up -- the markets are this quarter from 56% -- to 56% from 52%. In fact, the scripts grew much faster than the sales in the U.S. We had 26% growth of scripts. We had 19% of growth of sales and mainly, the gap is attributable to fluctuation of buying patterns. I think, it's going to be back to normal situation in the months ahead. And also, I want you to remember that the growth opportunities in the U.S. have not been exhausted by any means. Right now in the U.S., while the CDK market of first-line new patients is 69% for the CDK. If you see across all lines of treatment, it is only 53%. So we believe that there is significant opportunity to grow the class. And of course, Ibrance has now more than 90% of the class served right now. The size of the 2, I think that when it comes to utilization, penetration and volume of patients, yes, the European markets will do as well, if not better than the U.S. market. Of course, there is very different price points that needs to be factored when we try to assess the total market. Now a few comments on EUCRISA. The prescriptions were 90,000 this quarter and the 94,000 and that was the growth compared to previous quarter of 6%. However, it was slower growth than we had in the fourth quarter, but we had all times peak of growth. We have 55% growth in the fourth quarter of last year. And this slowdown in growth is attributable to the year beginning effort in which churn in the insurance market suppresses branded prescription demand as patients adjust to changes in their insurance plans. This has been reported by other companies as well and to give you a magnitude, we grew 6%, while the total atopic dermatitis there was flat. Right now, we are focusing our efforts in EUCRISA in 2 areas. One, to make

sure that -- to broaden trial and adoption rates. A lot of dermatologists are [in trance] to use steroids right now and also to improve access and we have plans in place to do both.

Operator

Our next question comes from Andrew Baum from Citi.

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

Couple of questions, please. Firstly, Ian and Frank, on capital allocation. Given that you've collected observations on some of your competitors' premium biotech acquisition together with your comments, Ian, about the pipeline strength, and it's underappreciation perhaps. Should we expect further additional buybacks on top of what you've already committed to this year? Second, on U.S. biosimilars, and this leads into your product business, do you expect the significant increase in the adoption of biosimilars in the U.S., driven by insurers taking on board their biosimilars first, given the pressure from the FDA HHS as well as the vertical integration taking place? Then finally, for Mikael. Should we expect an interim for the PALLAS adjuvant trial for Ibrance in 2019?

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

Sure. On the biosimilars, Andrew, we continue to make progress in the U.S. with our own commercial efforts. But I believe that it will take an effort by the administration to move that market, given the substantial advantage the entrenched companies have with the rebating system. So I'm looking forward to some activity from the administration on that. But that being said, we continue to look for a good growth in that area and it will certainly accelerate post any action from administration. PALLAS, Mikael?

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

Yes, we expect the PALLAS trial for intermediate and high-risk early breast cancer in adjuvant treatment to run until the primary completion date, which is in 2020, to have a sufficient number of ends. We remain very encouraged about the translation for metastatic to early breast cancer and have very much confidence in the strength of Ibrance based on other neoadjuvant studies of the same type of tumor that has been positive.

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

Okay, so on the -- I would agree with you, Andrew, 100% that the pipeline is undervalued. I would ask Frank to make a quick comment on capital allocation.

Frank A. D'Amelio - *Pfizer Inc. - Executive VP of Business Operations & CFO*

Yes. So on capital allocation, Andrew, our priorities haven't changed. They remain dividends and share buybacks, investing in the business and M&A where it makes sense. Specific to buybacks to answer your question, in the first quarter, we did $6.1 billion in share buybacks at an average price of $36.23. And just in terms of little history, if you go back to 2010, we've repurchased $61.7 billion worth of our shares, 2.2 billion shares retired, an average price of $27.35. This has been a very good trade. In terms of going forward, which is really what you asked me, we announced that $4 billion accelerated share repurchase on March 12 of this year, it will take several months for that to complete and once that completes, we'll assess where we are and then we'll make a decision on whether or not to do anything further on buybacks.

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*

I just wanted to dig in a little bit deeper on the opportunity for Ibrance in early-stage breast cancer. First, could you please discuss the NSABP's Ibrance PALLET trial? I understand that it's small. It's a neoadjuvant and it's 14 weeks, but I was hoping that you could frame your expectations for that trial. And then Mikael, I know that you commented on Ibrance in the adjuvant setting in response to the prior question. So if you could just comment about both of those trials, both PALLAS and PENELOPE- B, and your level of confidence in success in late 2020.

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

Albert, all yours. No, sorry, we're going to need Mikael to answer it.

