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PFE - Q2 2018 Pfizer Inc Earnings Call

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OVERVIEW:

Co. reported 2Q18 revenues of approx. $13.5b and reported diluted EPS of $0.65. Expects 2018 adjusted diluted EPS to be $2.95-3.05.

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PRESENTATION

Operator

Good day, everyone, and welcome to Pfizer's Second Quarter 2018 Earnings Conference Call. Today's call is being recorded. At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

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

Good morning, and thank you for joining us today to review Pfizer's second quarter 2018 performance. I'm joined today by our Chairman and CEO, Ian Read; Albert Bourla, our Chief Operating Officer; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; and Doug Lankler, General Counsel. The slides that will be presented on this call can be viewed on our website, pfizer.com/investors.

Before we start, I would like to remind you that our discussion during this conference call will include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. Additional information regarding these factors is discussed under the Disclosure Notice section in the earnings press release we issued this morning as well as in Pfizer's 2017 annual report on Form 10-K.

Forward-looking statements during this call speak only as of the original date of this call, and we undertake no obligation to update or revise any of these statements. Questions 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 prescribed by U.S. GAAP and may not be comparable to the calculations of similar measures at other companies.

We will now make prepared remarks, and then we'll move to a question-and-answer session. With that, I'll now turn the call over to Ian Read. Ian?

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

Thank you, Chuck, and good morning, everyone. 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.

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 the second quarter, global Ibrance revenues were up 19% operationally to just over $1 billion. 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 the 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.

The overall CDK class continues to grow within the eligible patient population, although penetration has decelerated, with approximately 64% of eligible first-line newly started patients in the U.S. receiving CDK therapy. Within the CDK category, which now includes 2 competitors, Ibrance's total prescription share is 91%.

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

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

With 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.

Worldwide, Pfizer's revenue for Eliquis were up 42% operationally to $889 million, 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 and equivalent 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.

Turning now to Pfizer's Essential Health. We once again saw strong operational growth in emerging markets and in our biosimilars portfolio. 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 $2 billion. China led the way, growing 24% operationally.

Revenues from our biosimilars business grew 44% operationally in the quarter to $188 million. 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 5 biosimilars to the market in the next 2 years.

In Australia injectables business, as stated in first quarter earnings, we expect to see improvements in the year-over-year 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 has had in decades.

Let me touch on some of our more promising recent developments.

In Rare Diseases, following a 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 these 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 our Phase 3 study evaluating subcutaneous administration of our investigational humanized monoclonal antibody, tanezumab, in patients with arthritis pain met all 3 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.

In Oncology, we currently have 4 potential medicines under priority review at the FDA, lorlatinib, dacomitinib, talazoparib and glasdegib.

In Inflammation & Immunology, we have built what we believe is a true leadership position of our JAK franchise and currently have 10 ongoing selective immunokinase programs. We are continuing to recruit for our Phase III study for our JAK1 molecule in atopic dermatitis for which we received a Breakthrough Designation by the FDA. We initiated a Phase 3 study evaluating 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's no approved preventative therapy or cure.

In Vaccines, we achieved proven 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 3 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. Our gene therapy program for Duchenne muscular disease has started dosing the first few patients in a Phase 1/2 trial. And our collaboration with Sangamo, 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 2 of these 15.

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 the beginning of the company's 2019 fiscal year, Pfizer will have 3 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 natural evolution for our business as we transition to a period post-2020, where 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.

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 end-market products remains 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 the 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 health care system, providing more access and relieving the burden on patients at the point-of-sale.

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

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

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

Now moving on to the financials.

Second quarter 2018 revenues were approximately $13.5 billion, which includes the favorable impact of foreign exchange of $377 million and operational growth of $194 million. Our Innovative Health business recorded 5% operational revenue growth in the second quarter 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.

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 the second quarter 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.

