Company Name: Pfizer
Company Ticker: PFE US
Date: 2017-08-01
Event Description: Q2 2017 Earnings Call

Market Cap: 197,416.30
Current PX: 33.08
YTD Change($): +.60
YTD Change(%): +1.847

Bloomberg Estimates - EPS
Current Quarter: 0.640
Current Year: 2.553
Bloomberg Estimates - Sales
Current Quarter: 13133.692
Current Year: 52752.222

Q2 2017 Earnings Call

Company Participants

- Charles E. Triano
- Ian C. Read
- Frank D'Amelio
- John D. Young
- Albert Bourla
- Mikael Dolsten

Other Participants

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

MANAGEMENT DISCUSSION SECTION

Charles E. Triano

Financial Measures

Discussions during the call will also include certain financial measures that were not prepared in accordance with U.S. generally accepted accounting principles

- Reconciliation of these non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's current report on Form 8-K dated today, August 1, 2017
- You can obtain a copy of the Form 8-K on our website, pfizer.com/investors

Any non-GAAP measures presented are not and should not be viewed as substitutes for financial measures required by U.S. GAAP

- They have no standardized meaning prescribed by U.S. GAAP and may not be comparable to the calculations of similar measures at other companies

Ian C. Read

Q2 Overview

During my remarks today, I will briefly talk about the progress and opportunities within each of our businesses and the areas where we see the greatest potential in our pipeline

YTD, our performance is on plan, and the results for the quarter are operationally comparable with the prior-year quarterly performance

If you exclude the impact of the Hospira Infusion Systems divestiture and the unfavorable impact of foreign exchange, revenues for the quarter increased 2% operationally compared to the prior-year quarter

We also raised the midpoint of our adjusted diluted EPS guidance range for the year

- When you look at our projected adjusted diluted EPS growth for this year and add the dividend yield, it is approximately 11%

Pfizer Innovative Health

I'll begin with a few words regarding the performance of each of our businesses, beginning with Pfizer Innovative Health

This business had another strong quarter, growing its top line by 9% operationally, driven by the performance of the core brands that are key revenue drivers: notably Ibrance, Eliquis, and Xeljanz

Their solid performance is enabling us to improve our growth profile through continued market penetration and the potential for additional new indications that are nearer term with Xeljanz and in the future of Ibrance

For example, we have submitted regulatory filings for two potentially new indications for Xeljanz in psoriatic arthritis and ulcerative colitis

- As you may know, later this week there's an FDA Arthritis Advisory Committee meeting to vote on a recommendation for a psoriatic arthritis indication

Xtandi

- Now a few comments on the performance of Xtandi
- This quarter we continue to see strong underlying demand
- Total sales were $300.7mm in quarter two 2017, up 10% from first quarter 2017, which translated into 8% growth for Pfizer's Xtandi alliance revenues
    - Of note, the number of urologists actively prescribing Xtandi in a given month reached an all-time high in May
- This is a key factor, given that increasing Xtandi prescribing by urologists was one of the commercial opportunities we identified for Xtandi prior to the acquisition
- I would note that the patient assistance program proportion of total demand was comparable with Q1
- We expect that the patient assistance program utilization will normalize as we move into next year

Phase 3 PROSPER Trial of Xtandi

- We're also excited about the amendment to the protocol of the Phase 3 PROSPER trial of Xtandi in non-metastatic castration-resistant prostate cancer, or CRPC
- We believe this will accelerate the timeline for potentially expanding the indication for Xtandi to include non-metastatic CRPC by two years
- With our collaboration partner Astellas, we anticipate having top line data later this year and soon hope to provide Xtandi to more men with earlier stages of prostate cancer
- Expanding the indication for Xtandi is another key factor and a value driver for realizing the product's full commercial potential as we continue to conduct trials evaluating the use of Xtandi in hormone-sensitive prostate cancer, allowing us to potentially move into even earlier settings
    - Including the ARCHES trial in metastatic hormone-sensitive prostate cancer and the EMBARK trial in non-metastatic hormone-sensitive prostate cancer

PARP Inhibitor Talazoparib

- Regarding the PARP inhibitor talazoparib, enrollment in the EMBRACA Phase 3 study in germline BRCA-positive breast cancer closed in April of this year, and we're expecting top line results by January of next year
- We continue to be very confident on the potential of the molecule and have an aggressive development plan that includes monotherapy and combinations with checkpoint inhibitors
- In addition to breast cancer, we are evaluating the potential to develop talazoparib in prostate cancer and in combination with avelumab in various tumor types
    - Overall, we remain confident that the Medivation acquisition was a good investment that will deliver value for the patients we serve and our shareholders
- As you know, we closed the Anacor acquisition last year
- We are seeing a solid uptake in the demand for Eucrisa
- Sequential prescription demand increased more than two-and-a-half-fold
- Due to the timing of building the inventory, which is normal during the initial launch period, net revenues did not follow the same pattern of growth
- We expect this will normalize when we move forward, and we'll start seeing net revenue sequentially grow in quarter three

Vaccine Business

- In our vaccine business for Prevnar 13, the recommendations and associated reimbursement in key EU countries for Prevnar 13 in the adult population have taken longer than anticipated
- I would note that in the EU reimbursement is a second step, which differs from the U.S., where ACIP governs both
    - We continue to work in securing additional recommendations and reimbursement programs within the EU adult population

Pfizer Essential Health

Revenues

- Turning now to Pfizer Essential Health
- While revenues for the quarter declined, we saw good operational growth in emerging markets and in Biosimilars, primarily in certain developed markets
- Within Biosimilars, Inflectra uptake in the U.S. is being driven by a number of factors, including Inflectra's clinical package, patient support programs, price differentials vs. innovators by channel, and the access reimbursement environment
- To date, reimbursement coverage has been mixed
- While we achieved 100% Medicare coverage, we have experienced access challenges among national commercial payers, where our lower price product has not received access at parity to the innovative product and remains in a disadvantaged position despite recent price increases taken by the innovative product
- Given our extensive experience working with commercial payers, we will look at all relevant factors impacting reimbursement to determine next steps to enable greater access for Inflectra
    - In aggregate, we have a strong Biosimilars portfolio and remain on track with our plans to file six biosimilar assets in the U.S.

