Q3 2017 Earnings Call

Company Participants

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

Other Participants

- Alex Arfaei, Analyst
- Andrew S. Baum, Analyst
- Christopher Schott, Analyst
- David Maris, Analyst
- David R. Risinger, Analyst
- Geoffrey Meacham, Analyst
- Gregg Gilbert, Analyst
- Jami Rubin, Analyst
- Jeffrey Holford, Analyst
- John T. Boris, Analyst
- Marc Goodman, Analyst
- Olivia Brayer, Equity Research Associate
- Richard J. Purkiss, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Tim Anderson, Analyst
- Umer Raffat, Analyst
- Vamil K. Divan, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good day, everyone, and welcome to Pfizer's third quarter 2017 earnings conference call. Today's call is being recorded.

At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

Charles E. Triano {BIO 3844941 <GO>}

Good morning and thank you for joining us today to review Pfizer's third 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 web site, pfizer.com/investors. Before we start, I'd like to remind you that our discussions 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 l1ooking statement.

Official 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 2016 annual report on Form 10-K, including in part one, item 1A. And that is filed with the SEC and available at sec.gov and at our web site at pfizer.com

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 those statements.

Discussions during the call will also include certain financial measures that were not prepared in accordance with U.S. generally accepted accounting principles. Reconciliation of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's current report on Form 8-K, dated today, October 31, 2017. You may obtain a copy of the Form 8-K on our web site at 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. They 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 {BIO 3358997 <GO>}

Thank you, Chuck, and good morning, everyone. During my remarks today, I will briefly talk about the progress and opportunities within each of our businesses, our recent announcement regarding our Consumer Healthcare business, and some of the promising assets in our pipeline, which we believe have the potential to become a foundation for our future growth prospects.

Starting with the quarter. We again reported solid operational revenue growth. If you exclude the impact of the Hospira Infusion Systems divestiture and the unfavorable impact of foreign exchange, revenues for the quarter increased 4% operationally compared to the prior year quarter. We also raised the midpoint of our adjusted diluted EPS guidance for the year.

I'll begin with a few words regarding the performance of each of our businesses, starting with Pfizer's Innovative Health. This business had another strong quarter, growing its top line 11% operationally. This increase was driven by continued growth of key brands, including Ibrance and Eliquis globally and Xtandi, Lyrica, Xeljanz and Chantix in the U.S.

Ibrance had another strong quarter with revenues up 59% on an operational basis compared with the same quarter last year. We remain confident in its continued growth potential and leadership, despite there now being two other approved CDK 4/6 inhibitors.

Ibrance share is now nearly 50% for first time, new patient starts in advanced breast cancer. And prescription volume continues to grow. As of the end of September, Ibrance has been prescribed by more than 11,000 physicians to 70,000 patients in the U.S. and more than 18,000 patients in the EU, and received regulatory approval in more than 70 countries, including Japan.

With Xtandi, we continue to see growth in prescription volume. Although Xtandi's revenue growth is not yet tracking in line with prescription growth, due to patient assistance free drug program utilization as a proportion of total demand, we are pleased to report that we have now recorded sequential revenue growth for two consecutive quarters.

I would also note that the patient assistance program proportion of total demand was comparable with that seen in the first and second quarters. And we continue to expect that the program's utilization will normalize as we move into next year. Of note, the number of urologists actively prescribing Xtandi again reached an all-time high this quarter, and these increases remain one of the key factors supporting Xtandi's continued growth.

In June we announced the readout of the Xtandi's Phase 3 PROSPER trial in non-metastatic castration-resistant prostate cancer has been accelerated by two years. We are pleased the trial met its primary endpoint of improved metastatic-free survival. And we have said previously we see these positive results as key value drivers that support our acquisition thesis for Medivation. And we are working with our partner, Astellas, on worldwide submission plans based on the PROSPER data to seek expansion of the label to non-metastatic CRPC.

We continue to hit all-time highs in terms of new rheumatology prescriptions for Xeljanz. We received a record 9.8% of weekly new prescription share for the month of September for our current indication of rheumatoid arthritis. And with the weekly high reaching 10% so far in October, Xeljanz continues to be the fastest-growing advanced RA therapy.

We see the potential for two additional and meaningful growth opportunities for Xeljanz with our two pending regulatory submissions for other conditions. For psoriatic arthritis, Xeljanz received an overwhelmingly positive vote in favor of approval at the FDA advisory committee meeting in August. We anticipate a final decision by the FDA before the end of the year. Xeljanz has also been accepted for review by the FDA for ulcerative colitis, with a PDUFA date in March. We've completed filings for both pending indications in multiple other countries.

For Eucrisa, we've seen steady progress. Approximately 83,000 patients started treatment with Eucrisa by the end of the third quarter. More than 23,000 prescribers have provided Eucrisa to patients across the dermatological, pediatric, and primary care communities. And more than 60% of those prescribers are repeat prescribers. Prescription volume and share velocity continue to strengthen through the third quarter, supported by the successful launch of our DTC campaign.

Turning now to Pfizer Essential Health, while revenues for the quarter declined, we once again saw strong operational growth both in emerging markets and in our biosimilars portfolio. We also continue to see the value of biosimilars in expanding patient access for important high-quality, low-cost treatment options.

Our biosimilars business continues to grow, with global revenue increasing 67% operationally in the quarter.

In September we presented two positive Phase 3 readouts for our first oncology biosimilar, trastuzumab, which is a proposed biosimilar to Herceptin. The readouts were presented at the European Society for Medical Oncology 2017 Congress. Both the FDA and EMEA have accepted our filings for this potential therapy.

As of the end of September, Inflectra in the U.S. has grown, albeit slowly, to a 4.9% share of the overall U.S. infliximab market by volume. We continue to have 100% Medicare coverage as well as strong coverage in Medicaid. And in situations where the insurer and provider are the same, such as the VA, we have seen rapid uptake of Inflectra, with share in these situations reaching 54%, up from 20% in quarter two.

That said, Inflectra penetration in the U.S. continues to be slower than expected due to the exclusionary contracting of Remicade by J&J, contracting that we believe violates the antitrust laws. As you know, we recently filed suit in the U.S. District Court against J&J. We did this to help ensure the true value of biosimilars can be unlocked for the benefit of patients, providers, and our nation's healthcare system. We are actively working on a range of strategies to help Inflectra accessibly to more patients and also to lay the groundwork for a smoother, more rapid uptake of all future biosimilars in the U.S. marketplace.

Additionally, just yesterday, along with our partner, Celltrion, we presented new data showing that switching patients with Crohn's disease to Inflectra from Remicade leads to a comparable efficacy, safety, and tolerability to treatment with Remicade. That's adding to the totality of evidence supporting switch to Inflectra.

Within our Essential Health portfolio, we have been experiencing supply shortages with some products. The shortages are primarily for products from the legacy Hospira portfolio and are largely driven by capacity constraints and technical issues.

When we acquired Hospira, we originally thought it would take one to two years to integrate the manufacturing plants and resolve the majority of the supply chain issues. We have a robust action plan in place, and we believe we will make substantial progress in 2018 towards reducing the sterile injectable shortages.

