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Pfizer Inc. (PFE) CEO Albert Bourla on Q2 2019 Results - Earnings Call **Transcript**

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Q2: 07-29-19 Earnings Summary



Press Release



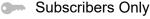
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Earning Call Audio



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Pfizer Inc. (NYSE:PFE) Q2 2019 Earnings Conference Call July 29, 2019 10:30 AM ET

Company Participants

Chuck Triano - Senior Vice President, Investor Relations

Albert Bourla - Chief Executive Officer

Frank D'Amelio - Chief Financial Officer

Angela Hwang - Group President, Biopharmaceuticals Group

Mikael Dolsten - President, Worldwide Research and Development

Doug Lankler - General Counsel

Conference Call Participants

Steve Scala - Cowen

Tim Anderson - Wolfe Research.

Terence Flynn - Goldman Sachs.

Umer Raffat - Evercore ISI

Chris Schott - JPMorgan

Andrew Baum - Citi

Jason Gerberry - Jason Gerberry

Louise Chen - Cantor

David Risinger - Morgan Stanley

David Maris - Wells Fargo

Mani Foroohar - SBC Leerink

Navin Jacob - UBS

Operator

Good day everyone and welcome to Pfizer's Second Quarter 2019 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.

Chuck Triano

Good morning and thank you for joining us today to review Pfizer's second quarter 2019 performance and our updated 2019 financial guidance. We appreciate your flexibility today. I know it's been a busy morning for everyone.

I'm joined today by our CEO, Albert Bourla; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Angela Hwang, Group President Pfizer Biopharmaceuticals Group; John Young, our Chief Business Officer; and Doug Lankler, our General Counsel.

The slides that will be presented on this call were posted to our website earlier this morning and are available at pfizer.com/investors. You'll see here that Slide 3 covers our legal disclosures. Also any discussion related to our recently announced proposed transaction with Mylan to combine Upjohn and Mylan to create a new global pharmaceutical company is subject to certain risks and uncertainties that are discussed under the forward-looking statements section in the press release we issued this morning. Today's call is not intended and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy any securities.

With that, I'll now turn the call over to Albert Bourla. Albert?

Albert Bourla

Thank you, Chuck, and good morning, everyone. During my remarks, I will discuss the progress we are making in the business, the latest advancements within our R&D pipeline, and our ongoing work to advocate for policies that support affordable access for patients.

But before I address these topics, I would like to make a few comments regarding our recent activities to reshape our company including the agreement we announced this morning.

We have been very busy. We recently completed the Therachon acquisition. We expect to close the Array acquisition very soon. We are about to create the joint venture with GSK for our consumer business and we just announced the proposed agreement with Mylan for our Upjohn business.

When all these actions are complete, Pfizer will be a smaller, more focused, science-based company with a singular focus on innovative pharma. We believe we will be in a position where our pipeline will be able to move the needle even more dramatically in terms of our long-term growth prospects.

In fact, we see our growth profile improving in three ways. We expect our five-year revenue CAGR to be higher than it otherwise would have been. We see the growth starting earlier because the Lyrica LOE cliff will go away. And given our smaller size, we believe the growth will be more sustainable.

We also will still have the financial flexibility to continue to invest in growth while returning capital to our investors. These are deliberate steps we are taking to make Pfizer a very different company and one that is even better equipped to fulfill our purpose; breakthroughs that change patients' lives.

Now, let me talk about the quarter. I am pleased to report that our performance for both the quarter and the first half of the year has been solid. In the second quarter, revenues were up 2% operationally company-wide. Our growth was driven again by volume increases, partially offset by price declines.

If we look at our Biopharmaceuticals Group which represented 72% of our revenue base this quarter, the volume increases had an even bigger impact on the growth despite a net pricing decline in the quarter.

Overall, we saw volume growth in several key brands emerging markets and biosimilars. These growth drivers were partially offset primarily by the continued impact of the loss of exclusivity of Viagra in the U.S. in December 2017, a 20% operational decline in Upjohn's revenues in China, declines in Enbrel internationally, and Lyrica in the U.S. and EU, and also product supply shortages and LOEs in the hospital business.

Let's begin with the results from the Biopharmaceuticals Group. We continue to be very pleased with the performance of this business which grew its top line 6% operationally in the quarter. Our Oncology business was particularly strong, up 23% operationally driven by Ibrance, Xtandi, Inlyta, and RETACRIT.

Global revenues for Ibrance were up 27% operationally in the quarter to \$1.3 billion. While most of Ibrance growth continues to come from international markets, we did see 12% growth in the U.S. during the second quarter. We believe this accelerated growth rate is the result of our effort to target specific physicians who had not been prescribing CDK inhibitors or had prescribed them to only a small set of patients. Overall, the CDK class appears to have gained additional ground in the U.S. which is good news for patients.

For Xtandi alliance revenues in the U.S. grew 18% operationally to \$201 million. Xtandi is the leading branded novel for monotherapy to treat castrate-resistant prostate cancer. We continue to see increased Xtandi prescriptions for new patients.

Inlyta revenues increased 34% operationally to \$104 million. This included 82% growth in the U.S. Inlyta has benefited from recent FDA approvals for the combination of Inlyta plus Bavencio and Inlyta plus pembrolizumab in first-line treatment of advanced renal cell carcinoma.

Finally, RETACRIT, our biosimilar for Epogen and Procrit, is off to a good start in the U.S. with \$30 million of revenues in its second full quarter following launch.

Beyond Oncology, we had several other strong product performances. Xeljanz continued to perform well. Global revenues were up 36% operationally to \$613 million. We saw continued volume growth in the rheumatoid arthritis indication. And the recent launches of ulcerative colitis and psoriatic arthritis also contributed to the growth.

Regarding the update to Xeljanz prescribing information in the U.S., we remain confident in the benefit-risk profile of the drug, which has been studied in more than 20 clinical trials and prescribed to more than 208,000 adult patients worldwide. At this stage, we do expect some impact to prescribing. But based on our initial commercial assessment, we believe that on an enterprise level the 2019 impact will be offset by strengths in other parts of the

business. Xeljanz remains an important treatment option for rheumatoid arthritis, psoriatic arthritis and ulcerative colitis in appropriate patients who are suffering from these debilitating autoimmune conditions.

