Company Name: Pfizer
Company Ticker: PFE US
Date: 2018-07-31
Event Description: Q2 2018 Earnings Call

Market Cap: 233,573.37
Current PX: 39.93
YTD Change($): +3.71
YTD Change(%): +10.243

Bloomberg Estimates - EPS
Current Quarter: 0.745
Current Year: 2.952
Bloomberg Estimates - Sales
Current Quarter: 13615.636
Current Year: 54288.737

Q2 2018 Earnings Call

Company Participants

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

Other Participants

- Gregg Gilbert
- Jami Rubin
- Chris Schott
- Umer Raffat
- Vamil K. Divan
- John T. Boris
- Alex Arfaei
- Andrew S. Baum
- Louise Chen
- David R. Risinger
- Jason M. Gerberry
- Geoff Meacham

MANAGEMENT DISCUSSION SECTION

Charles E. Triano

GAAP and Non-GAAP 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 those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's Form 8-K dated today, July 31, 2018

Any non-GAAP measures presented are not and should not be viewed as substitutes for financial measures required by U.S. GAAP, have no standardized meaning proscribed by U.S. GAAP and may not be comparable to the calculations of similar measures at other companies

Ian C. Read

Business Highlights

R&D Pipeline

- During my remarks, I will discuss the progress we are making within each of our businesses, the latest advancements within our R&D pipeline and some of the steps we are taking to prepare the company to accelerate top line growth in the future
- In the second, quarter total company revenues were up 2% operationally, driven by the continued growth of key brands, biosimilars and emerging markets
  - These growth drivers were partially offset by the loss of exclusivity of Viagra in the U.S. in December 2017, a decline in U.S. legacy-established products and product supply shortages related to our legacy Hospira products

Pfizer Innovative Health

- I'll begin with a few words about each of our businesses starting with Pfizer Innovative Health
- This business had another solid quarter, growing its top line 5% operationally thanks to the continued strength of several of our biggest selling medicines
- In Q2, global Ibrance revenues were up 19% operationally to just over $1B
  - This was driven by strong growth in international developed markets which represents our next avenue of growth potential for the brand
- And to a lesser extent, in emerging markets and the U.S., Ibrance continues to hold a leadership position in first-line hormone receptor-positive HER2 negative metastatic breast cancer
  - Since its launch, approximately 12,000 physicians have prescribed Ibrance in the U.S. and more than 140,000 patients have been prescribed the medicine worldwide

CDK Category

- The overall CDK class continues to grow within the eligible patient population, although penetration has decelerated to approximately 64% of eligible first-line newly started patients in the U.S. receiving CDK therapy
- Within the CDK category, which now includes two competitors, Ibrance total prescription share is 91%

Xtandi'

- Xtandi's U.S. alliance revenue grew 21% to $171mm
- We received good news earlier this month when the U.S. FDA approved a supplementary new drug application for Xtandi based on results from the Phase 3 PROSPER trial
- The approval broadens the indication for Xtandi to now include men with non-metastatic castration-resistant prostate cancer
  - This makes Xtandi the first and only oral medication that is FDA approved for both non-metastatic and metastatic CRPC and the anticipated approval of this indication was a key factor in our evaluation of Medivation

Xeljanz

- Xeljanz continues its strong performance, with revenues increasing 37% operationally in the quarter to $463mm

- We received several additional regulatory milestones since our last call
- In May, the FDA approved Xeljanz for the treatment of adults with moderately to severely active ulcerative colitis
- Days earlier, it was also approved in Japan for the same indication
- In June, the European Commission approved Xeljanz in combination with Methotrexate for the treatment of active psoriatic arthritis in adult patients
- In addition, we recently received a positive opinion from the CHMP in Europe recommending marketing authorization for Xeljanz for adult patients with ulcerative colitis, and we look forward to the potential approval of this indication
- For a broad array of indications, ease-of-use and a good tolerability profile, we see Xeljanz increasingly becoming a go-to product with rheumatologists and GI physicians

Eliquis

- Worldwide, Pfizer's revenue for Eliquis were up 42% operationally to $889mm, driven by strong growth in the U.S. and the EU
- In the U.S., Eliquis now makes up more than half of novel oral anticoagulant prescriptions, widening its market share lead in the quarter from 10% to 13 percentage points ahead of our primary competitors
- Finally, we continue to review strategic options for our Consumer Healthcare business, which delivered another solid quarter

Pfizer Essential Health

- Turning now to Pfizer Essential Health
- We once again saw strong operational growth in emerging markets and in our biosimilars portfolio

Revenues

- Overall Essential Health revenues for the quarter declined however, due in large part to the ongoing product supply shortages in the sterile injectable business, continuing product LOEs, namely Lyrica in developed Europe and a decline in the legacy established products portfolio in developed markets
- Emerging markets revenue within the Essential Health business grew 10% operationally for the quarter to nearly $2B
- China led the way, growing 24% operationally
- Revenues from our biosimilars business grew 44% operationally in the quarter to $188mm

Biosimilars and Sterile Injectables Business

- Our growth in biosimilars was driven primarily by Inflectra in certain channels in the U.S. as well as in developed Europe
- We expect to broaden our biosimilars portfolio in the U.S. by potentially bringing five biosimilars to the market in the next two years

- In our sterile injectables business, as stated in first quarter earnings, we expect to see improvements in the y-over-y comparisons during the third and fourth quarter
- We continue to strengthen and advance our pipeline, which we believe has the largest and most promising array of late-stage prospects it is had in decades

Developments

Rare Diseases and Internal Medicine

- Let me touch on some of our more promising recent developments
- In rare diseases, following the positive top line results from our Phase 3 study in patients with TTR cardiomyopathy, tafamidis received breakthrough therapy designation from the U.S. FDA and a similar designation from the Japanese Ministry of Health, Labour and Welfare
- We see this as a potentially highly important break for these patients and we look forward to presenting the full study results in August at the European Society of Cardiology conference
- In internal medicine, on July 18 we, along with our partner Eli Lilly, announced that a Phase 3 study evaluating subcutaneous administration of our investigational humanized monoclonal antibody tanezumab in patients with arthritis pain met all three co-primary endpoints
  - This study was a 16-week dose titration study evaluating tanezumab for the treatment of osteo pain
  - If approved, tanezumab would be the first in a new class of non-opioid treatments for this disease