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

Yes. First of all, on the PALLET study, which we think it's run by a collaborative organization, academic, but we think it will read out relatively soon and be reported in the fall. I have high confidence that we will see a very robust signal based on previous similar studies, neoadjuvant, such as the study run by Washington University's Dr. Ma and Dr. Ellis, that showed a very profound complete cell cycle arrest and also quite impressive responses, complete responses in the neoadjuvant setting. And it's a very similar patient population to the PALLET study that you referred to. And to study the primary endpoint, they used the very same KI-67 proliferation marker. So I have a strong confidence in good outcome of PALLET based on previous science, and we think therefore, that we should have a very optimistic view on PENELOPE and PALLAS, event-driven adjuvant trials to hopefully, for the benefit of patients expand Ibrance into a population of all the breast cancer that may be twice as big as the metastatic population. So we look forward to see those studies conclude.

Operator

Your next question comes from Vamil Divan from Crédit Suisse.

Vamil Kishore Divan - *Crédit Suisse AG, Research Division - Senior Analyst*

Just a couple of questions. One on the Innovative side with Xeljanz, the product was a little bit less than what we had expected. I'm just wondering if there's been any impact seen on that product given some of the concerns around thromboembolic disorders with baricitinib as that went throughout the review process. And maybe if you can also just frame what you see as the opportunity for UC ahead of that action date next month? And then on biosimilar side, just a question on the biosimilar, Remicade. I just noted it did have a little bit of a decline sequentially from last quarter in developed Europe. And I assume it's due to competition, but just wondering if you can give a little more clarity on what exactly is driving that. And if it is competition, is it driven by Biogen Samsung? Or is it driven more by the fact that Celltrion has other distributors selling the product as well?

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

Thank you. Albert, if you could take both those questions.

Albert Bourla - *Pfizer Inc. - COO & Director*

Yes. Xeljanz revenues were up this quarter, 30% in the U.S. particularly, but you referred the growth was 19%. However, the scripts grew 33%. So there is a sizable gap between the scripts and the sales, and most of that is attributable as with EUCRISA in buying patterns as I said, also other companies reported. But effective this quarter already, we see that this is normalized in the next -- in the months after the quarter. So there is no slowdown on scripts as a regard of any concern and as we have repeatedly said that we do not think that there is any correlation with Xeljanz with

this type of side effects. Going to the UC, on -- it is, as you know, under registration. The opportunity -- it is large. In the G7 -- the market, it is approximately $5 billion, affects approximately 1.8 million of people. We are very encouraged by the efficacy and safety results of Xeljanz in the OPAL study for psoriatic arthritis, and the OCTAVE study for UC. We had very positive advisory committee. We have very positive interactions with regulators, and frankly, we expect that, that product will be approved in the near future. Now ourselves, I cannot comment on Remicade, but ourselves, we grew 53% globally and 39% versus last year, and we are very happy with how things are evolving in the international markets.

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

Thank you. Our research is in the U.S., where there's disproportionately smaller penetration than whatever is happening in the rest of the world because of some contracting practices.

Operator

Your next question comes from John Boris from SunTrust.

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

First one for both Ian and Mikael. If you look at your portfolio of assets and your pipeline, you certainly have the makings of a decent sized orphan disease platform, certainly your hemophilia franchise through your factor VIII, IX business along with your gene therapy programs with Spark, along with tafamidis and other assets seems as though that, that might be going forward, a very important strategic area. So Ian, just your thoughts around that and the buildout of that pipeline, also, Mikael. Second question for Frank, on other income, it was $250 million in the quarter, but you're guiding to only $400 million. That seems to be a little low, what are some of the pushes and pulls there? And then lastly, FDA has been pretty vocal on advancing new policies to try and stimulate more biosimilar development with about a dozen policies that incrementally could move the ball in the direction to try and create more biosimilar competition. What are some of the policies and procedures that you think could move the needle in favor of biosimilars going forward? And then just any commentary on your Herceptin complete response letter, and when you think you might resolve that.

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

Thank you. Mikael, why don't you talk a little bit about our orphan disease portfolio? I believe we're investing in it. I don't think there's any restrictions in our capital investment. If we see opportunities outside, we'll take them, but internally, we have a lot of (inaudible) to work with. Mikael?