Eliquis continues to perform well. Global revenues were up 26% operationally to \$1.1 billion. Eliquis is now the number one oral anticoagulant in 10 countries including the U.S. and the U.K. Our recent launch of Tafamidis with the brand name of Vyndaqel has been in line with our expectations. As the first and only FDA-approved treatment for patients suffering from ATTR-Cardiomyopathy, Vyndaqel meets a previously unmet need. We have in place programs to help support affordable access for patients and we are working to facilitate early detection and diagnosis through the use of scintigraphy and by developing innovative AI solutions. AI I mean artificial intelligence solutions.

In fact, we have already seen a significant increase in diagnosis rates and since the launch have added approximately 500 commercial patients to the approximately 900 clinical trial and compassionate use patients that were already on the drug for ATTR-Cardiomyopathy in the U.S. We expect these numbers to grow as awareness and diagnosis rates increase.

Prevnar 13 pediatric revenues were negatively impacted by some government purchasing patterns in the year-ago quarter as well as during the first quarter of this year. However, year-to-date, it is performing in line. It is important to note that even with the recent change in its recommendation ACIP maintains a recommendation for the vaccine for adults 65 and older.

However, now it is under a new classification called shared clinical decision-making, wherein the decision to vaccinate should be made at the individual level between health care providers and their patients. The vaccine also maintains its reimbursement status with payers.

While the updated recommendation is not effective until the publication of the morbidity and mortality weekly report, we will assess any impact based on the customer feedback after the language is posted. At this stage, we anticipate some reduction in demand, but we believe that on an enterprise level the 2019 impact will be offset by strengths in other parts of the business.

In sterile injectables, manufacturing supply constraints continue to impact our top line in the U.S. We continue to make steady progress toward remediation and to expect these issues to be significantly improved by the end of 2019. Once we are back on track, we continue to expect this business to be a solid growth contributor in the future.

Now let me speak about Upjohn. Revenues for our Upjohn business were down 7% operationally. The main driver was China where we saw a 20% operational decline driven primarily by volume-based procurement reforms that were implemented in March 2019. These reforms unfavorably impacted Lipitor and Norvasc. This impact has been anticipated since the beginning of the year and was already included in our 2019 financial guidance.

Given first half 2019 operational growth of 13% and the outlook for the remainder of the year, revenues for Upjohn in China for the full year are expected to grow by low to midsingle digits operationally. In cities where our products did not win the tender in the second quarter, we expect continued volume growth although off a lower base.

In addition, we continue to see growth opportunities in non-tender products. We also saw a 9% decline in the U.S. The primary drivers were continued generic competition for Viagra and wholesaler destocking for Lyrica in anticipation of multi-source generic competition as well as continued industry-wide pricing challenges.

For our Consumer Healthcare, Pfizer Consumer Healthcare revenues were up 1% operationally in the quarter. This reflected 4% operational growth in international markets, partially offset by a 2% decline in the U.S. We anticipate the formation of our joint venture with GSK to occur by August 1 and we expect the newly created business to unlock meaningful value for Pfizer, our customers and our shareholders.

Turning to R&D. We continue to be excited with the progress we are making with our pipeline both in terms of the breadth of opportunities and the depth of our science. Since our last earnings call on April 30, we have received seven approvals for new medicines or indications.

In the U.S., the FDA has approved Vyndaqel and Vyndamax for the treatment of ATTR cardiomyopathy; ZIRABEV a biosimilar to Avastin for the treatment of five different types of cancer; a new indication for Inflectra, a biosimilar for Remicade, which is now approved for pediatric patients six years of age and older, with moderately to severely active ulcerative colitis; Ruxience, a biosimilar to Rituxan, for the treatment of certain cancers and autoimmune conditions; and BAVENCIO in combination with Inlyta, for the first-line treatment of patients with advanced renal cell carcinoma. In Europe, the European Commission has approved TALZENNA for patients with inherited BRCA-mutated locally advanced or metastatic breast cancer; and Lorviqua for treatment of adult patients with ALK-positive advanced non-small cell lung cancer. We are working hard to ensure patients have access to these important medicines as soon as we can.

In addition to the approvals, we continue to make progress with other candidates in our pipeline. In vaccines, we expect a proof-of-concept data readout in the coming months from the infant Phase 2 study of our next-gen 20-valent pneumococcal vaccine candidate. Our multivalent Group B streptococcus vaccine candidate started Phase 2 trials in pregnant women, with a study being conducted in South Africa, a region with one of the highest burdens of this potentially devastating infection.

In rare disease, we presented initial Phase 1b clinical data on our investigational gene therapy to potentially treat Duchenne Muscular Dystrophy. Data from the Phase 1b study are providing the basis for an informed decision on dose selection and the design of a currently planned Phase 3 pivotal study that could begin in the first half of 2020.

With our partner Sangamo Therapeutics, we announced updated results from the Phase 1/2I Alta Study, evaluating investigational SB-525 gene therapy for severe hemophilia A. The FDA recently granted a regenerative medicine advanced therapy designation for this potential therapy. The tissue factor pathway inhibitor, TFPI monoclonal antibody for subcutaneous weekly treatment of hemophilia A and B met the preset criteria for proof-of-concept. It is advancing to our pivotal studies. We expect pivotal readout during the third quarter for Rivipansel in sickle cell.

In Inflammation & Immunology, we set positive top line results from a Phase 3 pivotal study of our JAK1 inhibitor Abrocitinib in patients aged 12 and older with moderate to severe atopic dermatitis. Additional data from another study in the JADE program will be available later this year.

In internal medicine, based on our assessment of the tanezumab subcutaneous data and the initial discussion with the FDA, we will prioritize tanezumab 2.5 milligram for moderate to severe osteoarthritis. We are targeting a U.S. regulatory submission in late Q4 2019, or early 2020 to be followed by EU and Japan. At this time, regulatory submissions are not planned for the 5-milligram dose for osteoarthritis or in chronic lower back pain, but we are continuing to assess and will maintain an open dialogue with the regulatory authorities on future potential pathways for tanezumab.