Oncology

- In oncology we currently have four potential medicines under priority review at the FDA, lorlatinib, dacomitinib, talazoparib, and glasdegib
- In inflammation and immunology, we have built what we believe is a true leadership position with our JAK franchise and currently have 10 ongoing selective immunokinase programs

Phase 3 and Phase 1 Study

- We are continuing to recruit for our Phase 3 study for our JAK1 molecule in atopic dermatitis, for which we received a breakthrough designation by the FDA
- We initiated a Phase 3 study of our own Xeljanz, our first JAK inhibitor in adult patients with active ankylosing spondylitis
- We initiated a Phase 1 study of a topical agent in patients with mild to moderate plaque psoriasis, and later this year we expect to share progress in our next generation JAK assets that has the potential to be a first-in-class treatment for alopecia areata, a disease for which there is no approved preventive therapy or cure

Phase 3 Program

- In vaccines we achieved proof of concept for our next generation multivalent pneumococcal conjugate vaccine candidate with the potential to cover 20 serotypes, and we are currently planning our Phase 3 program
- We have currently three gene therapy programs in clinical studies, the Factor IX collaborative program with Spark Therapeutics has started to enroll patients for Phase 3

- This marks the first gene therapy Phase 3 program that Pfizer has initiated, and this remains an area of high interest to us

Gene Therapy Program

- Our gene therapy program for Duchenne's muscular disease has started dosing
- The first few patients in a Phase 1/2 trial and our collaboration with Sangamo is advancing the Phase 1/2 dose escalation study cohort
- Through 2022, we continue to see the potential for approximately 25 to 30 approvals, of which up to 15 have the potential to be blockbusters subject to some expected attrition
- The previously referenced approvals for Xeljanz and Xtandi represent the first two of these 15

New Structure

- Before I close, let me briefly recap the announcement we made on July 11 regarding the modifications we'll be making to our structure
- Effective at the beginning of the company's 2019 FY, Pfizer will have three businesses, a science-based innovative medicines business, which will now include biosimilars and a new hospital business unit for anti-infectives and sterile injectables, an off-patent branded and generic established medicines business operating with substantial autonomy, and a Consumer Healthcare business
    - This new structure represents a natural evolution for our business as we transition to a period post 2020 were we expect a higher and more sustained revenue growth profile
- And given the growing importance of emerging markets to Pfizer's business, we see this new structure better positioning each business to accelerate its growth

Summary

In summary, we continue to deliver on our strategy and believe we remain well positioned to deliver new medicines for patients, enhance shareholder value and prepare the company for accelerating growth in the future

Our in-market products remain strong

Our late-stage pipeline contains several potential blockbusters

We remain prudent with regard to capital allocation, and our engagement with policymakers around the world continues to focus on creating an environment that maximizes a benefit for both innovators and patients

It's our job not only to discover and develop medicines and vaccines, but also to advocate for affordable access so they can help the maximum number of people who need them

- As such, we will continue to work with the president on his blueprint for strengthening the healthcare system, providing more access and relieving the burden on patients at the point-of-sale

Frank D'Amelio

Financial Highlights

Revenues

- As always, the charts I am reviewing today are included in our webcast
- Now moving on to the financials
- Second quarter 2018 revenues were approximately $13.5B, which includes the favorable impact of foreign exchange of $377mm and operational growth of $194mm

Innovative Health Business

- Our Innovative Health business recorded 5% operational revenue growth in Q2 2018, driven primarily by Eliquis, Ibrance and Xeljanz globally, Prevnar 13 primarily in emerging markets and the U.S., and Xtandi in the U.S., which were partially offset by the loss of exclusivity of Viagra in the U.S. in December of 2017 and Enbrel in most developed Europe markets due to continued biosimilar competition

Essential Health Business

- I want to remind everyone that Viagra revenues generated in the U.S. and Canada shifted to the Essential Health business at the beginning of 2018
- Revenues for our Essential Health business in Q2 decreased 4% operationally, primarily due to a 12% operational decline in legacy established products portfolio in developed markets; a 17% operational decline in the sterile injectables portfolio in developed markets, primarily due to continued legacy Hospira product shortages in the U.S.; an 11% operational decrease in peri-LOE products in developed markets, primarily due to the expected declines in Lyrica in developed Europe, all of which were partially offset by the inclusion of Viagra revenues in the U.S. and Canada; 10% operational growth in emerging markets, reflecting growth across all portfolios; and 44% operational growth in biosimilars, mainly driven by Inflectra in certain channels in the U.S. and in developed Europe

Diluted EPS

- Second quarter reported diluted EPS was $0.65 compared with $0.51 in the year-ago quarter primarily due to higher other income, due to unrealized net gains on equity securities reflecting the adoption of a new accounting standard in Q1 2018; increased income from collaborations; out-licensing arrangements in the sale of asset rights; and lower charges for certain legal matters; as well as a lower effective tax rate due to the enactment of the Tax Cuts and Jobs Act, or the TCJA in late 2017; increased revenues and foreign exchange impacts; and fewer shares outstanding, all of which were partially offset by higher cost of sales
- Adjusted diluted EPS for Q2 was $0.81 vs. $0.67 in the year-ago quarter

Average Shares Outstanding, Expenses and EPS

- The increase was primarily due to the previously mentioned factors
- I want to point out that diluted weighted average shares outstanding declined by 85mm shares vs. the year-ago quarter, due primarily to our ongoing share repurchase program, reflecting the impact of shares that were repurchased during Q1 2018, partially offset by dilution related to share-based employee compensation programs
- As I previously mentioned, foreign exchange positively impacted second quarter 2018 revenues by approximately $377mm and negatively impacted adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses in the aggregate by $228mm