As we look ahead, in addition to continuing to expect revenue growth from our patent protected portfolio, we are very encouraged by the convergence of two positive trends, the decline in the number and revenue impact of LOEs facing our business and the further strengthening of our R&D pipeline and its potential to drive incremental revenue.

We expect the full-year year-over-year impact of LOEs to continue to be significantly lower than our recent past. We're forecasting the impact to be approximately $2 billion in each of the next three years, about $1 billion in 2021, and then $500 million or less from 2022 through 2025. At the same time, we expect a steady flow of new products to begin to emerge from our pipeline. Here are a few of our most recent advances.

The development plan for ertugliflozin for Type 2 diabetes remains on track, and we expect the decision from the FDA in December.

In oncology, our PARP inhibitor, talazoparib, top line results from the Phase 3 EMBRACA trial will read out by the end of the year. The EMBRACA trial is exploring talazoparib versus standard-of-care chemotherapy in germline BRCA-positive metastatic breast cancer.

In partnership with Merck KGaA, we expect data on Bavencio, our PD-L1 inhibitor, in combination with our 4-1BB agent later this year. The study is looking at patients who have not been previously treated with an immune checkpoint inhibitor. These data could be ready for potential presentation during 2018. We also anticipate data from our triplet combination with Bavencio, our 4-1BB agent, and our OX40 monoclonal antibody in late 2018. This study is recruiting on track.

Also, by the end of the year, we plan to submit an application with the FDA for lorlatinib, our next-generation ALK inhibitor for the treatment of ALK-positive metastatic non-small-cell lung cancer. On October 16, we presented full results of the lorlatinib Phase 2 data that will form the basis of our discussions with the agency.

In Inflammation & Immunology, we recently presented positive Phase 2 data for our once-daily oral JAK-1 inhibitor in atopic dermatitis, and we are planning to move this compound into Phase 3 studies shortly.

In Vaccines, we started Phase 2 trials for our next-gen 20-valent pneumococcal vaccine and have received fast track designation for it from the FDA.

These pipeline advances represent just a few of the assets that we expect to form the foundation for offsetting our remaining LOEs. We believe the combination of our strengthening pipeline and the anticipated continuing easing of LOE impact has the potential to support a nice inflection for our future revenue growth rates.

I'll close my remarks with a few comments regarding our Consumer Health business. Earlier this month, we announced that we were reviewing strategic options for this business. This could include everything from a full or partial separation of the business to ultimately deciding to retain the business.

We are taking this action as part of our regular ongoing reviews of our portfolio, pipeline, and business strategy. Although there was a strong connection between our Consumer Healthcare business and elements of our core biopharmaceutical portfolio, it is also distinct enough from our core business that there's a potential for its value to be more fully realized outside the company. We anticipate there will be broad interest from potential acquirers. And we expect to make a decision in 2018.

In summary, we continue to execute on our strategy. The fundamentals of our business are strong, and we have several key brands that we believe are positioned for continued growth. The unfavorable impact of LOEs remains lower than in previous years, and we expect it to drop off even further in the coming years.

And our innovative core is as strong and vibrant as it's ever been, which is positioning us well in the areas of greatest patient need and where science is evolving.

Now I'll turn it over to Frank, who will go into greater detail on the results for the quarter.

Frank A. D'Amelio

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

Now moving onto the financials. Third quarter 2017 revenues were approximately $13.2 billion and reflect year-over-year operational growth of $178 million. Third quarter 2017 revenues were also slightly offset by the unfavorable impact of foreign exchange of $54 million. If you exclude both the revenues of Hospira Infusion Systems, or HIS, in both periods as well as the negative impact of foreign exchange, third quarter 2017 revenues increased $458 million or 4%.

Our Innovative Health business recorded 11% operational revenue growth in the third quarter 2017, driven by Ibrance and Eliquis globally, the addition of Xtandi revenues in the U.S. from the Medivation acquisition in September of 2016, and Lyrica and Xeljanz both primarily in the U.S. All of which were partially offset by lower revenues for Enbrel in most developed Europe markets due to continued biosimilar competition and Viagra in the U.S. because of wholesale or de-stocking prior to anticipated generic competition beginning in December of 2017.

Revenues for our Essential Health business decreased 11% operationally, of which 5% was attributable to the divestiture of the HIS business in February of this year. The remainder of the decline was due to a 22% operational decline from peri-LOE products, including Pristiq in the U.S., which lost marketing exclusivity in March of 2017, and Lyrica and Vfend in developed Europe markets. As well as a 12% operational decline in the sterile injectables portfolio, primarily due to legacy Hospira product shortages in the U.S. All of which were partially offset by operational growth of 67% from biosimilars.

In emerging markets however, Pfizer's overall Essential Health revenues grew 7% operationally, primarily due to 6% growth from the legacy established products portfolio and 14% growth from the sterile injectables portfolio.

Third quarter reported diluted EPS was $0.47 compared with $0.22 in the year-ago quarter, primarily due to the non-recurrence of a re-measurement loss on HIS in the year-ago quarter, higher gross margins, and lower restructuring and implementation cost, all of which were partially offset by higher purchase accounting adjustments.

Adjusted diluted EPS for the third quarter was $0.67 versus $0.61 in the year-ago quarter. The increase was primarily due to higher revenues, adjusted gross margin, and adjusted other income as well as fewer shares outstanding, partially offset by product losses of exclusivity, product supply, and a higher effective income tax rate.

I want to point out that diluted weighted average shares outstanding declined by 109 million shares versus the year-ago quarter due to our share repurchase program, reflecting the impact of our $5 billion accelerated share repurchase agreement executed in February and completed in May of 2017.

As I previously mentioned, foreign exchange negatively impacted third quarter 2017 revenues by approximately $54 million and positively impacted adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses in the aggregate by $16 million.

As a result, foreign exchange unfavorably impacted third quarter 2017 adjusted diluted EPS by $0.01 versus the year-ago quarter.

As you can see on the chart, we narrowed the ranges for certain components of 2017 financial guidance. We narrowed our revenue guidance range. And we now expect 2017 revenues to be in the range of $52.4 billion to $53.1 billion. This range continues to absorb an anticipated $2.3 billion negative impact due to continuing product losses of exclusivity, $1.2 billion due to the divestiture of HIS, and an anticipated $100 million negative impact due to adverse changes in foreign exchange rates versus 2016 rates.

In addition, supply challenges primarily related to legacy Hospira products have had a negative impact on projected 2017 revenues of several hundred million dollars. Consequently, we lowered the midpoint of our 2017 revenue guidance range. That said, we expect these challenges to moderate in full year 2018.

I want to point out that if we exclude the impact of foreign exchange and the sale of HIS, the midpoint of our updated revenue guidance would represent a 2% increase from fiscal year 2016 revenue levels.