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 the first quarter of 2018; increased income from collaborations; out-licensing arrangements and 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 the second quarter was $0.81 versus $0.67 in the year ago quarter. The increase is primarily due to the previously mentioned factors. I want to point out that diluted weighted average shares outstanding declined by 85 million shares versus the year ago quarter, due primarily

to our ongoing share repurchase program, reflecting the impact of shares that were repurchased during the first quarter of 2018, partially offset by dilution related to share-based employee compensation programs.

As I've previously mentioned, foreign exchange positively impacted second quarter 2018 revenues by approximately $377 million and negatively impacted adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses in the aggregate by $228 million. As a result, foreign exchange favorably impacted second quarter 2018 adjusted diluted EPS by approximately $0.02 versus the year ago quarter.

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 and previously anticipated in the second half of 2018 due to our late-stage development programs.

Adjusted income in the first half of 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 onetime items such as milestone payments from certain collaborations and out-licensing arrangements and the gain on the sale of certain asset rights in the first half of 2018.

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.

I want to point out that our 2018 financial guidance assumes no additional share repurchases. To date, in 2018, we repurchased $6.1 billion 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, 2018, we have $10.3 billion remaining under our current share repurchase authorization.

Moving on to key takeaways. We delivered strong financial results in the second quarter of 2018, with 2% operational revenue growth and a 21% increase in adjusted diluted EPS versus the prior year quarter. We increased our adjusted diluted EPS guidance range. We also lowered the midpoint of 2018 revenue guidance range, solely to reflect recent unfavorable changes and 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 $10.1 billion to shareholders in the first half of 2018 through dividends and share repurchases. Finally, we remain committed to delivering attractive shareholder returns in 2018 and beyond.

Now I'll turn it back to Chuck.

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

Thanks, Frank and Ian, for those comments. Operator, if we could please poll for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from Gregg Gilbert from Deutsche Bank.

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

I'll ask 2. 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 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.

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

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 could talk to tafamidis. I'll make some opening comments on the reorganization and then Albert will continue to explain the reorganization. Thank you.

Albert Bourla - *Pfizer Inc. - COO*

Thank you. 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, but it is rare. But it is rare because it's significantly under-diagnosed. Right now it is expected that less than 1% of the people suffering from this disease are diagnosed actually. And the big role in that place, 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 are going to present the results in August in the Congress in Munich that offers a 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 diagnosed rates. So more to be said after the August conference in Munich when we will announce the results.

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

Thank you, Albert. So Gregg, on the restructuring. This is something that Albert as Chief Operating Officer 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 in the first quarter, 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.

Albert Bourla - *Pfizer Inc. - COO*

Yes. Thank you, Ian. And as Ian said, we had previous decision not to separate PIH and PEH as independent 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 on the basis of growth drivers, which will provide better operational ability to manage this business. So a few words about those 3 segments. The first one, it is the core 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 that it is increasing the demand for innovative medicines, but also science is in a position to deliver solutions right now. Frankly, Pfizer is in 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 5 years, so the fundamentals of growth are very strong. In addition to the 5 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 businesses, 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, 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 consideration, 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 of innovate. Now if we move to the Established business. The Established business also have very strong fundamentals of growth, but they are very different than the research-based, heavy-risk, heavy-reward innovative business. The growth drivers in this business are urbanization. The growth drivers in this business, it is the middle class that is rising, particularly Asia and provides access to hundreds of millions of people. If you see our Chinese business, this quarter, the first half of the year, is growing almost 25%. This means, for the size of our business that we are generating in the first half, approximately $500 million. If you extrapolate, you could expect something like $1 billion of growth into the 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 ELT 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, we are creating a division within Pfizer but will have relatively increased autonomy. And moving to the third business, we always have 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 and 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.

Operator

Your next question comes from Jami Rubin from Goldman Sachs.

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

I just have a couple of questions. Ian, you guys have clearly been ahead of the industry in creating separate business units for reporting purposes, giving yourselves optionality to spin if it made sense. And obviously, it had made sense, and we get that, and that's why you 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 a -- the Established business or the Essential 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 megadeal, 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.