Lastly, in Oncology, we are excited about the pending acquisition of Array BioPharma. We believe Array's assets fit neatly into our business and we expect the three key drivers of the acquisition, the colorectal cancer opportunity, the existing royalty stream and Array's research platform to become solid contributors to Pfizer's growth potential as we move into the next decade. We expect the deal to close in the near term.

As we have said in the past, none of our breakthroughs will do patients any good if patients can't afford them. Pfizer remains committed to working with policymakers at both the Federal and State levels and on both sides of the aisle, on common sense solutions to improve patients' affordability.

We continue to work on the policy solutions I laid out in testimony before the Senate Finance Committee in February. These include capping seniors' out-of-pocket costs in Part D, incentivizing value-based arrangements and establishing a robust biosimilars market to lower healthcare costs.

In summary, we delivered a solid second quarter and first half of the year. Our pipeline is producing new medicines. Our commercial strategy is helping us reach millions of patients around the world. And most important, we continue to see volume gains as opposed to pricing gains, driving our business.

Looking ahead, we expect the pending combination of Upjohn and Mylan to allow both Pfizer and Upjohn to have a singular focus on their respective parts of the business. We believe this will enable us to deliver enhanced value for patients, colleagues and shareholders.

I also want to congratulate Michael Goettler on being named CEO of the combined company. While I personally would be sorry to see him leave Pfizer, I know from having worked closely with him for many years that the new company is getting a strong leader and the right person to help it seize the tremendous opportunity that lies ahead.

Now, I will turn it over to Frank to provide details on the quarter and our outlook for the remainder of 2019.

Frank D'Amelio

Thanks, Albert. Good day, everyone. The charts I'm reviewing today are available on our website. Now moving on to the financials. Second quarter 2019 revenues were approximately \$13.3 billion, which reflects operational revenue growth of \$324 million or 2% and the unfavorable impact of foreign exchange of \$527 million or 4%.

Our Biopharmaceuticals Group business recorded 6% operational revenue growth in the second quarter 2019, driven primarily by Ibrance, Eliquis and Xeljanz globally and by 12% operational growth in emerging markets, led by 26% operational growth in China; partially offset primarily by Enbrel internationally, primarily due to biosimilar competition in developed Europe, and the unfavorable impact of timing of purchases made by governments in certain emerging markets, and Prevnar 13 in the U.S., primarily reflecting

lower government purchases for pediatric indication and continued revenue decline for the adult indication due to a declining catch-up opportunity, compared to the prior year quarter; and the hospital business in developed markets, primarily due to expected negative impact of generic competition and product supply shortages.

Revenues for our Upjohn business in the second quarter decreased 7% operationally...

Operator

Ladies and gentlemen, this is the operator. We are experiencing technical difficulty. Please remain on the line, and your call will resume momentarily.

Chuck Triano

Okay, folks, I think we're back. We had some technical difficulties. Apologize for that. I think at this point, we'll have Frank pick up just before where he left-off.

Frank D'Amelio

Yeah. And so, I'll start -- I'll try to connect the dots. So, as Albert stated earlier, revenues for Upjohn in China increased 13% operationally in the first half of 2019, and are expected to grow by low to mid-single digits operationally for the full year.

And the 9% decline for Upjohn in the U.S. primarily driven by lower revenues for Viagra resulting from increased generic competition and Lyrica reflecting volume declines due to wholesaler destocking in advance of anticipated multi-source generic competition, that was expected to begin on July 1, but instead began on July 19.

Revenues of our Consumer Healthcare business increased 1% operationally, reflecting 4% operational growth in international markets, primarily offset by a 2% decline in the U.S.

In the second quarter, we reported GAAP earnings per share of \$0.89, a \$0.24 increase compared to the year-ago quarter, which was primarily due to the favorable impact of lower income tax due to an IRS audit settlement, higher revenues on an operational basis, lower acquisition-related costs and fewer shares outstanding, partially offset by lower net gains in equity securities and foreign exchange.

Adjusted diluted EPS for the second quarter was \$0.80 versus \$0.77 in the year-ago quarter. The increase was primarily due to higher revenues on an operational basis, lower cost of sales and lower weighted average shares outstanding, partially and primarily offset by the unfavorable impact of foreign exchange as well as lower other income.

Finally, diluted weighted average shares outstanding declined by approximately \$280 million shares to \$5.67 billion versus the year-ago quarter, primarily due to Pfizer's ongoing share repurchase program, reflecting the impact of share repurchases during 2018 and in the first quarter 2019, which was partially offset by dilution related to share-based employee compensation programs.

As I previously mentioned, foreign exchange negatively impacted second quarter, revenues by approximately \$527 million and positively impacted adjusted cost of sales, adjusted SI&A expenses and adjusted R&D expenses in the aggregate by \$310 million. Consequently, foreign exchange had a \$0.03 per share negative impact on adjusted diluted EPS compared to the year-ago quarter.

Moving on to 2019 financial guidance. We updated certain components of our 2019 financial guidance primarily to reflect the anticipated August 1, 2019 formation of the Consumer Healthcare joint venture with GSK and the pending Array acquisition. As a result, our guidance now reflects revenues and expenses associated with the Consumer Healthcare business through July 31, 2019 but now excludes revenues and expenses from Consumer Healthcare from August 1st, through the end of the year.

Guidance now includes Pfizer's pro-rata share of the consumer JV's anticipated earnings, which will be recorded on a quarterly basis in other income/deducts with a one-quarter lag. As a result, guidance for adjusted other income/deducts and adjusted diluted EPS reflects Pfizer's share of only two months of earnings from the JV for the third quarter which will be recorded by Pfizer in the fourth quarter 2019. Therefore, on a net basis for the remainder of the year, the consumer JV is expected to have a \$0.03 negative impact on adjusted diluted EPS, representing the foregone PCS earnings, contribution from August through the end of the year, partially offset by the two months of equity income from the JV.

Our guidance update also incorporates the expected impact from the anticipated near-term completion of the Array acquisition, and to a much lesser extent the Therachon acquisition which closed earlier this month. These transactions are expected to modestly increase our adjusted R&D expense, and increase our net interest expense within our other adjusted income/deducts line resulting in an anticipated \$0.04 negative impact on adjusted diluted EPS.