With respect to adjusted diluted EPS, we increased the midpoint of our guidance range by $0.03. And we now expect 2017 adjusted diluted EPS to be in the range of $2.58 to $2.62. The midpoint of our updated 2017 adjusted diluted EPS guidance range, which is $2.60, versus our 2016 actual adjusted diluted EPS of $2.40, implies a growth rate of approximately 8% year over year.

It's important to note that this guidance range includes the anticipated negative impacts of approximately $0.03 due to the sale of Hospira Infusion Systems, $0.01 for foreign exchange compared to 2016, and $0.01 resulting from our May 2017 agreement with Sangamo to develop and commercialize gene therapy programs for hemophilia A.

Excluding these, the midpoint of our adjusted diluted EPS would have been $2.65, which represents a 10% increase versus 2016 actual results, which is significant given the $2.3 billion of top line headwinds we are facing due to the product losses of exclusivity that I just mentioned.

I want to take a moment to comment on the impact of the hurricanes that took place toward the end of the third quarter. First and foremost, we have nearly 2,000 Pfizer colleagues who live and work in Puerto Rico. And their safety and well-being is our first priority.

I'm pleased to say that we have confirmed the safety of all colleagues in Puerto Rico. And we are now providing direct assistance to them.

Pfizer also has three manufacturing sites in Puerto Rico. While these sites sustained some damage, we have made significant progress in repairing our facilities in anticipation of ramping up to full operations over the coming months.

As a result of dual source supply options and sufficient pre-hurricane inventory levels, our assessment at this point is that any revenue impact is expected to be insignificant. We will continue to monitor the situation closely and make any updates to our outlook if warranted.

Moving on to key takeaways. We continued to deliver strong financial performance in the third quarter of 2017. Excluding HIS revenues and the impact of foreign exchange from both periods, revenues increased 4% operationally year over year, driven by the strong growth from Ibrance, Eliquis, Xeljanz, Chantix, and the contribution of newly acquired products, including Xtandi.

We narrowed certain 2017 financial guidance ranges, including raising the midpoint of our 2017 adjusted diluted EPS guidance range by $0.03 to $2.60 from $2.57. We accomplished several key product and pipeline milestones. And we returned $10.8 billion

to shareholders year-to-date 2017 through dividends and share repurchases, which includes a $5 billion accelerated share repurchase agreement executed in February. Finally, we remain committed to delivering attractive shareholder returns in 2017 and beyond.

Now I'll turn it back to Chuck.

Charles E. Triano {BIO 3844941 <GO>}

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

Q&A

Operator

Your first question comes from Umer Raffat from Evercore.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, guys. Thank you so much for taking my question. Perhaps first, Ian, one for you. If there were to be no tax reform, is your bias at that point to look for an ex-U.S. company or not?

And I want to tie my second question back to the first one as well, which is when we get these updates on avelumab plus 4-1BB and OX40 combinations from your ongoing MEDLEY trial, how does that inform whether or not you'll look externally for a large IO acquisition? Thank you so much.

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

Thanks for the question. So on the tax reform issue, if there's no tax reform, we will continue to look at acquisitions based on the value creation for shareholders as we've always done. So I don't really speculate on that.

And on the IO development, obviously the IO is an interesting category. It has a lot of variability right now and in performance of different products. We remain focused on improving our business in IO. And we'll have to wait to see with the readout of those trials as to what it tell us and what direction we want to take.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, Ian. Next question, please?

Operator

Your next question comes from Chris Schott from JPMorgan.

Q - Christopher Schott {BIO 6299911 <GO>}

Great. Thanks very much. Just two questions here. Maybe the first was just elaborating a little bit on Ibrance trends in the U.S. You talked about 50% penetration right now. So the question is, where do you see penetration peaking over time? And what do you think it's going to take to get that additional penetration in the market?

My second question was on repatriation and tax reform. I think you've talked in the past of about $160 billion of foreign earnings at Pfizer. And that repatriation of these earnings could allow the company to bring back significant future earnings to the U.S. at a very low tax rate. To the extent we get repatriation, should we think of that as just fundamentally altering your approach to either leverage or capital deployment? I guess another way of looking at this, should we think about a step-up in Pfizer's annual capital deployment if this were to occur, whether that's large deals, small deals, or repo? Or is this just – be kind of business as usual as it relates to business development? Thank you.

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

Albert, do you want to deal with Ibrance?

A - Albert Bourla {BIO 18495385 <GO>}

Yes, thank you. First of all, let me say that we are very pleased with the results of Ibrance. We've had 59% growth globally versus the same quarter of last year. Ibrance last year was already a $2 billion product, so this is a significant growth.

Moving forward, the growth for Ibrance will come in the U.S. from expanded usage with already prescribing physicians, but also from expanding the CDK market as you well alluded. The penetration of CDK right now, it is 50%. But if you see the new patients, it is 57% and historical was always 50%.

I think the introduction of new CDK competitors in the market and, more importantly, the publication of more data is enhancing the confidence of physicians in the class and will benefit overall the class. So I see that – I don't see any reason why this will not go very high, because it is the standard of care anyway

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

Thank you, Albert. Frank?

A - Frank A. D'Amelio

Yeah.

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

Do you want to discuss the repatriation alternatives?

A - Frank A. D'Amelio

Sure. So, Chris, all the numbers you cited, the $160 billion is a number I've cited previously. Remember that's accumulated profit and earnings, that's not cash. You

basically said that in your question.

You really had two questions. One was, does it alter our approach in capital allocation? From my perspective the answer is no. Our priorities for capital allocation don't change. They are dividends, share buybacks, investing in the business, and M&A. Those will continue to be our capital allocation priorities going forward.

And then your second question was, would that alter our approach on business development? My answer is no. From my perspective our approach doesn't change. It's we're agnostic to size. And hopefully our actions over the past or in the past have demonstrated that. And our compass on deals has been, is, and will remain shareholder value.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, Frank and Albert. Next question please, operator.

Operator

Your next question comes from Andrew Baum from Citi.

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

Thank you. Couple of questions, please. Firstly, on talazoparib, given the recent Merck/Astra [AstraZeneca] deal and the anticipated heavy investments in the program, could you give us an outline of where you intend to go and how quickly with your DNA damage repair agent, both on monotherapy in selective patient populations as well as in combination with Bavencio and your broader portfolio?

And then second, while I know shareholder value will guide your direction, should I assume Pfizer has no interest in asset swaps with enthusiastic potential buyers for your Consumer business, such as GSK? In the event of a trade sale, most likely use will be cash to fund business development?

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

Sorry. Mikael, would you like to take the tala question?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, thank you for your interest in talazoparib. We regard it as a very potent PARP inhibitor. It's dosed as 1 milligram. And it has tumor activity that has been very efficacious in preclinical models and in early clinical studies.

We look very much forward to the near readout of our Phase 3 EMBRACA trial that's exploring talazoparib versus standard of care in germline BRCA-positive metastatic breast cancer.

We also are looking at avelumab plus talazoparib across a number of tumor indications, which may allow us to take benefit of the increased impact of talazoparib to make tumors immunogenic, in which avelumab can augment and benefit for patients. We are starting those studies and look forward to expanding them rapidly.