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

Jami, thank you for the questions. So I undoubtedly believe that Pfizer has always organized itself in a way that was structurally appropriate for the market at that time and our objectives. I think this recent reorganization is around growth drivers, does bring an element of simplification. And I think it allows us to continue to evaluate our business segments to see if they were more inside Pfizer than outside of Pfizer. So we will continue to do that. We're very focused, have always been focused on shareholder 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?

Albert Bourla - *Pfizer Inc. - COO*

Ian, you said it very well, and the only thing that I will say is we are 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. And then all options are open once we do that.

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

Good. Thank you. And Frank, do you want to answer Jami's beyond '19 perspective?

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

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.

Operator

Your next question comes from Chris Schott from JPMorgan.

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

Just 2 questions. The first on Ibrance, and just 2 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? Second part of the question is on the flip side, ex U.S. seems like it's really gaining momentum here. Maybe just update in terms of where we stand for penetration on the ex U.S. core markets. 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 it'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?

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

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.

Albert Bourla - *Pfizer Inc. - COO*

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 of -- the same quarter of last year and 10% sequentially versus the first quarter of this year. And let me start by addressing the international markets, then I will go to the U.S. Very, very strong performance in international markets, sales are up almost 125%, and this is driven predominantly by volume. We have 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, an 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 topical -- in the EU 5, in the 5 European markets were Ibrance. Although over there, the reimbursement didn't come with big distance, almost (inaudible) between us and competition. Now let's move into the U.S. In the U.S., the growth was 30% sequential versus the previous quarter, so obviously we had 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 there is actually a tendency to 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 harvested. And what remains, it is late adopters, but they need more time to be convinced to prescribe the new class. We do believe, though, that the class will grow, and we have a strong evidence for that. The fact that when you see the overall share of the class in metastatic breast cancer is in the 60s, as you have 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 to 70. And what we do to do that, we continue our DTC advertising. We continue to be able

to communicate to the broad based population about the benefits of CDK. But then also, we are working with current 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, 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 we know.

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

Thank you, Albert. On the present Blueprint, I mean, we have submitted comments, which I believe are a 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 the pharmaceutical prices are subsidies to the rest of the health care system. We realized 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 that are -- who are at launching -- those companies who are launching new products over the next 5 years or so would remove the rebates, 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. An example would be Xeljanz slow penetration but steady into the -- into its market given the situation of rebates of bigger competitors. I think the President is focused on improving free trade agreements, the free riding that occurs on American consumers and research. He wants to promote value-driven health care by linking payments to performance. He's focusing on improving the efficacy of the FDA, and I think that, that's going well so far. And he tends to reform the 340B program, which I believe is important. This is completely distorted compared to what Congress really intended for that program. So overall, I suppose we'll 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.

Operator

Your next question comes from Umer Raffat from Evercore.

Umer Raffat - *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*

Ian, can you -- sorry, I was just listening to your answers. Now can you just clarify, do you expect U.S. to not have a rebate system anymore? And then also in that same note, if the price increases in the 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 asked because Novartis recently terminated a Phase 3 trial, which had heterogenous 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.

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

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, goes to the rest of the health care 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 health care inflation. As new data becomes available, you may see different value equations for products, but in general, around health care inflation. And I don't see that as a -- 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?

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

Yes, thank you. We have 2 large Phase 3 adjuvant early breast cancer trials running for registration. PALLAS has both intermediate and high-risk early breast cancer with treatment duration up to 2 years. We also have 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 GI. So that really makes, I think, Ibrance unique, attractive drug for the trial like PALLAS. We look forward to the outcome of that trial.

Operator

Your next question comes from Vamil Divan from Crédit Suisse.

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

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. And suitably, are you looking for deals that might be more targeted to 1 of the 3 segments or a larger overarching deal still be something of interest? And then second question, more on the pipeline on the immunology side. You mentioned these 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 can maybe just frame the 2 or 3 opportunities maybe in the pipeline that you're most excited about out of all 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.