PEH Business

- As we saw this quarter, the PEH business continues to be impacted by LOE events, specifically Pristiq in the U.S.
- We also faced two upcoming events: Viagra in the U.S. later this year and Lyrica in the U.S. at the end of 2018
- To counter these headwinds, the PEH business is refining and strengthening its portfolio to ultimately pivot the business to grow
    - One example is a focus on our anti-infectives

Acquisition of AstraZeneca

- Late last year we acquired AstraZeneca's small molecule anti-infective business, and we just completed a license agreement with Basilea for the commercialization rights in Europe for Cresemba, a novel antifungal treatment for potential life-threatening fungal infections among immunocompromised patients
- The scale and global reach of our PEH business is unparalleled in the industry
- With its broad portfolio that span 600 essential medicines, it impacts the lives of more than 300mm patients in about 160 countries
- Emerging markets play a key role in enabling the business to achieve its growth objectives
- This quarter PEH revenues in emerging markets grew 5% operationally y-over-y
    - The most robust revenue growth came from the largest areas of PEH businesses within the emerging markets, namely legacy established brands and sterile injectables

Pipeline

- Turning now to the pipeline
- We have a strong pipeline with a steady flow of scientific innovation coming from Pfizer's key therapeutic areas

- Over the next five years, we project the potential for about 25 to 30 approvals, of which up to 15 have the potential to be blockbusters
    - And we believe half of these potential blockbusters could achieve approval by 2020
- The most noteworthy highlights include: In Oncology, we see an opportunity for five different potential blockbuster approvals over the five years, including Xtandi in non-metastatic prostate cancer and Ibrance in early adjuvant breast cancer
- We also see the opportunity for a number of Bavencio IO combinations, including doublets and triplets such as targeted combinations like avelumab and Inlyta or (11:59) IOi [ph] combinations like avelumab plus 4-1BB
    - And we believe we have a leadership opportunity with Bavencio combined with chemotherapy for ovarian and head and neck cancer indications

Vaccines

In Vaccines, we see the opportunity for three potential blockbusters, including our next-generation valent pneumococcal vaccine, which is in Phase 1 and we are working to accelerate given the continued burden of disease

We plan to start Phase 2 by Q4 this year

- In addition, our C. difficile vaccine is in Phase 3, and Staph aureus vaccine in Phase 2B, both of which have fast-track designation

Inflammation & Immunology

- In Inflammation & Immunology, we are in the registration phase for Xeljanz in ulcerative colitis and psoriatic arthritis in the U.S.
- We have a comprehensive program of several unique next-generation JAK inhibitors across multiple dermatological, gastrointestinal, and rheumatological indications
    - We have recently completed a Phase 2 proof-of-concept study for our JAK1 selective oral molecule in moderate to severe atopic dermatitis and are assessing the data with the potential to advance the program

Rare Disease and Internal Medicines

In Rare Disease and Internal Medicines, we have several pivotal Phase 2 and Phase 3 programs ongoing

This includes a Phase 2 trial for Duchenne’s muscular dystrophy and Phase 3 trial for rivipansel for sickle-cell disease, tafamidis in TTR cardiomyopathy, and tanezumab for chronic pain

- And in Biosimilars we have several assets across major cancer and inflammatory diseases which we believe are high-value opportunities

In total there are 14 distinct biosimilar assets in the pipeline, eight of which are in mid- to late-stage development, and six assets are in early-stage

Summary

In summary, the business is executing on our strategy

Our Innovative business is generating strong growth and is positioned to continue this growth

Our Essential Health business has well-documented revenue growth challenges in the near term given the upcoming LOE events but generates very strong cash flow, and it's working to solidify long-term growth drivers within its portfolio

We see a very attractive next wave of noteworthy pipeline products potentially starting in the next two years, and we expect there will not be a significant impact from expected LOEs during the period 2020 through 2025

Given this backdrop, over the near term our focus is to maximize the market opportunities we see for our inline portfolio as we continue to advance the pipeline while managing our cost structure and delivering attractive financial performance

Our businesses and our people are well-prepared and stand ready to meet the challenges posed by the uncertainties that exist domestically and in the global markets where we operate

Our compass remains bringing new therapies to patients that significantly improve their lives and create value for our shareholders

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

Frank D'Amelio

Financial Performance

Revenues

- As always, the charts I'm reviewing today are included in our webcast
- Now moving on to the financials
- Second quarter 2017 revenues were approximately $12.9B and reflect a slight y-over-y operational decline of $48mm
- Second quarter 2017 revenues were also unfavorably impacted by foreign exchange of $202mm or 2%
- If you exclude both the revenues for HIS in both periods, as well as the negative impact of foreign exchange, second quarter 2017 revenues increased $248mm or 2%
    - Our Innovative Health business recorded 9% operational revenue growth in Q2 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 Xeljanz and Lyrica, both primarily in the U.S. – all of which were partially offset by lower revenues for Enbrel in most developed Europe markets, primarily due to continued biosimilar competition and the 7% operational decrease in global Prevnar 13 revenues
- In the U.S., Prevnar 13 declined 16% due to the unfavorable impact, the timing of government purchases for the pediatric indication, and the continuing decline in revenues for the adult indication because of a smaller remaining catch-up opportunity vs. the prior-year quarter

International Markets

- In international markets, however, Prevnar 13 revenues increased 8% operationally due to the favorable timing of government purchases for the pediatric indication in certain emerging markets

- Revenues for our Essential Health business decreased to 12% 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 27% operational decline from peri-LOE products such as Pristiq in the U.S., which lost marketing exclusivity in March of 2017, Vfend and Lyrica in developed Europe markets, as well as a 3% operational decline in legacy established products, all of which were partially offset by a 60% operational growth from biosimilars, driven by Inflectra in certain developed Europe markets and in the U.S.
- In emerging markets, Pfizer's overall Essential Health revenues grew 5% operationally, primarily due to 7% operational growth from the legacy established products portfolio and 10% growth from the sterile injectables portfolio

EPS

- Second quarter reported diluted EPS was $0.51, compared with $0.33 in the year-ago quarter, primarily due to lower asset impairment charges, higher gross margins, and lower legal charges, all of which were partially offset by a higher effective tax rate and higher purchase accounting adjustments
- Adjusted diluted EPS for Q2 was $0.67 vs. $0.64 in the year-ago quarter
  - The increase was primarily due to a higher gross margin and fewer shares outstanding

Average Shares Outstanding

- I want to point out that the diluted weighted average shares outstanding declined by 112mm shares vs. the year-ago quarter due to our share repurchase program, reflecting the impact of two $5B accelerated share repurchase agreements, one completed in June of 2016, the other executed in February of 2017 and completed in May of 2017
- As I previously mentioned, foreign exchange negatively impacted second quarter 2017 revenues by approximately $202mm or 2% and positively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate by $247mm or 3%
  - As a result, foreign exchange positively impacted second quarter 2017 adjusted diluted EPS by approximately $0.01 vs. a year-ago quarter