We see also opportunity for talazoparib in other combination, such as Xtandi in prostate cancer. So indeed, it's a growing important asset for us.

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

Thank you, Mikael. On the question of the Consumer business. We have some time been looking and seeking strategic deals for our Consumer business, whereby we would – perhaps involving asset swaps. I think this process we're going to take in the strategic review may shake loose more alternatives in that aspect.

And in regarding the proceeds, it's really premature to speculate, given the fact it may not be – we may spin the division as a separate company, depending on how we create maximum value. So we'll have to wait to see exactly how we recover the full value of this business.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, Ian and Mikael, next question please, operator.

Operator

Your next question comes from Gregg Gilbert from Deutsche Bank.

Q - Gregg Gilbert {BIO 3565226 <GO>}

Thanks. Sticking on the theme of big deals, since you're asked about your willingness and interest in doing big deals so often, I was hoping you would offer your historical view on whether very large deals in the industry and for Pfizer in particular have been value enhancing.

Secondly, John, can you go into some more detail about what's causing the shortages? Is this a system-wide issue? Is it tied to FDA issues or just demand outstripping supply? And when do you expect the close out letter from McPherson? Thanks.

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

Okay. Frank, retrospective on big deals, please.

A - Frank A. D'Amelio

Yes, so I guess the big deal would be Wyeth in terms of what we've done. I think the retrospective on that is it's been very value enhancing. If you look at our portfolio today, much of it has come from the Wyeth acquisition. When we announced that deal, we announced $4 billion in synergies. We clearly exceeded that.

If you look at the value we got for the Nutrition business that came from Wyeth, if you look at the value we got in Zoetis, much of which came from the Wyeth acquisition, if you look at the Consumer business that we currently have. So quite frankly, if you look at the Wyeth business retrospectively, significant value creation from that acquisition.

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

I think in general, I would say that the big deals prior to that have also been value creation deals. So, as we always said, we're agnostic to size as we have a core competency in business development and integrating companies. And we'll continue to use that competence. John, do you want to comment on the shortages?

A - John D. Young {BIO 16960082 <GO>}

Yes, so thanks for the question, Gregg. So in the Essential Health portfolio, as Frank mentioned in his comments, we have been experiencing some supply shortages for some of our products. The shortages are primarily for products in the legacy Hospira portfolio. And they're driven by I guess a blend of what we term capacity constraints and technical issues.

I think as Frank also mentioned, when we acquired Hospira, we originally thought that it would take one to two years to integrate their manufacturing plants and resolve the majority of the supply chain issues that we were aware of. What I would say is we have a robust action plan in place, and we believe that we'll make substantial progress in 2018 towards reducing the sterile injectable shortages.

In regard to McPherson, I think all I would say is that we've submitted a corrective and preventative action plan to the FDA, and we've been diligently working to address the items outlined in the warning letter. We provide regular updates to the FDA on the status of that action plan and will continue to do so.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you. Next question please, operator.

Operator

Your next question comes from David Maris from Wells Fargo.

Q - David Maris {BIO 1498515 <GO>}

Good morning. On biosimilars and the J&J suit, maybe if you could, just address them. How pervasive do you think these types of anti-competitive contracts are? What do you think the timeline on resolution and potential outcomes could be? And do you think this largely explains the major difference in the uptake in Europe and other outside the U.S. markets on biosimilars versus the U.S., or do you think there's another dynamic going on? Thank you.

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

Doug, would you like to answer that?

A - Douglas M. Lankler {BIO 16615171 <GO>}

Sure. So taking the last part of the question first, we do think so. We think in what we're calling the closed market area, we're seeing uptake that we think supports our claim that J&J's anti-competitive practices concerning Remicade have denied U.S. patients and the broader healthcare system the benefits of robust price competition and therapeutic options in the biologics marketplace.

Our concern that J&J has threatened to withhold significant rebates to insurers for both current and future patients and also engage in what we think are inappropriate and inaccurate marketing claims, for example, suggesting that patients need to fail first on Remicade before using Inflectra – seem to be unique to J&J. But obviously, we believe it's a violation of the antitrust laws.

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

John, do you want to add something?

A - John D. Young {BIO 16960082 <GO>}

Yes, I would just add, David, that as Ian mentioned in his comments, Inflectra has actually performed well in closed systems in the United States, and those are systems which prioritize healthcare cost savings over short-term rebating. And as of quarter three, we've reached a 54% share in those closed systems.

And I think our perspective is that the performance in those closed systems demonstrates that where payers, providers, and patients have access to Inflectra, Inflectra can offer significant value. The closed systems obviously only represent a relatively small portion of the market, around about 5% of total infliximab volume. And I think as Doug has commented, due to J&J's exclusionary contracting, lower priced Inflectra has largely not received commercial access at parity to Remicade and remains disadvantaged. But overall, I think that our performance in the closed systems really represents the value that Inflectra can deliver to healthcare providers and to patients.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, John and Doug. Could we move to our next question, please?

Operator

Your next question comes from Jami Rubin from Goldman Sachs.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. I just have a couple. First for you, Ian, has Pfizer had discussions with other companies regarding alternative drug distribution models or potential new entrants into the drug distribution business? Obviously, I'm referring to the havoc that is wreaked upon that industry because of the threat from Amazon. I just would love your thoughts on that.

And just taking a five-year view, do you see new entrants entering the drug distribution industry, PBMs or drug retail pharmacy industry? Just wondering what your thoughts are on that.

And then just if I could move to the Essential Health business, that business continues to be a real drag on your overall performance. And there you cited specific reasons this quarter. At the time of the Hospira deal, I think you had projected that this business would eventually flatten out because of growth in emerging markets, opportunities from the sterile injectable business, as well as biosimilars. But that doesn't seem to be panning out. Is this business salvageable? Can it ever stop declining and in fact start growing, or is this just an anchor you're going to have to deal with? Thanks very much.

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

Thank you, Jami. On the potential changes in distribution, all I would say is that any system of distribution that can cut costs and get a wide availability of products to patients is something that the whole industry would be interested in vis-à-vis a distribution system going back into PBMs and adjudication. I think that's somewhat more of a difficult strategic proposal, as it then enters the whole issue of the world of insurers and PBMs and deciding on differential access, and that's a whole different skill set.

Regarding the Essential Health business, I'll ask John to make his comments on that.

A - John D. Young {BIO 16960082 <GO>}

So look, thanks for your question, Jami. And let me just reiterate what we've said in the past, which is we've always said that in the medium term, we believe that we can return the Essential Health business to low to mid-single-digit growth. We didn't specifically put a timeline on that. But we framed that out as being over a three to four-year period.

The reason that we believed that it was going to take time is because of the headwind of LOEs. Frank commented on that in his comments. And whilst for the corporation, the impact is moderating, in 2017 we still have some headwinds, predominantly in the Essential Health business.

So in quarter three, just to quantify that, the total LOE impact on the business in the quarter was around about $339 million, due to just a range of products that have gone off patent or are experiencing generic competition, Pristiq, Lyrica, Vfend, Relpax, Nitrostat, and so on.