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

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 our view of BD hasn't changed much in the last couple of years. We view BD as an enabler of our strategy, not an 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, then 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 will 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 5-plus years. So that would be our focus right now. As I said, the same -- situations change, valuations change. But at this moment, that is our thinking around BD, and it links to this new structure with this focus on growth in all segments of the business. Mikael, would you like to answer the question...

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

Yes. So thank you for your interest in the JAK franchise. And first, we think Pfizer is well positioned for a sustained and growing leadership. We have Xeljanz now registered in 3 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 5 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, its rapid onset of action, with strong efficacy on eczema skin clearance and pruritus, itching, which has really the potential to be differentiating 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 vitiligo. And we have 3 different assets in rheumatoid Phase 2 studies. Readouts from those will guide future potential pivotal study design. We're also planning to expand our presence in ulcerative colitis while we have Xeljanz and running several studies in Crohn's disease with new generation of JAKs specifically tailored for such diseases.

Operator

Your next question comes from John Boris from SunTrust.

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

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 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?

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

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 health care 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 -- will come online in the next couple of years, about $300 million to date. We've committed to that. We are committed to gene therapy. We have the gene therapy that Mikael just mentioned. We would look to tuck-ins if they were available as part of our view on buying intellectual property that has, over the next 5 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, we think, that's way overpriced, but we will buy gene therapy that we think has value. On the U.S. R&D, I will ask Mikael and Albert to comment on specific programs, but I would say that most of it is focused on our -- on ensuring that those 15 products get launched and in development spend. Albert, do you want to make a comment?

Albert Bourla - *Pfizer Inc. - COO*

You're exactly right, and Mikael can give more details, but we are focusing on the new phase starts. We are focusing on the next-generation pneumococcal vaccine, but it is about to start. We are focusing on JAK1 atopic dermatitis Phase 3 that has already 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 3 clinical programs that we are scaling up right now.

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

I think you said it very well. We have a growing Phase 3 registration portfolio where all areas are contributing. Indeed, the Pfizer 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 5 years as well as preparing for the next wave of even stronger productivity going from 23 and onwards.

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

Okay. I'd just to add to that, that we also have the 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 staph aureus, which is -- and the C. diff. Now C. diff is a large trial. We are a leader in that

category. One of our competitors withdrew from developing their product. 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.

Albert Bourla - *Pfizer Inc. - COO*

In rare disease, many Phase 3 are coming right now. So it's a good time for R&D in Pfizer.

Operator

The next question comes from Alex Arfaei from BMO Capital Markets.

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

Great. 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 very -- 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?

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

Thank you. Look, reform of systems is unpredictable. I believe that the administration is focused on rebate reform. I think the -- 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 into the commercial business very, very quickly, as I can't really see a bifurcated system where half the system's on net price and the others are on a rebate. It's just the transparency won't allow that. So I would see rebates going away and that 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 tanezumab?

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

Yes. 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 outcome for tanezumab compared to placebo. And all 3 primary -- co-primary, or the pain, physical functions and patient's global assessment, and the drug was well tolerated in general with less than 1% patients discontinuing therapy. Now concerning rapidly progressing OA, despite this OA study was conducted in a more advanced patient population where patients have already failed other therapies, the rate of RPOA, rapidly progressing OA, in the treatment group was less than 1.5%, which we think is a similar ballpark background rate to what's been seen in other large OA studies. The detailed profile of tanezumab will be further 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.

Operator

Your next question comes from Andrew Baum from Citi.

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

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 innovative pharma company. To what extent do you think that this structure could realize significant improvement of the cost structures, whether it's optimizing the growth? And then leading on from that, will you be giving guidance for each of the individual business units, revenue and/or EBIT?

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

We will not be giving guidance to the individual units. We're giving guidance for the stock ticker of Pfizer. But the -- 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, let's say it that way, in China, I think, 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?