Importantly, our guidance update absorbs the anticipated net impact of various other drivers, some of which are expected to have a favorable impact on our financial results offset by other drivers that negatively impact our outlook for 2019.

On the favorable side, we now expect greater contributions in 2019 from certain biopharma products, primarily within our Oncology and internal medicine businesses than we previously anticipated, and our Upjohn business benefited from the delayed entry of generic competition for Lyrica in the U.S. which is expected to begin on July 1 but did not start until July 19. However, we expect this operational upside to our forecast to be offset by foreign exchange, and other recent product developments for Prevnar and Xeljanz.

On foreign exchange, we had originally anticipated in January that FX would have an unfavorable impact on revenue of approximately \$900 million and \$0.06 on adjusted diluted EPS compared to foreign exchange rates from 2018. We now anticipate that foreign exchange will have a \$1.2 billion unfavorable impact on revenue and \$0.08 on adjusted diluted EPS for the year based on actual exchange rates in the first half of the year and mid-July FX rates for the remainder of 2019.

So foreign exchange is expected to have an incremental negative impact of approximately \$350 million on revenue and \$0.02 negative impact on EPS compared to our January guidance. On an operational basis the ACIP's provisional recommendation to the pneumococcal vaccination guidelines for Prevnar 13 in adults in the U.S. as well as the recent revision of the Xeljanz U.S. prescribing information have negatively impacted our outlook for both products for the remainder of 2019.

In summary, our guidance update slowly reflects pending business development activity and absorbs the various operational puts and takes that we have seen so far this year as well as the incremental negative impact of foreign exchange. Finally, as a reminder, our financial guidance for adjusted diluted EPS reflects share repurchases totaling \$8.9 billion completed in the first quarter, which we expect will be offset by about half from dilution related to share-based employee compensation programs.

Moving on to key takeaways. In the second quarter, we delivered solid financial results with 2% operational revenue growth, 4% adjusted diluted EPS growth and 6% operational revenue growth in our Biopharmaceuticals Group compared with the year-ago quarter. This keeps us on track to deliver solid financial performance in 2019. We updated our 2019 financial guidance based on the anticipated near-term completions of the Consumer Healthcare joint venture with GSK and the Array BioPharma acquisition and the completed Therachon acquisition. We accomplished multiple product and pipeline milestones since our previous quarterly update and we returned \$12.9 billion to shareholders during the first half of 2019 through a combination of share repurchases and dividends. Finally, we remain committed to delivering attractive shareholder returns in 2019 and beyond.

Now, I'll turn it back to Chuck.

Chuck Triano

Good. Thank you, Frank and Albert. And sorry about the technical glitch. Evidently, we didn't have unlimited talk time on our calling plan, I would guess. But with that, let's turn it to start the Q&A.

Question-And-Answer Session

Operator

[Operator Instructions] Your first question comes from Steve Scala from Cowen.

Steve Scala

Thank you. I have two. It looks like 2020 pro forma EPS for Pfizer alone could be about \$2.10. Is that a reasonable estimate at this juncture? So that's the first question. Second Albert, you had been steadfast that a major transaction was unlikely while Pfizer was in the midst of several important launches. I'm just wondering, what changed and what does this tell us about the outlook for the new products – thank you – meaning the Upjohn transaction? Thank you.

Albert Bourla

All right. Let me cover this one, and then I will ask Frank to comment on the EPS. And frankly, nothing has – we always said that the internal separation of Upjohn was a significant theme in the value creation thesis when we announced it's great. I mean, Upjohn has a significant business model. They remain in Pfizer. And the substantial autonomy was essential for its success. That was always the thesis. And we said that, we will not explore options before we spend after this business, because we want to focus right now on spending up this business. But I have to tell you that we substantially completed the internal Upjohn organization separation earlier this month. That involves multiple things including legal entities. We have a new organization but it is already operational worldwide. It is fully staffed. The Shanghai headquarters is already up and running. And the business it performed according to our expectations actually a little bit better.

So we always look of course to maximize value of the business. When we assessed the potential of combining these two companies, we quickly saw the potential to create value for shareholders in excess of what could be created if the businesses will remain as such.

Now, that doesn't create any disruption to our main biopharmaceutical business because it's already separate business, but continues to operate as separate business as it does. It's going to have a little bit of disruption in Upjohn as we integrate, but all of that we took into consideration when we saw how much bigger value we can create for our shareholders by combining those two businesses. Frank, on the EPS?

Frank D'Amelio

So Steve, what we did is we gave some -- I'll call it preliminary financial numbers for 2020. We covered revenue. We covered EBT as a percentage of revenue operating cash flow and we obviously made some comments about -- I made some comments about the dividend. We did that obviously to be helpful. In terms of specific EPS numbers, we'll do what we typically do which is we'll provide EPS guidance for 2020 on our fourth quarter earnings call as we've done in prior years.

Chuck Triano

Thank you, Frank. Next question, please.

Operator

Your next question comes from Tim Anderson from Wolfe Research.

Tim Anderson

Thank you. If I could just go back to split. So splitting up first contemplated in early 2011, then in 2017 you guys kind of called it off. And one of the reasons for that was the valuation and spec pharma went down. That was kind of viewed as the comp for established products. And I think on a sum of the parts basis you guys are worried you wouldn't unlock value.

So if I fast-forward to where we are today spec pharma multiples have gone even lower. That's going to be some variation if that's going to be what's applied to the Upjohn business. So that part of the problem hasn't really gotten any better. And I'm wondering kind of what changed in your viewpoint from -- impediment to today where apparently it's not. So that's the first question.

Second question is just the emerging markets part of Upjohn I think is about \$4 billion or 40% of total Upjohn revenues. Does this disrupt the corporate footprint in emerging markets that was a pretty sizable business that's a scale business as well? And was there

any contemplation on keeping the emerging market part within the parent Pfizer company?

Albert Bourla

Yes. Thank you, Tim. Look as you said the scenario split in the company was put to bed earlier on. And that scenario was mainly a scenario to take advantage of the multiples at the time so it was kind of a financial engineering. But it didn't work and will not work in Pfizer. This is why we moved away from this strategy.