The thing about those time-bound events, however, is that by definition they will moderate. And so that basic aspiration to return this business to be a low to mid-single-digit grower is something that we still retain.

And just to break out the performance in the quarter for you, Jami, although Pfizer Essential Health declined by 11%, if you actually exclude the impact of the Infusion Systems business divestiture and also the impact of LOEs, the business was actually flat in the quarter.

So I think whilst we are still on that path to recovery, I think we remain committed to and actually very positive about the aspiration to return this business to the growth profile that we've outlined in previous quarters.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, John. Next question, please.

Operator

Your next question comes from Seamus Fernandez from Leerink.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Great, thanks for the question. So first question, Ian and Frank, can you guys comment on the structure that you think would really optimize the value for the Consumer business? You guys have sold businesses in the past, but also I think the Zoetis split was a great example of success. And you've also done some creative combinations. So just trying to get a better sense of where you think the most value has really been added for shareholders in the context of those different decision points with Consumer?

And then the second question really is when we think about the opportunity in the IO space, would you guys please comment on clinical trials that could read out next year that you're most excited to see the results of? Thanks.

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

Okay, I'll ask Frank to answer – give you our thoughts on the structure that would most likely optimize value. And then I'll ask Albert to talk about IO studies – sorry, I'll ask Mikael...

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah.

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

...about how IO studies reading out.

A - Frank A. D'Amelio

So, Seamus, on structure. Let me just start with obviously we have a baseline view in terms of what we think that Consumer business is worth, based on obviously our projections on future cash flows, discounted back to a net present value.

In terms of structure I think it's really, what maximizes value? And if you look at what we've done in the past in terms of some of our larger divestments, we sold the Capsugel business. We sold the Nutrition business. And then we split, to your point, the Zoetis business.

Obviously when we were doing the Zoetis transaction, we were receiving incoming calls, had offers. But quite frankly, we didn't think that those offers exceeded the value that we could get from a split. And so we went ahead and we proceeded with a split.

So my answer, my short answer is we will pursue the structure that best maximizes the value to our shareholders. And hopefully our actions in the past have demonstrated that that's what we've done.

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

Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

So thank you for the interest in our IO portfolio. So we actually have, together with our partner Merck KGaA, a very much, well running IO portfolio. And we have 30 studies, including nine in new pivotal indications and more than 6,300 patients enrolled.

In the near-term readout from now towards 2019, we have actually eight pivotal readout, starting quite soon with gastric third line, followed by in 2018 lung second line, ovarian second line as we come towards end 2018 and into 2019, real interesting studies in earlier lines such as kidney cancer, combo of Bavencio and Inlyta, Bavencio in gastric first-line maintenance, in lung first-line, bladder first-line, and ovarian first-line, chemo, IO, all in 2019.

In addition to those eight pivotal studies that can be registration-enabling for us, we have a number of non-pivotal that can guide us to accelerate clinical programs. And that includes late this year and early next year, IO combos with 4-1BB followed by Bavencio with OX40. We'll share further data on Bavencio with lorlatinib and with also late next year, our triple combo will be part of this.

So I would also like to say that we have, beyond just the checkpoint inhibitor, a very interesting vaccine opportunity, where we have our prostate vaccines that will be followed by another vaccines go into human studies in the quite near future, that contains multiple vaccine components, plus PD-1 blockade, plus CTLA-4 blockade, really interesting concept.

And finally, beyond the IO, you probably are aware that we have a very rich and vibrant and quality portfolio where we recently announced in our targeted portfolio, positive data for Xtandi in PROSPER. We have in preparation for registration plans around dacomitinib, lorlatinib. We have soon readout of talazoparib. And we have positive data on glasdegib, which make us engaged in also registration study.

So it's a very rich and quality pipeline, where obviously the IO and Bavencio is an important piece. Thank you.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Thank you.

A - Charles E. Triano {BIO 3844941 <GO>}

Great. Thanks, Mikael. Can we move for our next question, please?

Operator

Your next question comes from Vamil Divan from Credit Suisse.

Q - Vamil K. Divan {BIO 15748296 <GO>}

Hi. Great. Thanks so much for taking my question. So first, I just want to see if you can give a little more color on the impact of price in the U.S. on the quarter for the Innovative Health business as a whole? Or at least for some of the key products, like Ibrance, Lyrica, Eliquis, Xeljanz.

And then my second question also on – touching on Eliquis. Just curious there what your thoughts are. Have we seen positive data from Xarelto from the COMPASS study? They have some additional data coming from their lifecycle management program over the next few years. So do you see that data in any way impacting Eliquis' growth?

And just curious, just looking back now, there's a very limited lifecycle management program around Eliquis. And I think it's just sort of surprising for such a large product. Is there anything that you and Bristol [Bristol-Myers Squibb] are doing in terms of trying to come up with new indications or somehow extend out that product beyond what it is right now? Thanks so much.

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

Thank you. Frank, impact of price? And then Albert can discuss Eliquis.

A - Frank A. D'Amelio

So globally, all-in, total company price for the quarter was 0%. In the U.S. it was plus 3%. That's for the quarter. If we go year-to-date, so the nine months cumulatively, same numbers. All-in enterprise-wide, total company globally, 0%. In the U.S. plus 3%.

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

Thank you. Eliquis, Albert?

A - Albert Bourla {BIO 18495385 <GO>}

Yes. First of all, let me say that Eliquis had a phenomenal performance again this quarter, 43% operational growth for the quarter. The U.S., significant growth of 39% operational growth. It is the number one NOAC prescribed by specialists and primary care physicians.

To your question on data already presented, based on the consideration that I'm going to say, we see the potential impact of COMPASS study upon Eliquis business will be limited.

First of all, in the broader protocol of exclusion of NVAF patients, the rivaroxaban-only arm did not meet efficacy endpoints. There were high bleeding rates for both rivaroxaban arms in the trial and at different dose and dosing regimen compared under rivaroxaban NVAF dose. That being said, I want to emphasize that we cannot make a comparison when we don't the complete studies. But we feel very confident on the growth projections that we have right now with Eliquis.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you. Next question, please, operator.

Operator

Your next question comes from David Risinger from Morgan Stanley.

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

Thanks very much. I have two questions. First, could you please update us on the recent IPR developments on your pneumococcal vaccine patents through 2026? And the potential implications for Merck's 15-valent vaccine or other potential pneumococcal vaccine competitors?

And then second, could you just frame for us where Ibrance's ex-U.S. rollouts stand and whether you ultimately expect ex-U.S. Ibrance sales to eclipse the dollar revenue opportunity in the U.S.? Thank you.

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

Doug, please, the IPR, inter-partes review, process.