EPS Guidance

We increased the midpoint of our adjusted diluted EPS guidance range by $0.02 to reflect the $300mm increase to the guidance for adjusted other income and deducts as a result of lower-than-forecasted net interest expense, higher-than-forecasted royalty income from certain products, and higher-than-anticipated dividend income from ViiV

- As a result, we now expect 2017 adjusted diluted EPS to be in the range of $2.54 to $2.60

I want to point out that our updated adjusted diluted EPS guidance range absorbs $75mm of adjusted research and development expenses that were recorded in Q2 2017 due to our agreement with Sangamo Therapeutics, which we announced in May 2017 to develop and commercialize gene therapy programs for hemophilia A

To punctuate what Ian said earlier, the midpoint of our updated 2017 adjusted diluted EPS guidance range, which is $2.57, vs. our 2016 adjusted diluted EPS of $2.40 implies a growth rate of approximately 7% y-over-y, which is above that of our peer group average

In addition, this implied y-over-y adjusted diluted EPS growth rate, in conjunction with our current dividend yield of 3.8% to 3.9%, equates to approximately 11%, which is again above that of our peer group average and which we

believe is robust for a company of our size

- With the exception of increasing the midpoint of the range for our guidance for adjusted diluted EPS and increasing guidance for adjusted other income/deducts, we reaffirmed all other 2017 financial guidance components

Key Takeaways

Now moving on to key takeaways, we continued to deliver solid financial performance in Q2 2017

Excluding HIS revenues from both periods, revenues increased 2% operationally y-over-y, driven by the strong growth from Ibrance, Eliquis, and Xeljanz and the contribution of the newly acquired products including Xtandi

We increased the midpoint of our 2017 adjusted diluted EPS guidance range by $0.02

We now expect the range to be from $2.54 to $2.60

We accomplished several key product and pipeline milestones, and we returned $8.9B to shareholders in H1 2017 through dividends and share repurchases, which includes $5B accelerated share repurchase agreement executed in February

- Finally, we remain committed to delivering attractive shareholder returns in 2017 and beyond

QUESTION AND ANSWER SECTION

<Q - Gregg Gilbert>: First for Ian and Frank, last quarter you suggested that doing big deals might be on hold tied to uncertainty on tax reform, as well as binary events in the industry. So looking for your updated thoughts on that. Taking a wild guess here that MYSTIC might've been one of those binary events. And my second question is for John. I was intrigued by Ian's comments about the Remicade – Remicade holding on commercial – commercial plans in particular. Now that Merck has jumped into the biosimilar Remicade market, can you talk about the implications of where they set price and what you think it's going to take to get Inflectra ramping the way you hope in the next couple of years? Thanks.

<Q - Ian C. Read>: Well, as we've always said, we have a base plan, and we look to improve that plan. And part of that may be improving or changing our capital allocations. We look at BD as a way of improving returns for shareholders, and right now I would reaffirm that I think there are short-term events in the marketplace, such as a tax reform, that may change asset values. So any focus on BD, to my point of view, is somewhat delayed by a resolution of that. And I'll ask John to talk about the Remicade.

<A - John D. Young>: Okay. So thanks for the question. So, first of all, let me just be clear that the Merck biosimilar, Renflexis, launched at exactly our Inflectra ASP. So ASP is the average selling price that is set by CMS on a quarterly basis. It is $753 for Inflectra, and that was exactly the price that Merck announced the pricing of Renflexis to be last week. So actually their pricing essentially is exactly on parity with our price.

In terms of the second part of your question, which is what do we think it's going to take to really accelerate performance, I think I would just start by saying actually overall biosimilar revenue was $121mm in the quarter. It grew by 60%, and that included $23mm of sales in the U.S. We continue to see the value of biosimilars in the marketplace and expanding patient access to important high-quality, lower-cost treatment options, but we know the market is still in development. Inflectra penetration in the U.S. has been slower than we expected due to some challenging marketplace dynamics. By the end of June, our Inflectra share was 2.3% of the overall infliximab volume, and that includes a mix of new and switch patients, as every provider customer is taking a different approach to adoption.

But we've made steady progress to improve the availability of Inflectra through contracting with GPOs. We've achieved some wins with integrated healthcare systems, particularly those where the insurer and provider are the same.

The VA would be a good example of such a provider, where we actually have an infliximab share of 20% or more, and that continues to grow. With insurance plans, we've achieved 100% coverage for Medicare patients. But in the commercial insurance space, access for Inflectra has been substantially limited due to J&J's pursuit of exclusionary contracting with insurers and providers.

And as Ian said in his comments, our lower-price product hasn't received access at parity to Remicade, and it does remain, in that sector of the market, at a disadvantaged position. So we are actively working on a range of commercial and other strategies to make Inflectra accessible to more patients and also make sure we lay the groundwork for a smoother and more rapid uptake of all future biosimilars in the U.S. marketplace.

<Q - Jami Rubin>: Ian, just – if I can just go back to the capital allocation question again. If I take your words in your prepared remarks or in the press release literally, it does sound like you're backing off from a large-scale deal and saying that you're going to focus on maximizing internal opportunities. And this coming off of the first six months of the year where you and your senior management have been on the road talking up your core competency of doing major acquisitions and aggressive cost-cutting. And that after two failed mergers to lower your tax rate and that around the time that you plan to break up the company into three parts and then two parts.

So it's just a little bit confusing what the message today is to investors. I mean, we understand that corporate tax reform is facing some headwinds and uncertainty, but that was also true after Q1. So just trying to get a sense for your general priorities here. Is it to get bigger in order to break up? Is it to lower your tax rate? Is it to get bigger in oncology? Is it to achieve significant cost synergies? I think we're all a little bit confused about that, and if you could clarify.

My second question, again going back to MYSTIC, just curious to know what you think the failure of MYSTIC tells you. We have heard that you have said in the past that if it did fail it would place a higher value on the PD-1 leaders, but just wondering how you think about that. Thanks very much.

<A - Ian C. Read>: Thank you, Jami. I'm sorry it's confusing. I don't think we've changed our approach at all in the seven years that I've been CEO. Our focus has always been to use BD as part of capital allocation to improve returns to Pfizer shareholders, and we look at it in the totality of our capital allocation. For instance, since September 2015 – not to use since 2010 but 2015 – we've paid out $12.9B in dividends, we've repurchased $10B of our shares, and we've spent $36B in BD. So we have been active in BD.