- As a result, foreign exchange favorably impacted second quarter 2018 adjusted diluted EPS by approximately $0.02 vs. the year-ago quarter

Revenue, Adjusted R&D Expenses and Income

- We updated the following components of our 2018 financial guidance
- Revenue guidance was updated solely to reflect recent unfavorable changes in foreign exchange rates from mid April of 2018 to mid July of 2018
- The adjusted R&D expenses guidance range was updated to reflect higher spend than previously anticipated in H2 2018 due to our late-stage development programs
- Adjusted income in H1 2018, which was much higher than one half of our previous full-year expectation for this component due to nonrecurring items; consequently we updated our guidance primarily to include unrealized net gains on equity securities and one-time items such as milestone payments from certain collaborations and out-licensing arrangements, and the gain on the sale of certain asset rights in H1 2018

Tax Rate

- The effective tax rate on adjusted income guidance was updated to reflect the implementation of the Tax Cuts and Jobs Act
- While this estimate will continue to be subject to further analysis, interpretation, clarification of the TCJA, we believe that this revised guidance will be sustainable beyond 2018
- As a result of these updated components, we are raising our 2018 adjusted diluted EPS guidance by $0.05 to $2.95 to $3.05, the midpoint of which implies 13% growth compared with 2017

Share Repurchases

- I want to point out that our 2018 financial guidance assumes no additional share repurchases
- To date in 2018, we repurchased $6.1B of our shares
- We expect the dilution related to share-based employee compensation programs to offset the reduction in shares associated with these share repurchases by approximately half
- Finally, as of July 31 of 2018, we have $10.3B remaining under our current share repurchase authorization

Operational Revenue Growth, EPS, Dividends and Share Repurchases

- Moving onto key takeaways, we delivered strong financial results in Q2 2018 with 2% operational revenue growth and a 21% increase in adjusted diluted EPS vs. the prior-year quarter
- We increased our adjusted diluted EPS guidance range, but we also lowered the midpoint of 2018 revenue guidance range solely to reflect recent unfavorable changes in foreign exchange rates
- We announced plans to begin operating under a new business structure beginning in 2019 and accomplished several key product and pipeline milestones
- We returned $10.1B to shareholders in H1 2018 through dividends and share repurchases
- Finally, we remain committed to delivering attractive shareholder returns in 2018 and beyond

QUESTION AND ANSWER SECTION

<Q - Gregg Gilbert>: I'll ask two. I want to start with a pipeline question on tafamidis, if I'm pronouncing that correctly. Can you talk about the potential for that asset in light of the low diagnosis rates there and what you plan to do to build that market?

And then a bigger-picture strategic question, Ian and team, I'd like to better understand the decision you've made to reorganize the way you decided on and want to better understand whether it's tied to Albert digging in as COO and making decisions based on operational factors? Is it a realization that biosimilars will look more like brands than generics? Just some more color on what the new structure will achieve that the current one does not would be helpful. Thanks.

<A - Ian C. Read>: Okay. Albert would you like to discuss tafamidis? I think it's a name that you'll very soon remember very clearly as you see its impact on patients. But Albert can talk to tafamidis. I'll make some opening comments on the reorganization and then Albert, continue to explain the reorganization. Thank you.

<A - Albert Bourla>: Thank you, Ian, and thank you for your question, Gregg. Tafamidis is a medicine that met its primary endpoint, demonstrating statistical significant reduction, but also meaningful clinical reduction in the combination of all-cause mortality and frequency of cardiovascular related events. This is for a disease that it is rare, but it is rare because it's significantly underdiagnosed. Right now it is expected that less than 1% of the people suffering from this disease are diagnosed actually, and a big role in that plays the fact that, until now, there was no efficient treatment.

We believe that the prevalence, which is unknown, it is quite large actually, and with a product that we're going to present the results in August in the congress in Munich, that offers significant treatment options. This market could become really large. Our efforts will focus on explaining to physicians about the treatment option but also helping them understand better the disease and increase the diagnosis rates. So more to be said after the August conference in Munich when we will announce the results.

<A - Ian C. Read>: Thank you, Albert. So, Gregg, on the restructuring, this is something that Albert as COO was reviewing in that role, discussed extensively with me. It basically represents I think a pivot in the company towards growth as we see the strength of our pipeline, the need to invest in our pipeline and the need to structure around growth drivers, certainly emphasized by the fact that the optionality construct, as we said Q1, we no longer saw as viable. So with that, I'd like Albert to explain a little bit why we are structured around growth and why this is good for the company.

<A - Albert Bourla>: Yes. Thank you, Ian, and as Ian said, the previous decision not to separate PA agent, PA testing dependent corporations but also with the comprehensive U.S. tax reform now in place, and more importantly with an increased confidence in our pipeline, now the growth is in sight in combination with the lack of LOEs. So as Ian said, we decided to organize our businesses from the base of growth drivers which will provide better operational ability to manage this business.

So a few words about those three segments. The first one, it is the cost segment of Pfizer, it's the fundamental 80% of our business and this is a science-based innovative medicines business. The fundamentals of growth in this area are very, very strong because we have an aging population, but it is increasing the demand for innovative medicines, but also science is in a position to deliver solutions right now. Frankly, Pfizer is a position to deliver strong solutions. We have made very public our release of 15 blockbusters that are expected to get registered in the next five years. So the fundamentals of growth are very strong.

In addition to the five already existing business units, we added biosimilars under oncology and I&I and immunology. The reason is that first of all this is, as the rest of the business is, high risk, high reward, heavy in R&D investments business, the biosimilars, but even more importantly right now all of our biosimilars are either registered or about to be registered in the next 12 months, which means that they are all entering commercialization phase. By placing them under the oncology and immunology businesses, that both of them, they have very strong expertise in the commercial,

in the scientific and in patient experience domains, we expect that the commercialization of these products will be very strong.