What we tried to do is to create operational value, value that is creating by putting similar things together. And the first step we did was to create Upjohn because Upjohn had very different characteristics from the previous established products. It was basically carefully selected assets that was trying to get advantage of the very positive demographics that were happening in Asia and particularly in China in terms of the types of volume creation. And that was something that we completed internally and we always knew that autonomous operation having them run almost like a company within a company was going to create value. So that's the first step

But when we assessed the complementarity of the Upjohn business together with Mylan we understood that then we can create a substantially better bigger company. So this is the reason why we said that Upjohn instead of keeping it inside which is very different than the established products it in all aspects very different portfolio very different size, very different everything is now going to create significant value by putting together with Mylan.

Now as regards the emerging markets not at all. Let's start with China and then I will take it to the emerging markets in general. Upjohn -- let's start with Upjohn. As part of the new company now we have a strong pipeline we didn't have before and they'll have a strong pipeline to put through the great commercial infrastructure in China to fuel the growth.

Now let's see China? The remaining -- the Biopharmaceutical Pfizer's presence in China. The remaining Pfizer it is almost half of the \$5 billion that we have right now in China. So the size will be significant. And then you can see the growth prospects of this business is growing 26% in the second quarter. So it's doing very well. But we are even more excited about the futures growth of this business. We maintain all our R&D and free force capabilities in China, by the way all of that are completely segregated right now. And in addition -- with Upjohn I mean -- and in addition we are expecting to file up to 19 new products in the next few years in China. So that's very significant.

Now let's move to in general the emerging markets in the remaining. The size of emerging markets currently in the Biopharmaceutical businesses is almost 20% of the total business. And if you see the growth trajectory of this business is growing almost triple the rate than the remaining of the Biopharmaceutical business. So with this transaction we do not reduce the scale or the growth prospects at all of the main Pfizer into emerging markets.

Chuck Triano

Great. Thank you, Albert of that. Move to our next question please, operator.

Operator

Your next question comes from Terence Flynn from Goldman Sachs.

Terence Flynn

Hi. Thanks for taking the question. Maybe for the Biopharma business you guided to five year growth rate at the high end of mid-single digits. So just wondering any meaningful differences there in your projections versus consensus? And then Albert would welcome any additional perspective on the proposed Senate drug pricing legislation and maybe your Part D exposure on a pro forma basis? Thanks.

Albert Bourla

Yes. Thank you very much and very good questions. First of all, on the first we never comment on other people's projections. I know that this is your job to do projections, but we have our internal. So Frank, you want to make a comment

Frank D'Amelio

Sure.

Albert Bourla

...on that and then I will take the second question.

Frank D'Amelio

Sure. So I can comment on the revenue and obviously to Albert's point we'll talk about our numbers -- I'll talk about our numbers. So from my perspective the 5-year CAGR -- revenue growth CAGR will improve. We've said previously mid-single digits. Now we're saying high mid-single digits. We'll see the growth faster. The reason we'll see the growth

faster is immediately upon close Lyrica LOE goes to Upjohn so we won't have that. We believe the growth will be more sustainable because it's on a smaller base. And then most importantly, we will leverage that growth to the bottom-line as we always do. So that's how we think about the revenue.

Albert Bourla

Yes. So let me make some comments about the Senate. As you know, last week there was a markup in the Senate Finance Committee. We cannot support this bill as written and it's not only us but in general the pharma has expressed their frustration. Obviously, there are some provisions of the proposed bill that we do support and we believe will help lower spending on prescription drugs. And -- such as instituting out-of-pocket caps for patients or improving incentives for biosimilars utilization. These are very positive things in the bill.

However, we believe that none of these in -- for none of these the bill goes far enough. We would expect that they would do much more to incentivize biosimilars and we would expect that they could do much more to create relief on patients.

Also the bill while it generates savings for the health care system, it does it with punitive measures for the industry and does not distribute the savings to patients. And thus does very little to fix the issue as a result of high out-of-pocket costs for them. This is the fundamental issue right now in the political life and this is the fundamental issue of the pharmaceuticals business. More there -- on that needs to be addressed.

Now we are working very productively with the administration and we are working very productively with senators and we plan to do it with also -- to continue to make it with Senator Grassley and Wyland and Senate members from both sides of the aisle to see how we can improve this proposal. And also we noted that in the Senate bill there was the unanimous support -- almost unanimous support to introduce a comprehensive rebate reform into this bill. This is very, very positive and I believe that will be one of the very meaningful tools that the Senate Committee has in their hands to reduce out-of-pocket costs.

Now as regards what will be the size of the impact it's very early to calculate because our experience is that typically these things are changing dramatically between markup and then what comes to the floor and then eventually what is becoming a bill. So I would rather stay on the basic principles that the bill is punitive for the pharma, but more importantly doesn't distribute all of the savings that is created for the patients.

Chuck Triano

Right. Thanks for the perspective, Albert. Next question, please.

Operator

Your next question comes from Umer Raffat from Evercore ISI.

Umer Raffat

Hi. Sorry about that. Thanks for taking my question. I wanted to touch upon a couple of things, if I may. First, as we think about the China pricing concerns, the question that I've been toying with is Lipitor and Norvasc were down 27% or so this quarter. We've seen some evidence online that the tenders in China could be as high as 70% price drop. So, is the price drop done on Lipitor and Norvasc or are we expecting more? And then, the same theme over to the antibiotics business as well, because presumably the 7 plus 4 initiative could expand to antibiotics, and your thoughts on China business as it relates to antibiotics? Thank you very much.

Albert Bourla

Yes. And I think Michael gave a very good overview of the situation in China in a previous call, but I can give you also a summary. I think the -- right now, the value -- the volume-based procurement will expand from 11 cities to more cities, and that will affect the price. So, I think that the prices will go down.

At the same time, we see that there is tremendous volume opportunity of going up. So, as a result, we think that eventually the business will be the base as these close to 31 cities, but there will be continued growth for the high-quality branded products, because the Chinese healthcare system, including physicians and patients, they place a lot of value in the brand equity of this drug.