Now you're asking me about, have we backed off any intention to do a big deal? My answer to that is we will look at the circumstances and the asset prices and determine the appropriate capital allocation when we feel that we have a realistic handle on what asset prices truly represent. And right now I believe we need to see tax reform or the absence of tax reform to understand what the market values are. We then would look at BD opportunities inside other opportunities with capital allocation, including share buybacks and dividends, investing in our own portfolio. And rest assured we will aggressively take the actions that we believe will improve the value to shareholders.

Now in regard to MYSTIC. I think MYSTIC certainly indicated that the IO-IO may be more problematical in the near term. Certainly I think reinforces the value of PD-L1 franchises and where they stand in the different therapies, and which order they stand. Surprisingly, the market didn't infer that really through to the other CTLA-4. We only saw it narrowly in MYSTIC. So I'm not quite sure what the market is saying that they believe that the read-through is. So we really want to see the full report, not just the top line. But certainly I think it strengthens the case that the PD-L1 is going to be for the foreseeable future a major player in the game. Thank you.

<Q - Alex Arfaei>: First on Ibrance, if you could just update us on the latest market share penetration – very impressive results. So just want to get a better sense as to what the upside there is. And then on Xeljanz, wanted to – again, solid performance. Wanted to get your thoughts on the latest, I guess, concerns about the risk of thromboembolic events with JAK inhibitors. And then finally, Ian, very impressive commentary about the R&D potential. Would you be interested, or are you considering, hosting an R&D day so that the investment community can better appreciate the potential of this pipeline? Thank you.

<A - Ian C. Read>: Okay. Alex. Thank you for the recommendation of the R&D day. We'll have a discussion internally and see what we think is the best way to communicate that more and more fully. I would ask Albert to talk

about Ibrance, and then Mikael Dolsten to talk about the issues you raised with – or the potential issues you raised around Xeljanz. Albert?

<A - Albert Bourla>: Thank you, Ian, and thank you, Alex, for your good words for Ibrance. Look, for Kisqali, it is a little bit early to comment, but so far we have seen a minimal uptake of this product. Its most recent market share has been 4% across all lines, 5% in first line. We have seen some early signs of market growth. The CDK market share in new patients has grown from an historical 50% to approximately 57%, indicating that the Kisqali introduction could potentially grow the total market. As you know, only 50% of the patients that they could receive benefits from CDK treatments are now under a CDK program.

We remain confident in our leadership in the class. Two years, more than 10,500 prescribers, more than 60,000 patients in the U.S., now more than 13,000 patients in the EU in just a few months from the beginning of the year. And this is testament not only to Ibrance's efficacy with over two years PFS, but also to its manageable safety and tolerability profile with no EKG or liver monitor required. And, last but not least, we have great access for patients. So we are very optimistic for the future of the project.

<A - Mikael Dolsten>: So thank you for the question concerning, I assume, the recent news surrounding venous thromboembolism for baricitinib, and you wanted to learn about Xeljanz. We are very pleased with the profile for Xeljanz. It has been extremely consistent, and our analysis from more than 21,000 patient-years in clinical studies and postmarketing experience in over 90,000 patients shows that there is no causal relationship between Xeljanz and venous thromboembolism. We have not seen any signals for thrombosis. This suggests that not all JAKs are the same, and the news around baricitinib is likely to be seen as compound specific and not JAK class specific.

I wanted also to add, as an example that underlines this, barcitinib has reported elevated platelets, thrombocytosis, which in some circumstances can be associated with increased risk for thrombosis. We have not seen that either with our Xeljanz inhibitor, and we are very pleased with its balanced and well-performing profile. Indeed, this week there was a Lancet oral strategy report that underlined how well Xeljanz was performing and compared its profile in a very, I think, favorable way also to Humira in that study. Thank you for your interest.

<Q - Christopher T. Schott>: Just a couple product questions and then one tax question. First on Xtandi, you mentioned patient assistance dynamics are expected to normalize as we move into next year. Can you elaborate a little bit more on what drives that confidence? And should we think about an uplift in realized price as that occurs?

Second question was Prevnar 13 adult in the EU. I think you mentioned here reimbursement's been a bit slower. What are the hurdles that are affecting that uptake? And is there anything the company can do to either accelerate this or address this?

And then the final question was on this topic of U.S. tax reform. What are the key elements that Pfizer is looking for as we go through tax reform in order for the company to best optimize its capital structure? Is repatriation the critical piece? Is the absolute tax rate the critical piece? I guess what aspects of tax reform are you most focused on as we hear various proposals over the coming weeks and months? Thanks very much.

<A - Ian C. Read>: On Xtandi, what we've discussed previously is that access to Xtandi in its present setting is concentrated more heavily in patients who are on Medicare or Medicaid, and there are access barriers there. And the industry in total have dealt with this by allowing foundations to provide funds to those patients to meet some of their copay obligations, and it's been done from a third-party stance, with us donating money to foundations who then dedicate themselves to making sure that individuals have access to these medications. There was a temporary, I think, chilling of that under a subpoena and some investigations from the legal system, which we believe that are temporary in nature and that there are clear guidelines as to how this should be done by different government agencies. We are clarifying these or have clarified them, and we believe the industry will return to funding these foundations within the established and clear guidelines of the U.S. government.

Hence, we would expect that the percentage of patients who are on our patient assistance program will drop as they move towards the foundation covering their copays. This will tend to be more abrupt at the beginning of the year, as most patient assistance programs guarantee you access for the remainder of the CY whenever you join. And then when

the CY changes, then most of these patients or new patients, we believe, will likely turn to the foundations as a source of financing or help with their copays.

I would ask – Prevnar adult; would you like to talk about that, Albert, in the European situation?

<A - Albert Bourla>: Yes. Absolutely. And, Chris, let me start by restating that we're not changing this in our assessments. We expect the Vaccines business to be flat to slightly declining in 2017. Now, in developed Europe, our revenues for the adult claim in Q2, they grew slightly. We had the 2% growth compared to the same quarter of last year. YTD, we are growing double digit at 15%, and this is in line with our expectations so far.