A - Douglas M. Lankler {BIO 16615171 <GO>}

Sure. Thanks for the question, David. So we were very pleased to see the October 20 denial of Merck's inter-partes review filings on two of our U.S. patents covering compositions of pneumococcal vaccines. So these patents stand as valid and will not expire until 2026. We believe these patents and others in our portfolio may present freedom to operate issues for Merck or anybody else trying to develop a pneumococcal vaccine. As Ian mentioned at the outset of the call, we've started Phase 2 trials for our next-generation 20-valent pneumococcal vaccine and have received Fast Track designation from the FDA.

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

Thank you, Doug. Albert, on Ibrance?

A - Albert Bourla {BIO 18495385 <GO>}

Yes, ex-U.S. Ibrance is performing very well, and we are very pleased. Let me focus on Europe right note. It is the best-performing area, because we have also the upcoming launch of Japan, but it's not started yet. The early EU launch indicators, they show rapid Ibrance adoption in first-line. There is also strong adoption of Ibrance in patients who were already treated with AR monotherapy, also in patients in later lines of therapy.

We are having positive discussions with reimbursement bodies right now. Pricing and reimbursement process are ongoing across Europe in accordance with national procedures and timelines. But we have already secure investment in several countries. We are in the middle of multiple negotiations, so I wouldn't like to speak more about that.

Our international sales were in this quarter $165 million. This is up 30% versus the previous quarter, sequential of the second quarter. In Europe in particular the growth was even greater, 35% up versus the previous quarter. We see this trend continue as we are launching in other jurisdictions and as we are getting price reimbursement in Europe and as we are going of course to places like Japan.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Albert. Next question please, operator.

Operator

Your next question comes from Tim Anderson from Bernstein.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. A couple of questions. On the lawsuit with J&J on Inflectra, if you don't win, do you think that would have broad negative ramifications to other future U.S. biosimilar launches? And it would foretell a different future uptake profile in the U.S.? My guess is that you'll answer that yes, otherwise you wouldn't be suing, unless you're suing for some other reason.

And second question is going back to a question I've asked frequently in the past. Your commitment to avelumab? The reason for my question is pretty obvious. In the past you've said you're committed. But some investors I talk to claim that over the last couple of months, management has said they would be willing to upgrade – you'd be willing to upgrade your anti-PD under the right circumstances. I'm wondering if you'd like to either confirm or deny that? Or maybe at minimum just add some current color to the question?

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

On the lawsuit, Tim, I think the lawsuit was taken because we strongly believe that the actions of J&J are not acceptable under the anti-trust litigation. More importantly I think the solution to this will come from a societal view on that biosimilars are there to provide access to patients once the patent has expired. And that enough is enough. That you shouldn't be using contracting mechanisms to extend your exclusivity, when society expects to get access to products once the patent is expired.

So we believe there will be quite rigorous debates within society, within the CMS, as how does the governmental systems accrue the benefits of biosimilars. So we sort of see it as both a legal strategy and a strategy of alerting policymakers that Europe is obviously benefiting from biosimilars, so why isn't the U.S.? Given that the law was passed to make biosimilars readily available.

On avelumab, we remain committed to our programs with our partner. Regarding any rumors you may or may not heard, I really can't speculate on them. I've actually I think addressed a couple of questions from you on calls about our partnership with Merck. And I don't really think it would be helpful to add any more comments.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, Ian. Next question, please.

Operator

Your next question comes from John Boris from SunTrust.

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

Thanks for taking the questions and congrats on the quarter. First question for Frank. I know you haven't outlined 2018 guidance, but could you maybe walk us through qualitatively what some of the headwinds and tailwinds are that you're expecting for 2018 that might impact or shape our models?

Second question on the Established (sic) [Essential] Health business. On some of the smaller companies we've seen multisource competition being accelerated by ANDA approvals on injectables. Are you seeing an increased number of ANDAs being approved across injectables? And is that having an impact on pricing?

Third question on Ibrance. In Europe in particular in markets where you have to negotiate pricing, do you – are you recording any deferred revenues or for revenue recognition purposes that might show up in 4Q or in 2018? And that should do it for the questions. Thanks.

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

Okay. Thank you, John. On Ibrance the answer is no. We continue to sell Ibrance under our traditional model of selling and booking sales when we make them. On the Essential business, perhaps John could make some comments.

A - John D. Young {BIO 16960082 <GO>}

Yeah, so, John, look, I think the FDA have been very clear about the perspective that they have that they believe that competition is the most important factor in being able to reduce health care costs. That's actually a position that Pfizer has long supported, that we believe in a competitive marketplace and we also believe that the availability of timely

approval of generic alternatives is critical to patient access and long-term sustainability of the health care system.

We manufacture and commercialize a number of products in the FDA's published off-patent pharmaceutical product with limited or no competition today. And we do anticipate that certain products on that list that we currently commercialize could face competition from additional manufacturers over the next several years.

All of that said, we also are currently exploring opportunities to bring to market certain other products on the list, which Pfizer could have the manufacturing capability and capacity to reliably produce. So the FDA have been very clear about their perspective in this space. It's a competitive market space. And one that we expect to remain so.

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

And I would add that the requirements from the FDA and the European Union on the manufacturing of sterile injectables continue to increase and ensures that any competitor needs to have robust good manufacturing practices, which is also positive for patients. Frank, on the models?

A - Frank A. D'Amelio

So, John, we'll give detailed guidance for 2018 on our next earnings call, as we always do when we close out the fiscal year. We'll close out 2017, and then we'll provide guidance on 2018. But in terms of you mentioned headwinds and tailwinds. The way I'll do this I think is maybe the rhythm of the revenue. So we'll have LOEs next year. Our current estimate on LOEs is about $2 billion, so that will be a headwind.

In terms of tailwinds, we continue to expect new products like Ibrance, Eliquis, and Xeljanz to perform very nicely. Our recently acquired products, like Xtandi and Eucrisa, we expect to perform very nicely in emerging markets. If you look at emerging markets for the quarter, up 11%, year to date up 9%, so we continue to expect those areas of the business to perform well. Biosimilars this quarter up 67% on a quarter-over-quarter basis. So lots of areas where we expect to see continued growth going forward. And we'll give details on guidance on the next call.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Frank. We'll take the next question, please.

Operator

Your next question comes from Richard Purkiss from Piper Jaffray.

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

Thanks. I have two quick questions. Firstly on Xeljanz, how much interest are you getting from rheumatologists and gastroenterologists on the prospects of its approval in psoriatic arthritis and ulcerative colitis?

And then also I noticed your JAK-1, you presented data in atopic dermatitis. Can you just give us some color on how it compares to other JAK inhibitors in that space? Thanks very much.

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

Thank you, Richard. Of course, on Xeljanz, we don't do any pre-marketing activities on indications that haven't been approved. But in discussions with experts who advise us, we think it is a competitive profile in both of those conditions. And on JAK-1, I'll ask Mikael to add some commentary.

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you for your interest in JAK-1. We shared data recently at the EADV conference in Europe. And obviously, there has been another JAK-1 that together define the JAK-1 class performance in atopic dermatitis.

On the efficacy side, we shared that it was a very impressive number of patients that reached cleared or almost cleared skin lesions, about 45%, in that range. What is very interesting with this class is that it has a rapid onset of action. Within a few weeks, you see improvement. And between weeks four and six, you have reached a very significant part of maximal effect.