The same comes with the hospital business unit that we are creating, putting underneath anti-infectives and sterile injectables. These are businesses that will grow. The sterile injectables is facing now some issues because of manufacturing supply considerations, but those will be resolved and the business will return into growth. And more, we have more than 100 research projects in this business. So that's why we created this business, to innovate.

Now if we move to the established business, the established business also had very strong fundamentals of growth, but they are very different than the researched-based high-risk high-reward innovative business. The growth drivers in this business are urbanization. The growth drivers in this business, it is a middle class that is rising, particularly Asia, and provides access to hundreds of millions of people. If you see our Chinese business, this quarter H1 is growing almost 25%. This means for the size of our business that we are generating in H1 approximately $500mm. If you extrapolate, you could expect something like $1B of growth into a business.

Significant fundamentals. What you need to be successful in this business, it is to make sure that you have good awareness of the local markets. This is why we are placing an [ph] EOT (26:57) team member in China to be able to manage these opportunities. And you also require good autonomy, because this is a fast-moving business. This is why we are creating a company, like we are creating a division within Pfizer that will have relatively increased autonomy.

And moving to the third business, we always had the consumer business, always was operated independently. We are increasing a little bit the independence of the business, because the fundamental growth drivers has nothing to do with our prescription medicines. It has to do with the growth of consumers, of consumer consumption and it has to do with the growing element of wellness that exists in the society. And we continue examining options of course as we said for this business, and we will make our decision by the end of the year.

<Q - Jami Rubin>: I just have a couple questions. Ian, you guys have clearly been ahead of the industry in creating separate business units for reporting purposes, giving yourself optionality to spin if it made sense. And obviously it hadn't made sense, and we get that, and that's why you've decided to keep those businesses. But clearly with corporate simplification sweeping through the industry and companies clearly being rewarded for such actions, do you still feel that if conditions are right, do you believe that spinning off say the established business or the Essentials Health business is a positive, would be positive, would add value to your shareholders? Or do you believe that keeping a large company intact better serves your shareholders? That's my first question. And maybe, Albert, I'd love your take on that as well.

And then, Frank, I had asked you this question on the last earnings call, not sure. The answer was what I think we were expecting to hear, but I'm going to give you a chance to answer it again. Assuming that you don't do a large mega deal, can you still drive bottom-line leverage post 2019, post your LOEs? Your margins are around 40%. Can they get to higher than that, 43%, 44%, 45%? I think on the last earnings call you were pretty definitive in saying no, but just want to make sure you understood my time horizon, which is beyond 2019. Thanks very much.

<A - Ian C. Read>: Jami, thank you for the questions. So I undoubtedly believe that Pfizer has always organized itself in a way that was structurally prevalent for the market of that time and our objectives. I think this recent reorganization is around growth drivers. It does bring an element of simplification and I think it allows us to continue to evaluate our business segments to see if they're worth more inside Pfizer than outside of Pfizer. So we will continue to do that. We're very focused, have always been focused on shareholders return, not the size of the company. And so rest assured that we will, as these businesses continue to develop, look at opportunities to maximize their value. Albert do you want to add anything to that?

<A - Albert Bourla>: Ian, you said it very well and the only thing that I will say is we're always examining options for our businesses. But right now the focus, particularly in the established business, is to stand it up as a successful emerging markets-based business.

<A - Ian C. Read>: Right.

<A - Albert Bourla>: And then all options are open once we do that.

<A - Ian C. Read>: Good. Thank you. And, Frank, you want to answer Jami's beyond 2019 perspective.

<A - Frank D'Amelio>: Yes. So, Jami, when I answered the question on the last call and I remember your question, I answered it for what I'll call the foreseeable future. And what I was thinking was really kind of through 2020 where we would see the impact of Lyrica, the Lyrica LOE. Beyond 2020, as we enter this period of growth, right, as we have this inflection point that we've talked about with LOEs declining materially, our in line portfolio continuing to perform, our pipeline playing out in a positive way, then yes, we do have the ability to see leverage to the bottom line.

<Q - Chris Schott>: Just two questions. The first on Ibrance and just two parts here. First, U.S. growth appears to be flattening out. I think you talked about penetration in the 60s at this point. I guess, what can you do to drive further uptake in the market? And where do you think penetration can go over time on the U.S. side? The second part of the question is on the flip side, ex-U.S., seems like it's gaining momentum here. Maybe just update in terms of where we stand for penetration on the ex-U.S. core markets.

The final question for Ian, talk a little bit more about the president's blueprint for reducing drug costs and potential changes to rebate structures. I know there's a lot of uncertainty of how this is going to play out. But how likely do you think it is that we're going to see changes to the current industry pricing structure? And how do you think about that and prepare for any changes from a Pfizer perspective? Thank you.

<A - Ian C. Read>: Thank you, Chris. I'll let Albert discuss Ibrance and then I'll come back to your question on the evolving pricing and our market access situation in the U.S.

<A - Albert Bourla>: Thank you, Ian. And Chris, again, thanks for your question. For Ibrance we are very, very pleased with the performance. We had 19% operational growth if you compare it to last quarter, the same quarter of last year and 10% sequentially vs. Q1 this year. And let me start by addressing the international market, and I will go to the U.S. Very, very strong performance in international markets. The sales are up almost 125% and this is driven predominantly by volume.

We had very strong uptake in all the European markets that we have launched and we have just launched in Japan and we see the same trends over there, very strong uptake of the brand. In fact, and important, I found it intriguing statistic it is that as of March, 96% of the total packs that were sold have been sold in the EU5, in the five European markets, were Ibrance. Although, over there the reimbursement didn't come with big disparities between us and competition.

Now let's move into the U.S. In the U.S. the growth was 3% sequential vs. the previous quarter. So obviously we have a deceleration here of the growth. The growth deceleration has nothing to do with us losing market share. Actually, our market share remains strong, remains stable and is actually a 10% increase. The deceleration has to do with the fact that the overall CDK market is decelerating because right now the low hanging fruit has been already been harvest and what remains, it is late adopters. They need more time to be convinced to prescribe the new class.