In Europe, the vaccine business is all about recommendations and subsequently reinvestment, and the process is slow, as Ian said. We wanted and we were hoping to be a little bit faster. And right now most of the effect of the reimbursement we expect to happen in 2018. To give you some examples, in France in April there was a national at-risk recommendation, but the process of getting from recommendation to reinvestment will likely take us into 2018. Before France, in Q1, Italy announced new national recommendations for 65, but then there is – from recommendation to reimbursement also takes some time. We continue to advocate with both the European technical committees for recommendations and payers for reinvestment.

<A - Ian C. Read>: So, thank you, Albert. I think net-net we realize that the Prevnar franchise is difficult to forecast, so we have given – I think in the last quarter we gave guidance that the total franchise will be flat to slightly down on a full-year basis, and I think that's what you should use for your modeling. Frank, why don't you talk about the tax situation?

<A - Frank D'Amelio>: Yeah, Chris. So I think in terms of what we'd like to see for tax reform, I think first a territorial tax system. Two, a repatriation holiday. Three, lower corporate tax rates. And then, four, and this kind of applies to a couple of these, which is if there's going to be some minimum tax, obviously the lower the minimum tax the better.

<A - Ian C. Read>: And we believe that type of reform will make us more competitive. It's not as good as a pure territorial system, but within the art of the possible and what they're trying to achieve, that would help us access our global capital.

<Q - Jeffrey Holford>: I have two. First on Consumer, I think you previously had – or shown little interest in any kind of disposal of this business, but as we're continuously talking about consolidation of pharma and on the watch for pharma asset prices, could this be a potential source of funds that is worth more in the hands of others rather than yourselves going forwards? That's the first question.

And then second, you talk about a number of blockbuster opportunities; obviously adjuvant Ibrance is one of those. That's more than just $1B opportunity. I would think it's very much more substantial than the metastatic opportunity. I wonder, can you can give us any more thoughts around potential timing with that being a partially event-driven study for a readout there? And then what kind of size do you think the market for adjuvant breast cancer could be for the CDKs? Thank you.

<A - Ian C. Read>: Thank you. On the Consumer business, I think we've commented on this before. We're investing in it, it's growing, it's a good source of U.S. cash flow, and we see stable growth. But the Consumer business, like any of our businesses, we subject to periodic reviews as to whether there'd be more value created being outside of Pfizer rather than in. And clearly, as we discussed before on this tax reform, the tax reform will change the net value of assets in the marketplace in various ways, and we think it's prudent to wait for a decision on tax reform so that we can really understand the valuation of our assets as we do these reviews across all of our business.

Now, with regard to Ibrance, Albert, would you like to take that one?

<A - Albert Bourla>: Yes, and you're right, we also believe that the opportunity in the early breast cancer is much larger than the opportunity of metastatic breast cancer. The populations are more than double, and the duration of treatments are expected to be much longer. So we are looking forward to bring in the Ibrance label the claim of early breast cancer.

Now, as regards the studies that we are running, in early breast cancer we have three studies that are running. The first one is PENELOPEB. And this is for high-risk early breast cancer patients. The estimated completion date of this is in 2020. The second is PALLAS, which is for patients with intermediate-risk early breast cancer, and we have here an estimated primary completion date in 2021. And there's also PALLET, which is a smaller study that has an estimation completion date end of 2018, beginning of 2019.

<A - Albert Bourla>: And these are all event-driven trial. This is a little bit difficult to estimate, and the better the product does, usually the events delay to complete. We need to wait see the results.

<Q - Umer Raffat>: I wanted to focus on the IO strategy for a minute, perhaps starting with the backbone itself. I notice you have an in-house PD-1, as well as the avelumab collaboration. So just wanted to understand how you're thinking about positioning both? And also on that same tone, you also have an investigational monthly subQ arm for your in-house PD-1, the wholly owned one. Any early thoughts on that? Was very curious.

And stepping outside of the whole PD-1 side, I find it interesting you do have preclinical CTLA-4s, you have a preclinical IDO. So, from your perspective, do you think you have everything you need for IO-IO combos in these particular assets? Or would you rather have something more advanced depending on the trial results in the next few months? Thank you.

<A - Ian C. Read>: Thank you. It's a very complicated and deep question, the whole issue of IO strategy. I'm going to sort of ask perhaps Mikael to make some initial scientific comments on the overall target selection and then have Albert add comments on the commercial implications. What I would point out is that in immuno-oncology, we certainly feel we have a good PD-L1 in partnership with Merck from Germany, but undoubtedly the depth of our clinical exploration is not the size of either of the two major competitors who have PD-L1s who are ahead of us. But, Mikael, why don't you –

<A - Mikael Dolsten>: Yes. Thank you very much. So I'll briefly touch upon what are key things to keep in mind here. As Ian alluded to, we are pleased with our partnership with Merck KGaA on avelumab, and we have more than 30 studies ongoing and some 10 that are in registration – intent fashion. Among those, I wanted to mention that we think we will be in a leadership role for ovarian cancer, both advanced, second, and third line, as well as first line in chemo combinations. We think we'll also have a leadership position in RCC due to various promising data reported for Inlyta in combination with avelumab at ASCO. And you may have seen recently also that Inlyta is running a combination also with Keytruda, and that will solidify, we think, that Inlyta drug combined with either avelumab or other PD-1 drugs. And finally, in head and neck cancer, combining radiotherapy and chemo we also think we can establish unique leadership for avelumab.

More recently, the organically generated PD-1, which is part of the alliance with German Merck, showed a very well-behaved molecule suitable for monthly delivery and good early efficacy signals. So we are looking at opportunities where that profile may have a differentiated role, such as treatment of very early cancers or possibly adjuvant cancers, and we will share more quite near term about how we see that molecule.

When it comes to combination, we are eager to see the readout of the areas where we think we are unique. Our 4-1BB should have data reporting later part of this year, OX40 with avelumab early next year, and a triple the later part of next year.

Finally, you spoke about CTLA-4. Clearly the native CTLA-4 antibodies have shown a tricky balance between efficacy and adverse events. We have embarked on modified CTLA-4 where we have two preclinical compounds that we think can have a more tumor-specific effect and a mitigated systemic effect to explore whether that second generation can be more easily developed. Albert, anything you want to add here?

<A - Ian C. Read>: So I think you gave a very extensive answer, Mikael. I would just add that our internally developed PD-L1 – as you say, it's earlier use; it's used in the adjuvant setting. If we can get its administration subQ, it would be a very important differentiating factor there. But, Albert, do you want to add anything?

<A - Albert Bourla>: No, no, no. Just what you just said. That could mean treatment in home vs. treatment in the infusion centers, which makes a big difference.

<A - Ian C. Read>: A big difference. Okay.