Atopic dermatitis patients suffer particularly from pruritus itch, and I think this is really unique in the yaquant clause (59:02) and was evident in our study that already two days – I repeat, two days of the initiation of therapy, you could see itch relief. And then within two weeks, it has reached really impactful effect and plateaued at 64% that got very substantial itch relief.

And to the best of my knowledge, there hasn't been any reported drug or recently approved drug that has had such favorable rapid onset, which is critical for these patients. Thank you for interest.

A - Charles E. Triano {BIO 3844941 <GO>}

Great. Thanks, Mikael. Next question, please?

Operator

Your next question comes from Steve Scala from Cowen.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have a few questions. I think the sale of Pfizer Consumer to J&J a decade ago was viewed as at a great price, but in retrospect a strategic mistake for Pfizer. Would you agree with that characterization, and why is it different now?

Second, regarding Xtandi and the PROSPER trial, the release says Pfizer will discuss the results with health authorities. Given the positive study, what is there to discuss as

opposed to just filing outright?

And then lastly, I appreciate that it is completely in line with background rate, but there are about 40 DVTs or PEs reported in Xeljanz studies. Has Pfizer looked at whether these patients were also on Celebrex or other COX-2 inhibitors? And if you have, then what did it show? Thank you very much.

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

Steve, thank you. I'm not sure that your general characterization of the J&J deal is accurate. But nevertheless, that's something that's in the past. We make decisions on future dispositions based on the facts we see today and the opportunities we see today. And we believe that it's well worth exploring the strategic alternatives for that business. Vis-à-vis PROSPER...

A - Albert Bourla {BIO 18495385 <GO>}

PROSPER, I can take.

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

Yeah, will you please?

A - Albert Bourla {BIO 18495385 <GO>}

Steve, I want to be clear. We were delighted with the PROSPER positive top line reports that came two years earlier than anticipated. We are looking forward to disclosing detailed results at an upcoming major medical congress.

Given the nature of the data and the importance of the claim, we have resourced very well. The team is preparing the dossier, and we expect to file soon.

A - Mikael Dolsten {BIO 16368411 <GO>}

Concerning Xeljanz, first of all, as you know, it's been performing excellent. It has been prescribed to more than 100,000 patients worldwide. And we had recently an advisory committee for expansion into psoriatic arthritis and got an overwhelming positive vote for the efficacy and safety profile.

Concerning specifically thromboembolic events, we have of course carefully looked at Xeljanz, both in clinical studies comparing Xeljanz to control group, as well as in registers and how it's performed in the market. And we do not see any difference between Xeljanz-treated or other treatment of rheumatoid arthritis patients.

We're aware that there have been some competitive reports of some other compounds in this space. But we do not see any issues with Xeljanz at all in all our different analyses, where the clinical registers on the use of the drug in the market. So we are very pleased with the profile of Xeljanz as it stands.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Mikael. Next question, please.

Operator

Your next question comes from Alex Arfaei from BMO.

Q - Alex Arfaei {BIO 15433937 <GO>}

Good morning, folks. Thank you for taking the questions. I have three, if I may. First, following up on Xeljanz ex-U.S., could you please comment on how we should think about the uptake there relative to the strong growth that we're seeing in the U.S?

Second, on Eucrisa, I think it's fair to say that the launch is slower than expected. Is the outlook for that product still peak sales of $2 billion, even with the JAK-1s emerging as competition?

And then third, on Hospira sterile injectables, I think, Frank, you said supply challenges led to sales being several hundred million lower. If that reflects demand, is it fair to say that most of that should come back in 2018 as you address those shortages? Thank you.

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

Albert, could you address the Xeljanz ex-U.S. and the Eucrisa performance?

A - Albert Bourla {BIO 18495385 <GO>}

Yes, let me start ex-U.S. with Europe. We are very pleased with the performance in Europe. Xeljanz can be given as monotherapy in case of intolerant methotrexate or when treatment with methotrexate is inappropriate.

So far, we have launched in nine markets, and those includes UK, Netherlands, Sweden, but we do not have still pricing negotiations completed with the rest. We think that the uptake in Xeljanz based on our initial interactions with physicians will be very strong in Europe.

Now let me go back to Eucrisa. First of all, let me start. Yes, we think that will be a $2 billion-plus product, and we are very excited with the progress. In the third quarter we almost doubled the number of patients versus the previous quarter, the second quarter. As Ian said, we have 83,000. And the product has been prescribed so far by more than 20,000 physicians. And the majority of them, 60% of them, are repeaters. We have 90% of commercial lives that have removed the NDC block, which is very, very good. And they're covering now Eucrisa. However, at this moment, only approximately 50% of the commercial lives have unrestricted access or require one electronic step edit, some require more. And they're working very hard to revisit that.

Also I need to emphasize that the net sales, the so-significant sampling and couponing, which was introduced to launch and to drive success. The free trial voucher now has

expired. However, we have a standard co-pay card that continues to be supporting patients' affordability.

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

And I think the JAK-1 marketplace is different from the topical Eucrisa marketplace. And they're appropriately medically segmented, giving opportunities to both – for both products.

A - Albert Bourla {BIO 18495385 <GO>}

Very different and a very different profile with Eucrisa have a very benign profile in terms of safety and could be given to kids as young as two years old.

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

Thank you, Albert. Frank, please.

A - Frank A. D'Amelio

Yeah. So, Alex, John mentioned that the Hospira remediation efforts in the legacy Hospira manufacturing facilities are taking a little bit longer to remediate than we thought. However, we believe those will be substantially completed by the end of 2018.

As a result, we expect that several hundred million in 2017 to moderate into 2018, which means we'll be lower in 2018 than 2017.

Q - Alex Arfaei {BIO 15433937 <GO>}

Thanks.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you. Thanks, Frank. Next question, please.

Operator

Your next question comes from Marc Goodman from UBS.

Q - Marc Goodman {BIO 1853567 <GO>}

Yes, Mikael, I was hoping you could give us some highlights on some of the key products in the pipeline that have moved into clinical studies, maybe into Phase 2 and stuff. I saw there was a NASH drug that moved in there. Maybe you can talk about that a little bit. And then also provide us an update on tanezumab. When are we going to see the first pivotal study? Thanks.

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

Good questions, Marc. Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes, thank you. Starting with tanezumab. We're very excited about that product. And of course given the national crisis with opioids, it's – the really main opportunity near term for novel pain relief mechanism that has no addictive abuse related profile.

So you should expect during somewhere between first to second half transition next year, that we will start to communicate the studies, osteoarthritis followed by chronic lower back pain. It's overall, six Phase 3 studies in approximately 7,000 patients, a very comprehensive package. And we are very encouraged and optimistic that this could be a real very important option for patients going forward. And that's why we look forward to see the data in this study.

In the portfolio that you asked me about, I will just mention that with the recent positive readout of our JAK-1 atopic dermatitis that I earlier commented on, is a really intriguing example of how this next-generation JAK can contribute very meaningful clinical efficacy.