So, that has been calculated in all our numbers, but were included for China, and you saw it in the previous presentation. And that will continue. By the way, our antibiotics, they are in Pfizer -- in the remaining Pfizer, they're not part of our Upjohn it's part of Sterling injectables, and they're not at QC, so they are not affected at all by that.

So far, as regard the trajectory for our business in China. From the rebates business, we think because of the volumes, after all this price hit the significant volume expansion, we will continue seeing volume growth -- revenues growth in China.

Chuck Triano

Thank you, Albert. Next question please, operator.

Operator

The next question comes from Chris Schott from JPMorgan.

Chris Schott

Great. Thanks very much. Just on the margin side of the story. As we think about high to mid-single-digit growth for the Pfizer Biopharma business, can you just elaborate on what that looks like in terms of the magnitude of margin expansion and pre-tax growth we can think about for Pfizer over time? I guess trying to get to the question here, is there areas you still need to ramp investment on that core innovative business? Or can we think about much of the top line growth over the next few years, falling largely to the bottom line?

My second question, which is coming back to Tafamidis, and just the launch dynamics on that product. Just any early color of how we should -- how you're thinking about the coming quarters, and the type of ramp that we should be thinking about as that product gets off the ground? Thanks so much.

Albert Bourla

Frank, would you like to comment how we see margins evolving in joint company?

Frank D'Amelio

Sure. So Chris, I talked about in my prepared remarks, margins -- IBT margins, I talked about in the mid-30s. The reason I did that was because we're shifting income from above the line to below the line with things like the consumer joint venture, think about above other income to in other income. So, we used IBT, as I'll call it, the benchmark to use going forward as a percentage of revenues, so mid-30s.

But, we fully expect as our revenues grow for us to leverage that to the bottom line. I think we've demonstrated that over the years, we will continue to do that going forward. So, yes, as our revenues grow, we expect margin expansion to the bottom line then obviously to not only to IBT but obviously to the EPS line as well.

Chuck Triano

Yeah. Chris, I can just -- just to clarify. IBT as income before tax, I'm not sure how common that phrase is used. But for us, as operating income, plus other income and that's the IBT, that Frank's been referencing.

Frank D'Amelio

Thanks, Chuck.

Albert Bourla

Thank you, Frank. Angela, why don't you give some color on Tafamidis please?

Angela Hwang

Great, thanks. And thanks for the question, Chris. So let me share with you what we're seeing, on our side in terms of the performance of Tafamidis. We are releasing some nice positive leading indicators, for this launch. And let me walk you through sort of the funnel of patients. And how we're seeing things play out.

First of all, we have approximately 3,000 ATTR-CM patients that we've already diagnosed. And these are patients outside of the 900 that you heard Albert talk about in his opening comments, that were part of an early access program as well as clinical trial supply.

So of these 3,000, about 1,400 of them have been prescribed Vyndaqel. And of those 1,400, 500 have actually received the medicine. And so, what we have here now are about 900 patients that are in process of clearing the access and reimbursement sort of logistics via prior authorizations that will then ultimately enable them to get the prescription.

And so I also would maybe like to mention that, so far, we're seeing the prior authorization process improve pretty much on a daily basis. And only 16 patients, 1-6, have received some sort of rejection. And even those rejections could simply be just due to documentation purposes.

So hopefully that lays out for you, where the patient flow is coming from. And how we're seeing patients get onto the drug. But also say that, we're very pleased with what we've seen so far. And what we're seeing both in terms of diagnosis as well as the process for patients to actually get their drug.

Chuck Triano

Great, thank you, Angela. Next question please?

Operator

Your next question comes from Andrew Baum from Citi.

Andrew Baum

Thank you. A couple of questions please. First, we are living in a very active M&A environment thinking of AbbVie, Bristol, Takeda and so on and so forth. Your new structure will leave you a smaller company, but you will have the \$12 billion additional cash from the Mylan transaction.

How are you thinking about deploying your balance sheet? And whether there is a need to reconfigure the recent historic stance of shying away from larger-scale, M&A? So that's the first question.

And then the second, more of a housekeeping question. Inlyta is an increasingly important drug as you called out in relation to the renal cell approvals. Do you have a crystal line patent which would take you out until 2030?

You list the basic patents in your annual report which is 25. What is your confidence that, in the fact you may be able to derive cash flows in the U.S. all the way out to 2030 using that second patent? Thank you.

Albert Bourla

Thank you very much, Andrew. Let me make a comment on BT, and then, I will ask Frank to comment on the capital structure of the new company. And then Angela you will answer the Inlyta.

So, as I said before, nothing is changing with this deal, in the way that we see business development for Pfizer going forward. You will see Pfizer to be active in BD continues to be active in BD.

And as we have said, preferably that will be on bolt-on opportunities, that would be on early to mid-stage opportunities, where maybe there is higher risk as you know, but the value creation is further greater. And the risk of operational disruption is perhaps lower.

So, we have this philosophy before and continue having it. Regarding large-scale M&A, as we said, we'll never say never and -- but right now the opportunity we have to advance our pipeline is unique. And I still do not see the need to do a large deal right now, because that can only create disruptions.

With that, I would like to ask Frank to give a more general overview on the capital structure.

Frank D'Amelio

Sure. So, Andrew, you mentioned the \$12 billion of cash that we're going to receive from the transaction. Our intention is to pay down debt with that \$12 billion of cash. That solidifies what's already a really strong balance sheet.

We continue to have -- we expect to continue to have a solid credit rating. And then as you mentioned, we'll also generate \$11 billion to \$12 billion in operating cash flow post-close.

Obviously, from that we will pay the dividend. And we said we will keep our shareholders whole on the dividend. We get the importance of the dividend. Obviously, CapEx investing in the business and then the remainder will be looking at relative to share repurchases and to business development.

Chuck Triano

Angela, do you want to comment on the patent?

Angela Hwang

Sure, just quickly. Our main composition of matter patent takes us up to 2025. But of course, because of the value of the product we will continue to pursue other patents. And so, we'll see and to be determined where that takes us.

Chuck Triano

Okay. Thank you. Next question please?

Operator

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

Jason Gerberry

Hi. Good morning. Thanks for taking my questions. Just coming back to the top line growth target of high mid-single-digits, could you just walk us through your assumptions?