We do believe though that the class will grow and we have strong evidence for that, the fact that when you see the overall survivor class in metastatic breast cancer, is in the 60s, as you mentioned, Chris. But if you see the new starts, it is already in the 70s, which means that we have a tendency to see over time we'll see the 60, 70. And what we do with that, we continue our D2C advertising. We continue to be able to communicate to the broad patient population about the benefits of CDK. But also we are working with currently prescribing physicians to increase usage and to increase the scripts that they progress.

So growth in the U.S. I think in the short term will come from expanding the usage or the prescription habits of physicians already prescribing. But in the midterm of course, and this is by far the biggest growth opportunity, we are expecting to come into the earlier settings with a few pivotal studies currently running, as you know.

<A - Ian C. Read>: Thank you, Albert. On the present blueprint, I mean we have submitted comments which I believe are public record. Pharma has submitted comments. Overall, we're very supportive of the blueprint. I think the president is trying to maintain a market-based system in the United States which is positive. Probably one of the largest changes, which I think would be overall positive for the industry, is the secretary's intention to remove the Safe Harbor

for discounts so as to eliminate rebates.

At the moment in time, about 40% of pharmaceutical prices are subsidies to the rest of the health care system. We realize some 58% of our list price. The rest goes to subsidize profitability of PBMs, insurance companies and frankly premiums for those that are healthy. This is not a sustainable position, and so removal of the rebates I believe will be very beneficial to patients and our industry, especially those companies who are launching, those companies who are launching new products over the next five years or so.

With the removal of the rebates, we will remove the sort of what we call the rebate trap, whereby access is denied to innovative products because of a strong position of another product with its rebates. That example would be Xeljanz's slow penetration but steady into its market, given the situation of rebates of bigger competitors. I think the president is focused on improving through trade agreement the free riding that occurs on American consumers and research. He wants to promote value-driven healthcare by linking payments to performance. He's focusing on improving the efficacy of the FDA and I think that's going well so far.

And he intends to reform the 340B program, which I believe is important. This is completely distorted compared to what congress had originally intended for that program. So overall, I suppose we see more focus on net prices, rebates going away and the blueprint being implemented, which is I believe is positive for patients and positive for innovative companies.

<Q - Umer Raffat>: Ian, sorry I was just listening to your answer just now. Can you just clarify, do you expect U.S. to not have a rebate system anymore? And then also on that same note, if the price increases in future are limited to low single digits, do you think that impacts your expectation for mid-single digit top line growth for the overall company?

And a quick one on R&D if I may as well. One of the key trials for Ibrance, the PALLAS trial in adjuvant setting, can you confirm it has both low and medium risk patients along with the high-risk patients? And I ask because Novartis recently terminated a Phase 3 trial which had a hydrogenase mix of risk status across the trial. So I'm just curious if you think that introduces a layer of risk in that trial or not? Thank you.

<A - Ian C. Read>: Okay. On the rebates, I do believe that the intention of the administration is to remove the Safe Harbor for rebates. Today, I would believe we're going to go to a marketplace where we don't have rebates. I don't know the speed of that, but I do believe the administration has been focused on that because that will reduce pharmaceutical prices at the point-of-sale and very positively by removing the 40% subsidy that goes to the rest of the healthcare system and putting it back on reducing pharmaceutical prices at the point-of-sale.

So we will be focusing on net price increases and you would expect them to fluctuate around healthcare inflation. As new data comes available, you may see different value equations for products that in general are around health care inflation and I don't see that as any obstacle to us growing to middle to high single digits as our growth will be coming from innovative products creating new markets. So, and as I said before, I think the removal of the rebate trap will be advantageous to Xeljanz and be advantageous to our biosimilars programs. Would you like to answer the Ibrance question please, Mikael?

<A - Mikael Dolsten>: Yeah. Thank you. With two large Phase 3 adjuvant early breast cancer trials, one is in registration, PALLAS has built intermediate and high-risk early breast cancer treatment duration up to two years. We also have the PENELOPE-B trial with high-risk adjuvant early breast cancer setting. We are very confident in our CDK and Ibrance leadership and I think the particular compelling part of Ibrance for adjuvant therapy which may be different to some other CDK is the great tolerability and the limited need for monitoring of liver EKG or difficult tolerability with G.I. So that really makes, I think, Ibrance a unique, attractive drug for a trial like PALLAS. We look forward to the outcome of that trial.

<Q - Vamil K. Divan>: So the first one I guess is for Ian and then one on the R&D side. So for Ian, just on the new structure, I'm curious regarding business development and if this new structure in any way impacts your views around how you would pursue deals? Specifically, are you looking for deals that might be more targeted to one of the three segments? Or could a larger, overarching deal still be something of interest?

And then second question, more on the pipeline on the immunology side, you mentioned, I think you said, 10 unique programs in immunology but obviously it's a very competitive space now with a lot of players. So I'm wondering if you could maybe just frame the two or three opportunities maybe in the pipeline that you're most excited about out of all of the various kinases that you have in development and when we'll see some of the key data for those assets to help us better assess those opportunities. Thanks.

<A - Ian C. Read>: Okay. Let me answer the structure as it relates to the type of deals and then Mikael will answer your questions on the pipeline, Vamil. So you know our view of BD hasn't changed much in the last couple of years. We view BD as an enabler of our strategy, not a strategy in itself, and our compass for any deal has always been generating value for Pfizer shareholders.

Specifically, at this time, regarding a large or transformative deal, I don't believe we need such a deal to drive the growth of this company. I would be and I think our leadership team is united on this view, we'd be far better off focusing on developing our pipeline, investing in our pipeline, bringing these products to market, growing these products, than undertaking a large deal. A large deal is always available to us, but the chance of developing this pipeline is unique in this moment. It requires more research, more focus and as I say, any large deal is always available to a company with our balance sheet and size.