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

Thank you. Basically, we are focused on hemophilia, neuromuscular disease and with some interest also in metabolic rare disease. Hemophilia, as you know, we have a long history and successful presence in the marketplace treating hemophilia A and B. We're very excited about our hemophilia B program that concluded successfully, based on gene therapy, successfully proof of concept and is progressing in partnership with Spark towards pivotal studies. We have a Hemophilia A partnered with Sangamo where we make progress in dose escalation. And we also have a Pfizer monoclonal antibody against TFPI for weekly subcutaneous convenient delivery for all types of hemophilia where we have seen some early encouraging sign. So we think it's a really interesting portfolio. On the neuromuscular disease side, Ian alluded to that we started gene therapy for Duchenne's and we also have a pivotal readout with a monoclonal antibody against myostatin in Duchenne's, which we look upon as high-risk, high-reward opportunity. And of course, within cardiomyopathy with tafamidis, we look very much forward to share the data and to swiftly advance the regulatory dialogues. And finally, end of the year, in sickle cell disease another component of our hematology opportunity in rare disease, we have also likely here at the end of the year, readout for rivipansel, and we look forward with encouragement based on that mechanism has played out well in Phase II. As Ian alluded to, we think we are well resourced with all modalities in gene therapy and end-to-end capability as well as non-gene therapy modalities and we will continue to do internal as well as licensing/bolt-on to accelerate.

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

Thank you. Other income [induction], Frank?

Frank A. D'Amelio - *Pfizer Inc. - Executive VP of Business Operations & CFO*

Yes. So John, other income for the quarter was actually about a $320 million, [good guide], income for the quarter, so the net relative to the $400 million for the year, really 3 major drivers there. One is we had some onetime milestone payments to the tune of about $115 million. We had $110 million in unrealized gains on equity securities and we don't try to project those, and those could turn one way or the other going forward. And then the third big ticket item is net interest expense. Interest income for the quarter, about $75 million, interest expense about $315 million, and net that out about $240 million per quarter and net interest expense going forward for the remainder of the year. When put that together, we think it's prudent to leave the other income at approximately $400 million.

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

Albert, biosimilars including Herceptin.

Albert Bourla - *Pfizer Inc. - COO & Director*

Yes, let me start, the first one was around the policy of biosimilars. Look, we are very encouraged by the words of FDA and other people in Trump's administration. We just wait now to translate these words into tangible actions that can reverse the situation. Keep in mind that biosimilars' penetration, let's take infliximab. In Europe, it's 56%. In the U.S., are 36%. So there is something wrong with that.

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

They're not in closed systems.

Albert Bourla - *Pfizer Inc. - COO & Director*

Actually, thank you for raising that. If you've seen closed systems, we have 66% in this quarter, half of our sales are coming in closed systems. Closed systems meaning when the provider is the same person with the person who could be the payer. And when it comes to value, we always win. And this is what we want to see that prevails. Now back to your question about trastuzumab. We did receive, unexpectedly actually, a complete response letter from the FDA. Basically, FDA was asking additional technical information clarification. We didn't think that's something like that would come to a complete response letter. I want to clarify that those questions were not related neither to safety, nor to clinical data submitted and they have nothing to do with pertaining to our manufacturing abilities. But nevertheless, at this time, we do not anticipate that the FDA action will have any impact on our plans to launch of trastuzumab. We think that we will be able to respond to these queries and get it approved before our projected launch date.

Operator

Your next question comes from Chris Schott from JPMorgan.

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

Just 2 here. Maybe first on the Essential Health business. Can you just give a little bit more color on the legacy Hospira shortages? I believe you said you're expecting the injectable business to be flat year-over-year, but your Q1 results are still showing some erosion. So could you just talk a little bit about how you see these issues resolving? How quickly do you think you can recapture share once you're back at normalized capacity? And the second question was on tafamidis. Can you just comment on the size of the cardiomyopathy patient population you're going to be pursuing? And do you believe the [ATTRACT] data suggest potential for this product in polyneuropathy? And if so, do you have to run additional studies there? Or can you refile in that setting?

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

Albert, why don't you handle those questions and ask Mikael to comment as you see fit?