Does that include the success -- clinical success for Ibrance adjuvant as well as status quo in the pneumococcal vaccine space? And then your comment on, Vyndaqel the 3,000 patients, so I think that's about 1,400 additional patients versus what were out there maybe diagnosed and on dexlinosol.

Is that I mean sort of you're already seeing the impact of cardiologist testing and diagnosing TTR cardiomyopathy? Just trying to get a sense of what's driving that increase in the diagnosed and treated patient pool?

Albert Bourla

Thank you, Jason. Let me first clear the question about what's included in our projections of high end of mid-single-digit growth. And the way we always do it, it is with risk adjustment. There is nothing that is fully baked in.

We have a very big pipeline. And we have particularly a very big Phase III portfolio. And all of them they are appropriately risk-adjusted, so there's nothing that it is assumed a success over there or failure per se.

The fact that, we have the risks spread in many, many assets. Because, as you know we have submitted everything in time, this is what gives us a lot of confidence, that the risk adjustments are accurate.

With that I will ask Angela to comment.

Angela Hwang

On the diagnosis, so what we're seeing from a diagnosis perspective and what's helping us are the following: I think first of all, we're seeing some good use of PYP scintigraphy, which is the non-invasive method for identifying and diagnosing ATTR-CM and a good -- a high utilization of that as a non-invasive mechanism.

But also in terms of where the diagnoses coming from, we're seeing a good spread between the centers of excellence, between specialty cardiology, as well as general cardiology. So I think that the education efforts that we have ongoing about the signs and symptoms of ATTR-CM has as creates suspicion around them. It's happening across all different aspects of cardiology, whether it's in academic centers or in the community. And I think that this is why I was saying that we have some really positive leading indicators of this launch and it's going according to plan.

Albert Bourla

Great. Thank you very much, Angela. Next question please operator.

Operator

The next question comes from Louise Chen from Cantor.

Louise Chen

Hi. Thanks for taking my question. My first question is as you trim down to these core assets that higher end of the mid single-digit range, is that organic growth or does that include M&A? And then I wanted to ask you also on Array. The Anchor CRC and the Adjuvant setting how do you think about those opportunities in light of the BEACON data that you've seen so far?

And then my last question is on your DMD product. Do some of the safety issues that came up in your Phase 1 study change your view about the market opportunity? What doses of the hospitalizations occur and was it due to promoter or AAV9? Thank you.

Albert Bourla

Thank you very, very much Louise. Let me first take out of the way the first one which is an easy. We do not include any M&A in our projections. When we speak about high end of mid single-digit growth, we mean organically. Now Mikael, can you please comment on Array and DMD?

Mikael Dolsten

Yeah. So on Array, we are very excited about overall opportunity for the team. And as you know recently in May, there was communicated both very convincing updated data from the Columbus melanoma trial. The data from the second and third-line BEACON trial, which was received I think extremely well about the strong data including survival response rate of the triplet.

We're pleased that our additional trials such as the Anchor trials that served as a first trial for first-line BRAF-mutant metastatic CRC and additional trials are flours and foros [ph], fluorescence is in BRAF-mutant melanoma, foros is in BRAF-mutant lung cancer. And we've earlier stated that we've seen opportunity actually to consider extend that to normal tissue-agnostic opportunity for BRAFTOVI, MEKTOVI. So overall we see this as a very strong platform.

As you know the Array also has a large number of partner program that will continue to advance in development and grow as products that provide a third leg of future opportunity, plus R&D engine that will be added to our pipeline pending close of the deal.

On the DMD, we presented at the parent project muscular dystrophy conference recently an update of our trial. And we continue to be optimistic about the field in general and as well looking at our aggregator safety data as well as data on muscle fiber distribution minidystrophin concentration and the early data we reported on NorthStar Ambulatory Assessment and creatine kinase as a muscle health marker.

We think the integrated data set are sufficiently encouraging to support the continued development of the investigational therapy. And as Albert alluded to in his introductory remarks our manufacturing including large-scale 2,000-liter bioprocessors are on track, as we continue the trial to support a potential pivotal study June next year.

Albert Bourla

Great. Thank you so much answering Mikael. Next question please.

Operator

Your next question comes from David Risinger from Morgan Stanley.

David Risinger

Yes. Thanks very much. I have a couple questions. First, could you please comment on the innovative business in China excluding Upjohn? What is your revenue run rate in China excluding Upjohn?

Second, with respect to Ibrance adjuvant readouts, could you please update us on the timing?

And then third, with respect to U.S. biosimilars, could you update us on the expected launches in coming months? And if you have any specific timing that would be helpful. Thank you.

Albert Bourla

Thank you very much. I will cover the innovative business in China, and then I will ask Angela to cover biosimilars and the question about Ibrance. Our innovative business in China, it is approximately in the first half of the year half the size of the business. So it is in the north of \$2 billion I think for the full year. If you extrapolate it is around \$5 billion.

The business is extremely healthy. It's growing right now 26% in this quarter and the growth we expect to maintain or accelerate. We are maintaining the capabilities of the innovative business compared to the capabilities of the Upjohn have been already segregated at once. There's very little connectivity, which is mainly in enabling function systems, et cetera, but in terms of marketing, management, research and development, manufacturing all of that are already separated.

The Biopharmaceutical business has many more resources than the Upjohn, because it's a much more demanding business, and we plan to maintain them all. And you need to know that we have a very strong research organization in China, but also we plan to maintain and enhance.

As regards to the outlook of this business in China, we plan to launch approximately to introduce 19 new products in the next few years. So, let me take it back to Angela and also Angela if you want to make some comments about the innovative business in China, feel free, but also cover the biosimilars and the Ibrance question.

Angela Hwang

Sure. Sure. So, just to follow what Albert was saying, we have a strong portfolio of innovative products in China. In 2018, we have -- we saw the other listings on the NRDL of very important Oncology products. And in this year 2019, we are continuing to look forward to driving growth through the continued listing of other notable products such as Ibrance and Xeljanz, which is coming up in 2019. So, hope that just gives you a flavor of the types of launch activities that we're looking forward to and what we see as the drivers of growth.