Within that JAK portfolio, we have a lot of momentum. And we expect next year to have readouts of two different JAKs in alopecia. And I remain very encouraged that these two novel JAKs could represent new treatment options for a patient group in alopecia that haven't really had any new treatment in decades.

We also have a readout for our 2Q (1:09:15) JAK-1 in psoriasis Phase 2. And you may have remembered from an earlier small trial readout that that drug performed in a very impressive excellent manner. So these are example in the JAK portfolio.

We recently also shared positive data from our gene therapy Factor IX study. And we're now advancing that together with Spark Therapeutics towards planning for pivotal studies. We have data ongoing with Sangamo on our Factor VIII gene therapy.

And finally, on the ACC NASH study, we are very encouraged about the ACC drug that we have. We think there is opportunity due to its liver selective profile to give it that really optimal level to get a very meaningful lowering of lipids in the liver. And we are just, right now, on the cusp of starting those studies. And hope to have readout late next year or early the following. So stay close to us.

Q - Marc Goodman {BIO 1853567 <GO>}

Thank you.

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

You're quite welcome.

A - Charles E. Triano {BIO 3844941 <GO>}

Next question, please.

Operator

Your next question comes from Tony Butler from Guggenheim Partners.

Q - Olivia Brayer {BIO 20319651 <GO>}

Hi. Good morning. This is Olivia Brayer on for Tony. I have a two-part question regarding the JAVELIN Lung 100 study for Bavencio. What was the reasoning behind the dosing amendments to the trial? And can you provide some sort of color on how you were thinking about those amendments and on PD-L cutoffs that you were using?

And then my follow-up question is, do you see crossover as a potential problems for your overall survival data? And for which hazard ratio did you power the study? Thank you.

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

Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. So I will only comment since this was a while ago that we introduced a hierarchy of PD-L1 cutoffs that were basically aligned what other current studies are using that allow us to study high, medium, or low. And we have sized the study appropriately.

Of course there is always in first line studies an issue that patient may crossover. But the unique characteristics of IO will allow you really to look at the benefit, given that you have this tail of patients that will stay responders if you've got a good mix of patient selection and study planning.

So we remain optimistic about this study. I should say that we also have included a high dose Bavencio arm that could offer a unique differentiation versus other PD-1 or PD-L1 lung cancer studies.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you for the background, Mikael. Next question, please.

Operator

Your next question comes from Jeff Holford from Jefferies.

Q - Jeffrey Holford {BIO 4872636 <GO>}

Hi, everyone. Thank you for taking my questions. Just first for Ian, I think you've been one of the most shareholder friendly and proactive CEOs across the whole industry. But in light of some of the frustrations you've had around M&A, inversion, splits, et cetera, I wonder if you can discuss a little bit the succession plan for the CEO role? And the potential timing of that? And what if any structural changes you would still like to look at implementing at Pfizer during your tenure?

And then second, sorry to go back to the J&J litigation again, but maybe you can help me a bit on this. Maybe for Doug. Is it not fairly standard for companies to remove or adjust rebates on the loss of formulary positioning? For example, has Pfizer not engaged in that practice in the past? Or is it that you're potentially suggesting that there should be some kind of double standard for biosimilars with respect to that? Just because they don't have an equivalent to an AB rating just as yet? Thank you.

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

Well, while Doug is thinking about that question. Succession, Pfizer, like all major companies, the board has a responsibility on succession planning. We have a robust succession process within Pfizer. And at due points they – that succession plan will become active.

My focus in Pfizer has always been focused on creating shareholder value for all the moves we make and all of the actions we take. And of course I'm extremely pleased about the maturing and – the maturing nature of our pipeline and the very promising assets that I see sit in that pipeline, which will come to market 2019 through 2025 or more. Thank you for the question. Doug?

A - Douglas M. Lankler {BIO 16615171 <GO>}

Yeah. So thanks, Jeff. So rebate programs in and of themselves are accepted industry practice, so long as they are legally structured. We think J&J's practices in the character of the biologics marketplace in particular, where, among other things, there's no mandatory substitution at the pharmacy, and thus originated firms have substantial leverage over existing patients, make this a violation of the federal antitrust laws.

A - Charles E. Triano {BIO 3844941 <GO>}

Thank you, Doug. And can we take our last question, please, operator?

Operator

Your final question comes from Geoff Meacham from Barclays.

Q - Geoffrey Meacham {BIO 21252662 <GO>}

Hey, guys. Thanks for the question. Just have a couple. Albert, on Xtandi, do you feel like commercial trends in prostate have stabilized in the U.S.? Or is there a risk that co-pay and reimbursement, et cetera, could be a headwind looking to next year? And then as you move upstream in the paradigm, what's been the progress with new urologists as first-time prescribers?

And then, Ian, real quick on the deal front. Where does geography fall in the priority list? I know previously it was more of a lever for inversion. But I wasn't sure if there was an objective, for example, to grow specifically outside the U.S. Thank you.

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

On the geography, once again, it comes back to value for shareholders and opportunity. A dollar made in China is worth the same as a dollar made in Europe.

So we're more focused on what does it do to our strategy? How does it strengthen the enterprises we're in? We've already got a very big international footprint. So how do we leverage that footprint? So all of those things come into consideration of how we produce value. Albert?

A - Albert Bourla {BIO 18495385 <GO>}

Yeah. On Xtandi, let me take the opportunity to speak about the investment thesis of Medivation and that will answer all your questions for Xtandi as I do.

When we bought the acquisition – when we bought Medivation, we said that the value drivers are, one, continue growth in the metastatic setting, primarily by growing prescription from urologists, as you said. The second was to obtain a broader indication in non-metastatic prostate cancer. And the third was to develop and commercialize talazoparib.

In the metastatic prostate cancer we are very pleased, because Xtandi total demand continues to demonstrate some growth. This quarter, we have 15% growth compared to the same quarter of previous year. Urologists were growing 37%, as we have predicted that we would be able to grow. As Ian said, there is an all-times high with approximately 1,700 urologists prescribing the product. This, compared to Zytiga, that prescribed almost 407, so very big difference.

In the non-metastatic prostate cancer, we were delighted with the positive results of PROSPER, two years earlier than expected. And as I said before, we are working very hard to file.

And for talazoparib, we had an extensive discussion before. And Mikael alluded to the very robust development program. So the fundamentals of this acquisition are very, very helpful.

We know that the next sales are lagging behind because of the Patient Assistance Program. So let me tell you where we stand with that. The program as a proportion of total demand was generally stable compared to the previous quarter, as Ian said. And as we stated previously, any change this year will be very gradual. And the reason is because all patients already enrolled in the program, they remain in this program for the entire calendar year. So there is not a possibility to have radical changes over there.

But we believe as we move to the next calendar year, that the patient assistance as a percentage of total demand will start normalizing. Thank you.

A - Charles E. Triano {BIO 3844941 <GO>}

Thanks, Albert, and thanks for everyone on the call for your attention this morning.

Operator

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