So we would be looking at, if we were doing business development and we continue to look at the market for business development, more in single deals, things around late Phase 2, early Phase 3, something that can continue to boost our pipeline in sort of five-plus years. So that would be our focus right now. As I said, never say never, situations change, valuations change, but at this moment that is our thinking around BD and it links to this new structure with its focus on growth in all segments of the business. Mikael, would like to answer the question?

<A - Mikael Dolsten>: Yeah. So thank you for your interest in the JAK franchise. And first, we think Pfizer is well positioned for sustained and growing leadership. We have Xeljanz now already used in three indications, RA, UC and PSA, and are conducting additional pivotal studies in ankylosing spondylitis. We have now 10 Phase 2 and 3 studies running with new generation of JAKs and five different NME JAK-related drugs in clinical studies.

For the specific examples, JAK1 is in Phase 3 for atopic dermatitis. We are very excited about the JAK1 drug class, with rapid onset of action, with strong efficacy on eczema skin clearance and pruritus, itching, which has really the potential to be differentiated from the first marketed biological in atopic dermatitis.

The second would be, we have a novel JAK that we'll present first-in-class data in alopecia areata later this fall. This has the possibility to be swiftly followed by a pivotal study, pending regulatory dialogues. This novel JAK represents a new treatment option possibility for alopecia and other autoimmune diseases with similar mechanisms such as impetigo.

And we have three different assets in rheumatology in Phase 2 studies. Readouts from those will guide future potential pivotal study design. We're also planning to expand our presence in ulcerative colitis where we have Xeljanz and are running several studies in Crohn's disease with new generation of JAKs specifically tailored for such diseases.

<Q - John T. Boris>: Ian, since you did have an opportunity to speak with the president on pricing, did he indicate anything about the timing for implementation of the new plan on rebates? Is that something we'd see before the midterms or after the midterms?

Second question has to do with the increase in R&D investment that Mikael was able to secure. What are the programs that you're going to be allocating that several hundred million dollars behind?

And then third question has to do with gene therapy and your strategy behind your portfolio of gene therapy assets, most notably the Factor VIII/IX program and the neuroscience program in Duchenne's Muscular Dystrophy. Can you articulate what your strategy there is in gene therapy? Do you want to grow that organically or potentially do some tuck-ins around that area? And do you have the adequate manufacturing capabilities to be able to produce enough product for the areas that you've targeted? Thanks.

<A - Ian C. Read>: Hey, John. Thank you for the questions. My conversations with the president were centered around his blueprint and the actions he wants to take in those blueprints. I didn't obviously – you don't get definitive dates out of an administration. But I think I would say I see a huge sense of urgency on the part of the administration to act on the rebate part of the middlemen where they see that the subsidy that pharmaceuticals is delivering to the rest of the healthcare system is unsustainable and needs to be corrected. So I expect the administration to act on that with as much urgency as they can.

With regard to the gene therapy, I mean we have made a substantial investment in manufacturing in gene therapy. The plan is, we'll come online within the next couple years, about $300mm to date. We've committed to that. We're committed to gene therapy. We have the gene therapy that Mikael had just mentioned. We would look to tuck-ins if they were available. That's part of our view on buying intellectual property that has within the next five years launch potential. And we're committed to this area and we think we have a strong franchise. We certainly are not going to buy gene therapy that we think is way overpriced, but we will buy gene therapy that we think has value.

On the U.S. R&D, I'll really ask Mikael and Albert to comment on specific programs, but I would say that most of it is focused on ensuring that those 15 products get launched and in development spend. Albert, do you want to make a comment here?

<A - Albert Bourla>: You're exactly right and that Mikael can give more details, but we are focused on new Phase 3 starts. We are focusing on the next generation pneumococcal vaccine that it is about to start. We are focusing on JAK1 atopic dermatitis Phase 3. That has already been started. We are focusing on starting Phase 3 studies with other JAKs right now. Mikael? In gene therapy that we just spoke, we are having three clinical programs that we are scaling up right now.

<A - Mikael Dolsten>: I think you said it very well. We have a growing Phase 3 registration portfolio where all areas are contributing. Indeed, the pace of pipeline today is close to 100 clinical projects, of which more than 40%, 4-0, are in Phase 3 registration, and we're geared up to deliver up to 15 blockbuster potentials over the next five years as well as preparing for the next wave of even stronger productivity going from 2023 and onward. Thank you.

<A - Ian C. Read>: Thanks, Mikael. Okay. I'd just add to that, that we also have trials that are extremely large in the vaccine, 20, where we're entering into Phase 3, and we tend to be very competitive there and also in our vaccine for [indiscernible] (50:31) which is – and for C. diff. Now C. diff is a large trial. We are the leader in that category. One of our competitors withdrew from developing their products. This is a significant disease burden. We need to invest. We need to make sure we get to the events and expand the cohorts. So we're putting a lot of money into vaccine trials as well.

<A - Mikael Dolsten>: And many Phase 3 are coming right now, so it's a good time for R&D pipeline.

<Q - Alex Arfaei>: Ian, a follow-up on your comments on the administration's blueprint and planned changes to rebates. Obviously per your comments, under the current structure there are billions of dollars at stake and probably thousands of jobs, so there will be pushback to this. I'm just wondering, are you still confident that the administration will pursue this with urgency? And also, do you believe the changes will be limited to the government business or will it also extend to the commercial side as well?

Then a follow-up on tanezumab, if I may. You're obviously looking at rapidly progressing OA in a much more systematic way than you did in the prior trials. So given that, are you using the same definition for RPOA? And given the methodology differences, is it appropriate to compare the rates in the new trial to the prior trials? Thank you very much.