<Q - David Maris>: How do you feel about the administration's understanding of the drug industry and its contribution to jobs and innovation? Maybe you could tell us a little bit how you've been integrating or engaging with the administration. And do you think what we've heard and seen so far as to potential executive orders is really what we should expect, which is marginal or incremental change, not price controls or anything more ominous? Thank you.

<A - Ian C. Read>: Thank you, David. Well, we've had long conversations about this. I believe that the pharma industry has worked hard, along with other parts of the healthcare industry, to ensure that the administration has a full view of the contribution that the industry makes. It's a – I think $1.6 trillion contribution to GDP, the pharmaceutical industry, and about 4mm jobs that are created by this industry. And we are the only part of the industry that actually prices go down. If you did a triple bypass operation 10 years ago, compare that to what you pay today, it has significantly gone up, whereas Lipitor has significantly gone down in price. So we're one of the few parts of the healthcare system that automatically have price reductions built in and the utility of that product remains for society.

So we've been working and discussing with this administration. I think they understand the importance of the industry. They understand the importance of innovation. And I would expect that we've discussed with the administration that any executive order should help increase competition, should help get generic products to the market faster. This is where in fact most of what we may call – has been called – outrageous pricing issues have occurred in the generics sector. The Brand Effect has only seen a 2.3% price increase in 2016. So there seems to be a mischaracterization of what's creating issues.

Cost and affordability is an issue for most patients because of large deductibles and high copays and the fact that the rebates that we give to insurance companies to help get access are not being used to ensure the patient pays the net price after the rebate. And this has been a conversation we've been having with the administration. So overall I think we've given several suggestions to the administration. It's been a good conversation, and I expect that from a public policy point of view, the administration understands the importance of our industry to patients.

<Q - John T. Boris>: Ian, just a question on the environment. Over your seven-year tenure, what are some of the things that appear to be going right for the industry? Seems like on the regulatory front, certainly the FDA is approving things, and cycle times are coming down. But certainly on the generics side you're getting a lot faster approval of ANDAs. On the reimbursement side, certainly seems to be a lot of pressure. But just some general commentary about the environment and the pushes and pulls that are going on there.

Secondly, you mentioned that some of your businesses are subjected to periodic reviews. You have the Genetics Institute business that's in hemophilia. You have some competitive threats there from ACE910 and gene therapies. Have you considered a spin or split of that business like one of your peers had recently done?

And then lastly for Frank, just on foreign exchange. Certainly, the headwind is lessening, but you didn't move your guidance range on revenues at all. Can you maybe just discuss some of the pushes and pulls there that forced you to leave guidance where it was? Thanks.

<A - Ian C. Read>: Thanks, John, wide-ranging questions. I think in the environment, certainly on the registry side through actions taken by the FDA, certainly the new commissioner and the PDUFA negotiations I think we're beginning to see an improvement in the FDA's speed in approving and bringing new products to the marketplace. I would say the oncology division is probably one that I would call out as being the most active there.

On the negative side of the situation, I suppose you would say that we've seen increased pressure from payers. We've seen the marketplace devolve a little bit into high deductibles, high copays, which is denying access to patients, which is not well-understood. And overall I think we've also seen an uptick in our ability to take science and take what we've learned in science over the last few years to improve our understanding of how to get vaccines and precision medicine through to the marketplace.

On the hemophilia franchise, we think we're well-placed. While I would agree with you, we are seeing entrances that have longer half-lives, but we think we have a strategy to use that business and move on to new formulations and new products. And I would just ask Mikael to talk a little about our research in that area.

<A - Mikael Dolsten>: Yes, thank you. As you mentioned, John, gene therapy has the potential to transform incremental gains by slightly increasing half-life. We have shared with Spark Therapeutics recently experiences from factor IX for hemophilia B patients. 10 patients have been dosed, single infusion. We see a robust level of synthetic gene giving rise to dramatic reduction in bleedings or the need for any infusions, and patients basically without the need for any treatment beyond a year or year and a half, because this is as far as we've gone in the observation period.

As we noted at – advance in the field, we recently licensed, in a partnership with Sangamo, a factor VIII gene therapy, which is quite a big market. We're just embarking on clinical studies with that. And we are exploring to take a step into really difficult diseases like Duchenne's muscular dystrophy. We're planning our internal program to go into the clinical study early next year. So as Ian alluded to, we decided to move from more incremental to more transformative therapies, and so far are very encouraged about the quality of these technologies.

<A - Ian C. Read>: Okay. Thank you. Frank, would you like to do the –

<A - Frank D'Amelio>: Foreign exchange?

<A - Ian C. Read>: – foreign exchange?

<A - Frank D'Amelio>: Yeah. So, John, you're correct. If you look at the impact of foreign exchange on our revenue guidance, let's say the First Call we had this year, early February, to today's call, it's a negative, but it's less of a negative. So you're absolutely correct, and the reason we chose not to change guidance was there's many parts of the portfolio that are performing very well. We've mentioned some of those today – Ibrance, Eliquis, Xeljanz – but there's other parts of the portfolio that we've mentioned today that aren't performing the way we thought they were going to from a planning perspective. We mentioned Inflectra on the call. We mentioned Xtandi on the call. We mentioned Prevnar 13 adult in Europe on the call. So when we put that all together, we thought it was prudent to leave the revenue range where it is, $52B to $54B.

<Q - Timothy Minton Anderson>: Thank you. I want go back to Inflectra if I can, your comments about being disadvantaged. Am I correct to think that the only way to overcome the reimbursement hurdles is price, and the experience of payers today basically says the product is priced too high? Or could it simply be a prediction by payers that prescriber demand just won't be there regardless of price? And to answer that, I think one of the ways you could – would be to look in channels where you do have full coverage – I think you said Medicare – and what the uptake has been in those channels.

And then another question is one that I've asked in the past, so forgive me, but your commitment to avelumab, you've described in the past, but I interpret to be to be kind of an unwavering commitment to that relationship and to that product. So is that a fair characterization? Is it full speed ahead with avelumab?

<A - Ian C. Read>: Okay. On avelumab, we were in a very good partnership with Merck. We have a plan to develop avelumab. You've heard on this call today where we think we can be successful in first line, where we can be successful in combinations. And we always review all of our strategies and all of our potentials to see how we can maximize participation in any sectors. So we're – have a strong partnership, but we continue to review the best way to be successful in IO combinations, but that extends beyond PD-L1. It extends to our own 4-1BB, our own OX40, our own other targeted agents, our own vaccine, oncolytic vaccine strategy there. So I think, as I say, we enjoyed a very good relationships with Merck. And the first question was – remind me again.