Albert Bourla - *Pfizer Inc. - COO*

I think you said it very well, Ian, and I would add that indeed, it is different, the cost structure of the business. It is not like in innovative, which is heavy in R&D. That business will not. But also it's not like a generic business. Because this is a business, it is a growing in depth as a markets business where you have 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.

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

The only thing I would add is it's a business where we've taken significant savings already.

Operator

Your next question comes from Louise Chen from Cantor.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

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 JAK, 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?

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

Okay, why don't we have Albert talk about the size of the market, alopecia areata, and the -- and then we'll have pipeline answered by Mikael.

Albert Bourla - *Pfizer Inc. - COO*

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

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

Yes. First, on tanezumab, I'm really 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 subcutaneous administration and good tolerability. Of course, all approvals are pending final readouts 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're 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 tolerable 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 we'll start this readout next year.

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

So Louise, just adding to Mikael's and adding to Albert's comments, I do think we see the alopecia areata and the -- potentially our indications around that mechanism of action to be a blockbuster status. So where I've been doing forecast, I would consider that to be a blockbuster. And I just want to correct something on the gene therapy plans. It will be ready to produce on an industrial scale in early, early 2019.

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

And 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 are wild-type excess production of TTR, and the smaller proportion of patients are mutants. 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 CV-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 4 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 the identification of patient and have likelihood to be the only drug for many years that have such a study on this patient group with real hard endpoints.

Operator

Your next question comes from Dave Risinger from Morgan Stanley.

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

Yes. So I have 2. Ian, if you could just help us better understand how 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 if -- I was hoping that you might be able to help us better understand HHS initiatives to impact rebates in the private sector or 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.

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

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 on which commercial companies pay. But it'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 don't -- 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 you'll effectively force transparency into the private sector as well. And I would see 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. But -- 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 uncertainties. So what you're getting is basically a simplified view from my perspective in saying that if the administration is determined to take rebates out and they can act in the public sector, I'd expect that transparency to push the private sector to remove rebates, and we'll be pricing over net price. I think it's very positive for the pharmaceutical industry and for patients.

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

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 yes, 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.

Operator

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

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

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, which is largely driven by patients with wild-type cardiomyopathy, just trying to understand, my understanding is the only noninvasive 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 products 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?

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

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 do -- 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 we'll -- I think we'll leave it at that on that one. And then the other question was, Mikael, on tafamidis?

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

Yes. 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 patient, 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 ofrelevance. Specifically, there are noninvasive 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 the combination of improved triaging in the clinic scintigraphy and also just biopsying the skin 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, potential new treatment alternatives that may change the lives of many of those patients that today have a very limited life expectancy.

Operator

Your final question comes from Geoff Meacham from Barclays.

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

Ian or Albert, you guys have a lot of new product cycles coming in Innovative that should drive growth. I know you said a spin-off 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 and I-O? And is this a strategic priority for you guys?

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

Jeff, thank you for the questions. I think what we said was that the previous construct we didn't believe would produce value, why 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 units with a leader working out of China and that we would continue to look at all alternatives to maximize value of 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.

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

Yes. 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 check. 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 kind of keeping an eye on. Specifically, we think we also have some unique trials that are based on drug combination that we have initiated. We have tissue-agnostic study in BRCA and ATM-mutated cancers across many solid tumors, which can be 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. And it's really based upon that such patients are likely to respond stronger to I-O plus PARP blockade. Roche initiated very recently avelumab-talazoparib ovarian frontline in high-risk patient Phase 3 study, which we think has a unique design, and it's 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 are building up a quite leading focused talazoparib portfolio of indications. And near term, of course, the EMBRACA data for breast cancer patients with the BRCA mutations have an action date for potential approval December this year.

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

Thank you, Mikael, and thanks, everybody, on the call today for your attention.

Operator

Ladies and gentlemen, this does conclude the Pfizer's Second Quarter 2018 Earnings Conference Call. You may now disconnect.