Albert Bourla - *Pfizer Inc. - COO & Director*

Yes, thank you very much, Ian. Look, in PA, it's a general comment, as you know, we -- the business declined 9%, but if you see the legacy Pfizer, the decline was only 2% despite the loss of exclusivities. Most of the decline came from the Hospira, legacy, 38%, partly because of the divestment of the device business, but also because of supply issues that we [failed] with our sterile injectables. We do believe that the revenues from this portfolio roughly will be flat this year compared to last year. I think we will -- we had the decline this quarter and likely we'll see a decline next quarter as well, and then we will see growth in the third and fourth quarter. So overall, it will be roughly flat. We anticipated this situation and we have incorporated into the guidance that Frank provided beginning of the year. And we continue our very comprehensive remediation plans to upgrade and modernize these facilities in Hospira. We are in content -- in constant contact with the FDA and we have increased substantially our investments into these manufacturing sites. So we believe that, as I said, we will be flat and then next year, we will start providing much more capacity available than we -- that we do not have now. As regards to tafamidis, let me make a comment on the market opportunity and then I will ask Mikael to help into the more scientific question. The TTR cardiomyopathy, it is a rare progressive disease and it is a fatal disease. People that are diagnosed with this disease, they have a life expectancy of 3 to 7 years, unfortunately. It is almost like, unfortunately, a death sentence. The prevalence of the disease is currently unknown, but it is expected that less than 1% of the people are diagnosed in the U.S. And already, this number is several thousands. So we believe that by working towards improving awareness and diagnostic rates of this disease, we will be able to provide meaningful assistance to those people that they have virtually no options. Mikael?

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

Thank you. That was terrific background of the disease. So I can only build on what Albert said. It's -- data suggests the disease is vastly underdiagnosed and we have seen some recent external figures estimating that just in U.S., it may be more than 100,000 patients related to TTR cardiomyopathy. This is likely driven by the wild type, the senile systemic amyloidosis caused by the wild type as it increases dramatically has contributed to cardiomyopathy with growing age in an aging population. And now with increasing availability of diagnostic tools and, of course, availability of drugs potentially pending regulatory dialogues in a drug like tafamidis, there will be a large incentive to do more early diagnosis that will allow patients to be treated for longer time before they progress and have this dire prognosis that Albert alluded to. There is also the mutant form that can be diagnosed very easily earlier in life, but we do think there are opportunities to also diagnose wild type in a more efficient manner. So that's why we're excited about this, having this large data set on wild-type TTR cardiomyopathy, and we look forward to the dialogue with regulators and potentially, how to contribute to early diagnosis awareness of the disease to help patients.

Albert Bourla - *Pfizer Inc. - COO & Director*

And the population of our study, Mikael, included both types, right? Wild types and...

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

It does. Of course, initially, in a patient group accessible will be mainly with academic medical centers, which is a fraction of the number I shared, but as awareness grows, the disease will be likely diagnosed at many cardiology clinics.

Operator

Your next question comes from Steve Scala from Cowen.

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

Ibrance Q1 EU sales were flat with that in Q3 of '17. Given the negative sales in Q4, I would've expected a nice recovery. So can you speak to that specifically? And is price the explanation for this disparity? Second, what were Ibrance and Xeljanz stocking numbers in Q1? And then lastly, on tafamidis, sorry to ask again, but just to clarify prior answers. Based on the data you have and the data you'll present this year, can you get a broad label for patients with predominantly neurological manifestation and a broad label covering a range of disease severities? It sounds like the answer is yes on both, but please just confirm.

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

Mikael, could you give a brief comment on the potential avenues for diagnoses and the labeling?

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

We certainly believe on the comprehensive data that we have an opportunity to discuss a broad label for cardiomyopathy. Concerning neuropathy, we do have earlier trials, smaller in nature, but it was sufficient for registration in Europe and we do have registered data of many patients in Europe that are doing very well on tafamidis. And we will look at opportunity in dialogues with various divisions at FDA for an opportunity that would cover multiple patient population, as you alluded to.

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

On the Ibrance question, the -- when you're in a phase of looking for listings in Europe, it's very difficult to get a read on the total value of the product. As very often, you sell under emergency protocols at a price that is not necessarily relevant to the final price you get or to the U.S. price, for that matter. So we see very robust uptake with physicians of Ibrance and we see an impact, of course, on the revenue as we adjust to the reimbursement levels of Ibrance that will give us sustained and a growing opportunity for substantial patient number increase in Europe. So I think this is part of what we do and when we negotiate for access and we feel we have a very strong strategy around access and future growth in Europe. Albert, do you want to add anything to the questions.

Albert Bourla - *Pfizer Inc. - COO & Director*

For Euro, I think you said it very well, and we think that the prices that we got represent good value, and they are in line with what usually products are priced in Europe.

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

And the inventory levels of the movement -- it's very difficult for us to measure that because it's very -- it's -- lot of it's specialty and we don't have a very strong control of whereas in with the distributors in general, we know very well what inventory levels are. So by deduction, we know that

the scripts were up. We know where the revenue was. We know that we don't believe it's a net pricing effect so by difference, it has to be inventory movements.

Albert Bourla - *Pfizer Inc. - COO & Director*

And just to add that our calculations reveal that most of the gap, it is because of inventory [complications].

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

Yes.