<A - John D. Young>: Inflectra.

<A - Charles E. Triano>: Inflectra.

<A - Ian C. Read>: Inflectra. I think the key for me – and I'll ask John to expand upon it – is the issue of – I think we have the right strategy on our pricing strategy. I think we are competitive on price. But in enclosed systems we have a

20%-plus market share but in the commercial plans, certainly, there are exclusive provisions that are in place by the originator's owner that make penetration difficult regardless of price. John, would you like to add anything?

<A - John D. Young>: Yeah. I mean, I think Ian's covered it well, Tim. I think all I would say is we're very clear that by definition biosimilars are defined in law as being highly similar and having no clinically meaningful differences. So, therefore, we recognize the value proposition vs. the originator has to offer value to the healthcare system in the form of savings. And I wouldn't add to Ian's comment other than to say we remain extremely vigilant as more competitors have and will continue to enter this and other marketplaces, that we need to offer our customers value in order for them to both stock and also to provide insurance coverage for their patients.

<Q - Richard J. Purkiss>: On Xtandi, could Albert outline how he sees the opportunity in additional patient numbers from PROSPER if it reads out positively later this year? And then on pipeline efforts, could you just flesh out expectations for Besponsa in ALL and also just the filing timeline on lorlatinib? Thanks a lot.

<A - Ian C. Read>: Albert, please see what you can – give an answer to those, and if you need, I'll ask Mikael to add a contribution.

<A - Albert Bourla>: Yeah. Let me start with PROSPER. We are very excited with the prospects of bringing Xtandi to early stages of prostate cancer, and PROSPER is just one of the studies that we are having running in order to do that. EMBARK, ARCHES, and PROSPER are three studies that are focused on early prostate cancer. EMBARK is focusing on non-metastatic hormone-sensitive prostate cancer, ARCHES in metastatic hormone-sensitive prostate cancer but early, and PROSPER in non-metastatic castrate-resistant prostate cancer.

We think about, as we discussed in the breast cancer, the opportunity's significant because the population of early non-metastatic prostate cancer is almost double than the population of the current registered claims in the opportunity of Xtandi. And we are expecting the duration of treatments to be much longer, so significant commercial opportunity. Mikael, do you want to answer the – ?

<A - Mikael Dolsten>: Yeah. On lorlatinib and I think you also mentioned ALL and Besponsa.

<A - Albert Bourla>: ALL and Besponsa, yes.

<A - Mikael Dolsten>: Yeah. On the R&D side, as Besponsa got approved in EU and we expect positive outcome soon in the U.S., it's a highly differentiated drug for patients at great need.

When it comes to lorlatinib, that drug has performed really well. It's to the best of my knowledge the second generation ALK/ROS inhibitor that covers most mutations, mutations that patients progress on also on other currently new ALK inhibitors. And it also has good brain exposure for patients. So we, for us, it's really the best-in-class drug that can extend the franchise and complement Xalkori, and we expect to file it later this year.

<A - Ian C. Read>: Any quick comment on Besponsa?

<A - Albert Bourla>: Just, I wanted to say, first of all, I misheard the question. So, yes. On the Besponsa, it has received already registration in Europe. We have breakthrough designation, and fast track in – by the FDA for acute lymphoblastic leukemia in adults. And ALL is an aggressive form of leukemia, has a very poor prognosis in adults, and has limited treatment options. And we estimate that approximately 2,250 new cases of ALL occurring in adults will be diagnosed in the U.S. every year. And, as a result, this represents a meaningful new option for patients and a meaningful opportunity for us.

<Q - Geoffrey Meacham>: Ian, just on the topic of deals. When I look at your NME slide, what strikes me is how crowded some of these categories are, and Rare Disease obviously looks less so, as is neurodegeneration. So I know ROI and tax reform are inputs, but how much does the landscape inform your priority for deals?

And then second question for Albert, can you go into a little bit more on the PROSPER protocol change, what went into the decision? Was it competitive? Was it something you were seeing in the data so far? Thank you.

<A - Ian C. Read>: So on the deals, a lot of areas are crowded. It's an issue of finding products that have significant clinical differentiation. And I think if you look through our franchises we see that we have that opportunity in Vaccines; we have the opportunity in Inflammation. We continue to see that opportunity in Oncology with the future development of Xtandi, with the PARP inhibitor of Ibrance, with the PD-1 strategy with Merck, which is a core part of our strategy. And I think if you extend it out into CVMED or internal medicine, we continue to see huge opportunities to differentiate in inflammation, in our JAK franchises. And in neuroscience it's a hard area, and we continue to work at it. We're sort of refocusing somewhat on neuroscience into sort of Alzheimer's and Parkinson's, and away from psychiatry.

But I think our deals need is to play to the strengths we have. The deal has to be part of a strategy, and the strategy is to strengthen your anchor disease areas and ensure you can get synergy savings and also – both synergy savings and synergies in the revenues. So I feel comfortable with the position we've taken on our deal targets.

Albert, do you want to comment on PROSPER?

<A - Albert Bourla>: Yes. We did announce in June, together with Astellas, an amendment of the protocol for PROSPER, which is a multinational randomized double-blind placebo-controlled study evaluating the efficacy and safety of Xtandi. The primary purpose of the amendment is to revise the plan for the analysis of the primary endpoint of metastasis-free survival and secondary endpoints. The amendments also reduce the target sample size to approximately 1,140.

Basically, the fundamental reason for the acceleration was that we were able to decouple the metastasis-free survival from the overall survival. And now the metastasis-free survival is the primary endpoint, and will read first. Because we knew we have let's say many more data that have been read out since the time that the protocol was established, we feel very comfortable in discussions with the FDA that we can maintain the same power and reduce the number of patients that are needed to complete the target sample size, and this is the reason for the acceleration. I want to say that, as I said, the enrollment has been completed in June, and results are expected this fall.

<Q - Marc Goodman>: We talked about Ibrance in the U.S. before, but can you give us a flavor for what's going on in Europe? How much geographical growth has there been? We've seen a pretty good ramp quarter-to-quarter; just trying to get a sense for how fast this ramp is going to occur over the next year or so?

Second, Xeljanz, can you just give us a flavor for how it's being used? How much is being used second line or third line or just – we haven't heard from you on that in a while.

And then, third, can you give us an update on the trends in China and how that's going? Thanks.

<A - John D. Young>: Yes.