<A - Ian C. Read>: Thank you. Look, you know, reform of systems is unpredictable. I believe that the administration is focused on rebate reform. I believe that initially their reforms will be focused on the public sector where they have the authority to take the rebates out of the Safe Harbor, but I believe that will extend to the commercial business very, very quickly as I can't really see a bifurcated system where half the system is on net price and the other is on a rebate. It's just the transparency won't allow that. So I would see rebates going away and the system accommodating itself to negotiations on value and net price. But as I said, this is a political decision, and you have one person's view and we'll

have to see. But I do think it's a priority for the administration. Mikael, would you want to talk about Phase 1?

<A - Mikael Dolsten>: Yeah. Thank you. First, I just wanted to say that we are really pleased with the readout of the recent tanezumab OA 1056 study which showed positive outcomes for tanezumab compared to placebo in all three primary, co-primary or pain physical function in patients' global assessment. And the drug was well-tolerated in general with less than 1% patient discontinuing therapy.

Now concerning rapidly progressing away, despite this, OA study was conducted in a more advanced patient population were patients have already failed other therapies. The rate of RPOA rapidly progressing away in the treatment group was less than 1.5%, which we think is a similar ballpark back run rate to what's been seen in other large OA studies.

The decent profile of tanezumab will be partly supported by the readouts next year, and overall we believe that tanezumab has the potential to offer a valuable treatment alternative for pain patients that are currently poorly managed by a variety of treatment alternatives, such as opioids and NSAIDs.

<Q - Andrew S. Baum>: Just one question please. The culture and cost base of an optimal established product business I would imagine is very different from a business which is buried within its pharma company. To what extent do you think the restructure could realize significant improvement of the cost structures, whether it's optimizing the growth? And then beading on from that, would you be giving guidance for each of the individual business units, revenue and/or EBIT? Thank you.

<A - Ian C. Read>: We will not be giving guidance for the individual units. We'll be giving guidance for the stock ticker of Pfizer. But I believe this is about more about getting the right focus and the right management and positioning our headquarters of this new BU or positioning the leader that's that way in China. I think it will lead to simplification, will lead to savings in our expense base. But that is not a primary motivation for doing this. It's more about getting focus of management around key sectors. Albert, would you like to add to that?

<A - Albert Bourla>: I think you said it very well, Ian. And I would add that indeed it is different, the cost structure of a business in aggregate. It is not likely innovative, but just heavy in R&D. That business will not. But also it's not like a generic business, because this is business. It is a growing in the emerging markets business, where it has significant field force presence, and this is how we are driving our growth. And this is why I think we have a competitive advantage to be able to lead in that space, exactly because we are very well entrenched into the physicians and the prescription base of these markets.

<A - Frank D'Amelio>: The only thing I would add is that it's a business where we've taken significant savings already.

<Q - Louise Chen>: I had a few on your pipeline. So first on tanezumab, could you comment on what you think the approvability of your drug would be despite some of the safety concerns? And then secondly on tafamidis, just curious how you distinguish your product from others that are potentially in development. And then the last one is just on the JAKs, the alopecia areata opportunity, could you size what that market opportunity might be and what you think the right pathways are for a JAK product to deal with alopecia areata? Thanks.

<A - Ian C. Read>: Okay. Why don't we have Albert talk about the size of the market for alopecia areata and then we'll have pipeline answers by Mikael.

<A - Albert Bourla>: We think it is a significant market, because this is a market that is that it is extremely emotional for people. We've done extensive market research with patients. And one of the things that it was very indicative for me, it is in our clinical studies. We are enrolling faster than anything I have seen so far, which is an indication of how much patients they consider what a very big medical need. With that I will ask Mikael to comment on all the R&D questions.

<A - Mikael Dolsten>: Yeah. First on tanezumab, I'm real excited about the way forward for tanezumab supported by the positive primary endpoint that I spoke to in the doses we have selected, the convenient substitute cutaneous administration and good tolerability. Of course, all approvals are pending final readout and regulatory dialogues, but

what makes me excited is that there is a real scarcity in new pain drug classes and pain patients, which has a real impact on the life quality needs new drug classes. And you are obviously aware of the challenge we have as a nation with extended and excess use of opioids. And tanezumab offers for patients that are not eligible or well tolerating or willing to take opioids, or progress on opioids, NSAIDs, are really I think attractive alternative. And we look forward to detail the benefit risk profile as all studies read out next year.

<A - Ian C. Read>: So, Louise, just adding to Mikael's and my detail on those comments, I do think we see the alopecia areata and the clinical indications around that mechanism of action to be a blockbuster status. So where I can do forecasts, I would consider that to be a blockbuster. And I just want to correct something on the gene therapy plant, it'll be ready to produce at industrial scale in early 2019.

<A - Mikael Dolsten>: Thank you, Ian. And finally on tafamidis, what is distinct in that trial, Albert alluded to earlier that we are studying the cardiomyopathy indication which has the majority of patients wild-type excess production of TTR and a smaller proportion of patients are mutant. We have recorded a really great tolerability profile and we'll share that outcome in more details of what was a positive study including all-cause mortality and severe related hospitalization. But to the very best of my knowledge, this is the only pivotal study available that have outcome data and includes the most prominent patient population, the wild-type.

To run such a study takes more than four years, so we think that tafamidis will have an opportunity pending regulatory dialogue, to be a real first-in-class drug for severe patient needs and Albert spoke to how we hope to grow the diagnostic rate and lead indication of patients and have likelihood to be the only drug for many years that have such a study on this patient group with real hard endpoints.

<Q - David R. Risinger>: So I have two questions. Ian, if you could just help us better understand how the U.S. pricing system might evolve. Currently, the largest percentage of the U.S. drug market is the commercial market which is employer driven, private coverage where the employers and the insurers dictate patient co-pays, et cetera. So, I was hoping that you might be able to help us better understand HHS initiatives to impact rebates in the private sector for out-of-pocket costs in the private sector since that's the majority of the market and the majority of profits for the industry.

And then second, with respect to the reorg, are there cost efficiency opportunities? Maybe, Frank, you could comment on whether this yields cost-efficiency opportunities at all to help offset the Lyrica patent cliff pressure starting next year? Thank you.