Operator

Your next question comes from Alex Arfaei from BMO.

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

First on Xeljanz. Roughly what proportion of Xeljanz in the U.S. is coming from TNF-naive patients as opposed to the TNF-experienced? And a follow-up on biosimilars. It appears that the Europeans are becoming more aggressive in their adoption of biosimilars, wondering if I could get your thoughts there. And could you comment on the implications of that both as a headwind for Xeljanz and a tailwind for your biosimilars pipeline? Specifically, would you be able to provide some expected launch time frames for some of the key biosimilars products in Europe?

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

Albert, would you like to address this question?

Albert Bourla - *Pfizer Inc. - COO & Director*

Yes. On the Xeljanz questions, we estimate that more than 50% of our patients come from naive patients and...

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

And the other question, I think, the Xeljanz opportunities in Europe are just beginning. It's in the actual usage of the product, it's not the majority is naive to TNFs because the growth of the marketplace itself is slow. So it has to be people who have converted over from TNF to using Xeljanz. The important thing with Xeljanz is that it's a lot of usage in monotherapy, which we think allows us to distinguish ourselves from the TNFs as they go off patent. So I see a very aggressive growth rate for Xeljanz in Europe and a very aggressive growth rate for our biosimilars as well.

Operator

Your next question comes from Tony Butler Guggenheim Partners.

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

Two brief questions. Mikael, given the outcome of the JAVELIN lung study, what's the position that you feel Pfizer will be in relative to lung as a histology for Bavencio or any other combination and/or combinations moving forward? And then second to that, does that actually change or

does the outcome actually change your strategy or the focus from one of identifying patients who may respond to a particular monotherapy, IO monotherapy or simply combinations for everybody? Is that strategy -- is there a difference that may occur perhaps as a result of JAVELIN lung?

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

Mikael, and if Albert may want to add anything on the strategy, on commercial strategy.

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

Yes. We've always been focusing on combinations as the way to go over the longer term and over the next 18 months, we have 6 pivotal readouts plus 5 tumor types, of which 5 of them are combinations and only 1 is monotherapy, the first-line lung, including first- and second-line ovarian with chemo, renal with Inlyta as a targeted therapy, gastric with Bavencio as maintenance after chemo, bladder with Bavencio maintenance after chemo. And the first-line lung was designed very differently from the second-line. It contains hierarchical readout for high PD-L1 and intermediate PD-L1 and combined endpoint for PFS and overall survival. So I think we will be able to mitigate any impact of crossover from control group to other marketed PD agent that we recorded in the second-line earlier. So we feel pretty good about this cohort of readouts in the next 18 months and of course, many early clinical studies that are not pivotal, but will generate a good combination data.

Operator

Your final question comes from Marc Goodman from UBS.

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

Just a continuation on the IO, I was curious, your thoughts, Mikael, about TMB as a biomarker. How much development work you think should be put into that? And then just on Prevnar, just in the U.S., I know [U.S.] if you can give us a little color on what's going on, and how you think about the growth there?

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

Concerning TMB, we think it's interesting to explore additional biomarkers beyond PD-L1. To the best of my knowledge, I think PD-L1 is the biomarker right now that has solid data concerning both PFS and overall survival while TMB is, at this stage, mainly reported PFS data and far less OS data. So I think we need more time to understand how TMB will fit into it, but obviously, we think it's the way to go to have numerous ways to analyze high responders, but our strategy, as I said previously, will be to utilize those information pieces with drug combinations.

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

Albert?

Albert Bourla - *Pfizer Inc. - COO & Director*

Yes, on the Prevnar, first of all to say that the overall sales were slightly declined, 3% and as you mentioned, U.S. was the main driver of the decline with 12%, but I want also to emphasize a significant growth in emerging markets. We had 45% growth and this is due to multiple factors, but the most important is we just launched in China where we expect that we will have very good uptake. Now the specific information that you asked for the U.S. In the U.S., we had 12% decline and this is a combination of both, adult and pediatric. Pediatric actually declined 14%, but that was purely [CDC] patterns. This is common CDC when you have big governmental purchases, they can happen one month or the other and that can affect

your growth. So we think that the pediatric U.S. will grow eventually for the year. And the U.S. adult declined 7%. Actually, I think it is rather positive with the fact that now we are slowing down the decline as we are coming more to a steady state of the adult penetrations.

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

Thank you, Albert, and thank you, everybody, for your attention this morning.

Operator

Ladies and gentlemen, this concludes Pfizer's First Quarter 2018 Earnings Conference Call. Thank you for your participation. You may now disconnect.