<A - Ian C. Read>: Thank you, Marc. Why don't – China, I'd ask just to have John start on China, which is – a major part of the business there comes under John's leadership, although Albert can also comment on the innovative in China. And then Ibrance and Xeljanz from Albert.

<A - John D. Young>: Yeah. So China is our largest emerging market. It represents around about 45% of our emerging markets sales, and we see China remaining an attractive growth opportunity. In the quarter for the Essential Health business, revenues were around about $690mm, about 13% operational growth, and we continue to see strength across our portfolio for the Essential Health business. Our portfolio remains a great fit, with priority areas of treatment for the Chinese government, cardiovascular disease, treatment of serious infection, and other noncommunicable diseases. So we actually think that we're very well-placed to continue to grow our business in China. It's a major market where we have invested in the past, and we will continue to be opportunistic in making investments in order to drive our business.

<A - Ian C. Read>: Let's have Frank do the –

<A - John D. Young>: Maybe Frank can talk about the overall performance of the company.

<A - Frank D'Amelio>: Yeah, I'll do enterprise-wide. So, for the quarter as well, China remains a very strong marketplace for us. For the quarter, revenues grew 13%. YTD, revenues grew 16%, and that's compared to last year where revenues grew 11%. And just in terms of how we think about China, it has an increasing population, rising personal wealth, higher spending on healthcare and that's a government public objective – and continues to have a strong GDP. So when we look at China, we remain very bullish, and the results there have been very strong.

<A - Ian C. Read>: Albert, if we can get to you on Xeljanz –

<A - Albert Bourla>: Yes. And Ibrance.

<A - Ian C. Read>: – and Ibrance.

<A - Albert Bourla>: Yes. You're right that Ibrance approvals are continuing across the world. In this quarter we've had approvals in Australia, New Zealand, Taiwan, Jamaica, Jordan, and Oman. In total right now Ibrance is registered in more than 65 countries.

Specifically, in the EU and how we are doing there, through June or through the end of the quarter, the sales in the EU were approximately $200mm, and we have approximately 13,500 patients that have been treated. We are very, very pleased with this performance. Also, the early launch indicators – they saw very rapid Ibrance adoption in first line, but also we have very strong adoption in patients that have already been treated with AI monotherapy, with aromatase inhibitor monotherapy, and in patients in later lines of therapy. We are having positive discussions with reimbursement bodies right now, and generally speaking, I think they are doing well. So we are awaiting – as you know, in Europe it takes time to get the reimbursement, and that will accelerate the sales much more.

Coming to Xeljanz, Xeljanz demonstrated a very, very strong quarter. We had a growth of 56%, and this is primarily driven by volume. In the U.S., the same, 53%, the growth again primarily by volume. The reason of this growth is primarily because there is an increased confidence as an effective monotherapy agent. There is inclusion now in the ACR guidelines. The Xeljanz XR also played a significant role. Right now we have approximately 40% of the prescription volume in total and 60% of the new patients' prescriptions in Xeljanz XR. There is a growing brand awareness among patients. And, last but not least, we had significant improvement in access.

<Q - Tony Butler>: A brief two-part question. I'd love for you to comment on Mylotarg because after seven years it looks like it may be able to resurrect itself. And I'm curious if in fact now with chemotherapy as opposed to single agent, do you actually change the name? Or do you call it the same? And moreover, do you feel like [indiscernible] (1:13:15) would be, let's just say, reticent to try it again even under the umbrella of chemotherapy? Or do you think they embrace it because there hasn't been much new in the AML – at least in newly diagnosed AML category in some time? Thanks very much.

<A - Ian C. Read>: Interesting perspective, Tony. I think we intend to commercialize under its original brand name, and we feel that the new data package and the new label we have will lead to appropriate use of the product, and the physicians should be willing to embrace it. Thanks for the question.

<A - Albert Bourla>: There was a positive opinion just a few weeks ago from an advisory committee in the FDA that was almost unanimous, I think it was minus one vote, to recommend the positive benefit-risk assessment.

<Q - David R. Risinger>: I have two questions. So first for your oncology team, I just wanted to get your perspective on CTLA-4's ability to offer a better benefit-risk ratio than chemo in lung cancer. And I ask you the question because obviously you previously owned the CTLA-4, you know the existing agents quite well, you're developing a more targeted set of early-stage CTLA-4 agents, but just wanted to get some perspective on your current opinion.

And then second, with respect to biosimilars, I was wondering if your biosimilars team is planning to conduct any U.S. biosimilar interchangeability studies? I ask because the Inflectra uptake has been disappointing and also because BI announced in the last few days that it's started enrolling patients in a U.S. Humira interchangeable study. Thanks very much.

<A - Ian C. Read>: Thank you. On CTLA-4, I'll ask Mikael to make some comments, but really his comments are more in the nature of his understanding of the science and general observations of his reading of the science. So, Mikael, what would you like to comment on CTLA-4?

<A - Mikael Dolsten>: Yeah, you know the CTLA-4 antibodies have played some role in melanoma and it's used as a treatment there. It has been hard, I think, looking at the science, as Ian says, to fully develop the potential of that system, as it has a very narrow therapeutic window between the benefit and the systemic side effects. And we noticed in the MYSTIC trials the difficulty of getting those regiments and patient selection at least initially to unleash the potential of that pathway. That led us to focus on second-generation CTLA-4. It's early stage, but aiming to see if we can deliver it more locally into the tumor when it comes to its efficacy. And we've also explored CTLA-4 locally delivered with vaccines, where we think we may be able to get a different type of balance as we've seen systemically. So that's my kind of science comment, and we'll carefully monitor the remaining ongoing trials and see what we can learn.

<A - Charles E. Triano>: Thank you. John, you want to take the last question on – ?

<A - John D. Young>: Yeah. So thanks, David, for the question. So on interchangeability, obviously that is still relatively new guidance from the FDA. We don't believe in our assessment that interchangeability is necessarily going to be equally important across all biosimilars. As a company, we are actively looking at our portfolio and assessing where we believe that actually interchangeability data and an interchangeability designation from the FDA may be valuable both commercially but also to patients and healthcare professionals and their ability to take up and use biosimilars.

And, lastly, I would say on Inflectra, just as a reminder, that obviously as the development program is completed by our partner Celltrion, we don't believe that the profile in the near term is going to be at a competitive disadvantage vis-à-vis any immediate competition that we see that would have an interchangeability designation vis-à-vis us, so we think we're going to have a level playing field there. So thanks for the question.