<A - Ian C. Read>: Well, thank you for the question, Dave. U.S. pricing, I accept that it's companies, that companies and PBMs that set the co-pays and set the structure by which commercial companies pay, there's a system that's opaque in many ways to the end user and to the payer for that matter. So I think that if you have the public sector with clarity on what net price is, then I think you'll see that the private sector will not ignore the net prices that are occurring in the public sector, so I think it will effectively force transparency into the private sector as well. And I would see a situation where patients are paying their co-pays and their coinsurance over net price and not list price, and so I think it's very positive for the health of the pharmaceutical market.

Of course, you may see that rebates in the commercial sector hold on for longer than we expect and we'll have to see exactly how the administration does in fact take away the rebates in the public sector, so there's a lot of uncertainty. So what you're getting is basically a simplified view from my perspective of saying that if the administration is determined to take rebates out and they can act in the public sector, I would expect that transparency to push the private sector to remove rebates and would be pricing over net price. So I think it's very positive for the pharmaceutical industry and for patients.

<A - Frank D'Amelio>: So, Dave, on your question about the reorg and potential cost efficiency opportunities, the way we think about this, the way I think about this is whenever there's a reorganization like this, it gives us an opportunity to review our processes, to review our operations, and in particular to see if there's opportunities to simplify what we do, how we do it. So yeah, I think there's clearly some opportunities to simplify parts of the business. That simplification could generate some synergies, but our current thinking is we would take those synergies and

reinvest those and in particular in areas where we could double down and accelerate on our pipeline to get those products that everyone's been talking to, to market as fast as possible.

<Q - Jason M. Gerberry>: Two questions for me, just first on tafamidis, one of the pushbacks we get from investors is, can Pfizer launch a drug in rare orphan disease and really build the market out just based on limited track record. So my question to you is, as we think about this market that's largely driven by patients with wild-type cardiomyopathy, just trying to understand. My understanding is the only non-invasive diagnostic is an imaging technique that's not really widely used amongst cardiologists. So can you just talk about, do you just think a new drug drives awareness and that imaging technique would, I don't know, gain broader utilization? Or just how do you ultimately envision the treatment rate expanding?

And then a quick one just on Xeljanz, 2019 formulary negotiations, I imagine you guys have some view there. With the Lilly product coming in at a bigger discount, I'm just kind of curious if you're anticipating any impact from a gross-to-net perspective assuming the current system holds next year. Thanks.

<A - Ian C. Read>: Well on Xeljanz, I think our marketplace is clearly replacing injectable TNF factors and that would be the structure of the pricing. I don't think we're going to be particularly concerned about the pricing of a product that comes in with a, what I would classify as not as strong a label as Xeljanz. So I think we'll leave it at that on that one. And then other question was, Mikael, on tafamidis?

<A - Mikael Dolsten>: Yeah, thank you very much. I think although TTR cardiomyopathy is a rare disease and we spoke about the opportunity to really support early diagnosis of more and more patients, we need to recognize, it is often ending up being managed by cardiologists. And of course, that's a patient and customer group, the cardiologists, where we have years and years of experience and are likely one of the leaders in having the right dialogues and ways to communicate and influence with information of relevance. Specifically, there are non-invasive scintigraphy techniques that can define the amyloidosis of the heart related to TTR.

We are working on algorithms that can help to increase probability that someone has TTR cardiomyopathy and not heart failure and vice versa. And we think combination of improved trials in the clinic scintigraphy and also just by offsets in the scin that proves the position of amyloid will be increasingly common and simple ways to increase diagnosis. And of course, as Albert spoke, as there is a drug, there is an incentive to increase awareness, diagnostic rate and we look really forward to work with physicians and patients to make a drug like this, pending regulatory dialogues, a potential new treatment alternative that may change the lives of many of those patients that today have a very limited life expectancy.

<Q - Geoff Meacham>: Ian or Albert, you guys have a lot of new product cycles coming in Innovative that should drive growth. I know you've said a spinoff of Essential isn't a strategic priority, but does a more aggressive pace of divesting later cycle or say underperforming franchises make sense? I'm just thinking about what you can do to drive faster growth that may involve shrinking the revenue base.

And then for Mikael, for talazoparib, the PARP class has been less dynamic for investors than originally thought. Maybe you can speak to how you view differentiation and how aggressive you could be when looking at combinations in I-O? And is this a strategic priority for you guys? Thank you.

<A - Ian C. Read>: So, Geoff, thank you for the questions. I think what we said was that the previous construct we didn't believe would produce value, the optionality construct we had previously that we were reorganizing around growth factors, that our priority was standing up the new construct of the established products unit with a leader working out of China and that we would continue to look at all alternatives to maximize value, all our different business units to Pfizer. So I hope that answers your question on that and, Mikael, would you like to discuss the other issues?

<A - Mikael Dolsten>: We are increasingly excited about the opportunity with talazoparib. It's a really potent PARP inhibitor, and we think it's a unique way of binding and trap the DNA process of replication. May play out as we learn more of it in the clinic to the higher end of efficacy in this drug class and that's really what we are keeping an eye on.

Specifically, we think we also have some unique trials that are based on drug combinations that we have initiated. We have a tissue-agnostic study, EMBRACA, in then mutated cancers across many solid tumors which can be a really pioneering approach for patients that have these mutations and allow, in a tissue-agnostic manner, patients to get a combination of talazoparib and avelumab. It's really based upon that such patients are likely to respond stronger to I-O plus PARP blockade.

We also initiated very recently avelumab/talazoparib ovarian front-line in high-risk patient Phase 3 study which we think has a unique design and it's a tumor that is likely to have potential to respond to both of these agents in a favorable manner. We really look forward to that study.

And finally, you may know, we have Xtandi and talazoparib combination in DDR positive castration-resistant prostate cancer. So we're building up a quite leading focus, talazoparib portfolio of indications and near-term of course, that EMBRACA data for breast cancer patients with the BRCA mutations have an action date for potential approval December this year