To your second question, which I think was about Ibrance adjuvant, those -- in that regard, we're looking forward to the two trials PENELOPE as well as PALLAS, both in the high-risk early breast cancer patients. Both of these trials, if successful will allow us to double the number of patients that we can put on Ibrance. And because these are event-driven trials, I think we've spoken about these before, we expect to report to you when the recruitment and when the numbers of patients have been finalized. But that looks like approximately sort of middle of the year next year is what we're anticipating, so more to come on that one.

And then your final question was about -- yes, biosimilars. So, as you can see to-date, all three of our monoclonal antibody biosimilars have now been approved by the FDA. So we're really pleased with that. That's a major regulatory milestone that we have accomplished. And now, we look forward to the launches. That will be coming up in short order. I don't -- I can't really give you exact dates, because as you know, there's just many things that go -- or many considerations that get factored into when a biosimilar can get launched. But I think that commensurate with the successes we've seen in these approvals, we are very much gearing up and looking forward to the launches coming up soon.

Chuck Triano

Great. Thanks Angela. Next question please.

Operator

Your next question comes from David Maris from Wells Fargo.

David Maris

Hi, just a simple one. The opioid litigation, can you give us an update on whether or not the opioid products are going with the Upjohn business or are they remaining with Pfizer? Thank you.

Doug Lankler

Yes. So it's Doug Lankler. Thanks for the question. So, Upjohn has no opioid liabilities, so -- and Pfizer has a very, very small amount of them as well. But Upjohn doesn't have any, so nothing will be going in the opioid area to the new business.

Chuck Triano

Okay. Great. Thanks Doug. Next question, please.

Operator

Your next question comes from Mani Foroohar from SBC Leerink.

Mani Foroohar

Thanks for taking my question. I wanted to dive in a little more detail on tafamidis' and I have a follow-up after that. You've commented on 500 commercial patients, 900 on compassionate use in clinical trial, which would imply an incremental 1,600 patients outside of those two buckets to get to the 3,000 number of diagnoses that you've hopefully given to us. My question is the breakout of that population. Of the 500 commercial patients are zero or some other number from the -- of the EAP. If zero of the patient -- if zero EAP patients are in that 500 commercial, are all 400 of the EAP patients that were on EAP in December 2018 in the 900 population you disclosed today, if all 400 of those EAP patients are in that 900, when if ever will they get -- will they become commercial patients generating revenue? And then beyond that for the other 1,600 diagnosed patients, but not yet in either those two buckets, can we think about time...

Albert Bourla

I think we lost Mani.

Operator

Your next question will come from Navin Jacob from Senior Research Analyst.

Albert Bourla

Before we do that, I know we lost Mani, but let me ask Angela to answer at least the part of the question that we were able to listen to.

Angela Hwang

Okay. Great. So, just to pick up on the numbers, the 1,400 patients -- commercial patients that I referred that have been prescribed tafamidis have nothing to do with the early access program. So, the early access program has 700 patients. And of those 700 patients, 25 have already been transitioned over into commercial, but I'm not counting that as part of the 500. So that's a separate stream. So, if you think just purely newly diagnosed commercial patients who came on Vyndaqel for the first time as commercial patients that's the 500.

There's a different stream that we need to follow for the 700 early access program getting commercialized or getting moved into commercial product. And like I said, there's 25 of those. And that's a different process that we have to work through with our clinical trial size in order to transition them, so that's they move at a slightly different pace with a different process, but we anticipate that over the next several months, all of these patients will need to be moved over.

Albert Bourla

Great. Thank you. Angela.

Chuck Triano

Thank you, Angela. Next question? If we can take our last question please, operator.

Operator

Your final question will come from the line of Navin Jacob from Senior Research Analyst.

Navin Jacob

Hi, sorry, Navin from UBS. Thanks for taking my question. On tafamidis -- sorry if I missed this, but Angela, is there's any color around how much usage you're getting in sort of the pure cardiomyopathy market versus any usage in the mixed phenotype market that would

be great. And then just on Xeljanz, any color on just given the label change, how you're now sort of thinking about the UC market opportunity, any color on peak outlook there would be helpful? Thank you.

Angela Hwang

Sure. So as you can tell, we have 500 patients that have received drug even though we've diagnosed a great deal more. So at this point it's a little difficult because we don't have enough numbers to be able to be exact with you in terms of how many are the hereditary type and how many are the wild type.

But just order of magnitude of all the ATTR-CM patients that exist 90% of them are going to be wild type, meaning very little are hereditary. So I would anticipate that as we are diagnosing these patients that that distribution would apply. But I don't have definitive numbers on that quite yet.

In terms of UC, so here how we're looking at it, which is that if we look at how our UC scripts are being generated today, most of them are coming from second line use, a second line after anti-TNF. So where the new label is going is in fact where -- that's in fact how our business is operating today. A large majority of our patients are our second line after anti-TNF.

So I think that this is one where we're going to have to monitor. I think as you can imagine that there is just an incredible and a significant education effort that needs to go on now with our physicians. And I think as a result of that education method we'll get a better feel of how they are looking at UC second line. But certainly this is very much aligned with how we're doing business today anyway.

Albert Bourla

Thank you very much Angela. And let me make some final comments to give the highlights of the business and I want to see it from the Pfizer shareholders as well what the Pfizer shareholder is receiving.

So first of all, our shareholders will receive 57% of a new created company. The new company will be stronger will have a great scale, great diversification, great R&D and much more focused. And, of course, it will have a great capital structure. We believe that Mylan's equity is right now significantly undervalued.

Five months ago their stock was \$32, which is more than \$73 than were Friday's close. We have done a lot of due diligence as a responsibility for our shareholders and we feel comfortable with what we have seen.

We do not believe the issues were related to the underlying business of the undervaluation of their stock. In fact, we discovered they have done a very good job with their pipeline and they have diversified the result -- their business. Also discovered that they have a very credible cost to control -- their cost.

They soon were related to uncertainties around strategic direction around governance, around shareholder friendliness, and to believe that this transaction checks all boxes. This results in a materially less leverage company, robust cash flows, which facilitates payment of an attractive dividend, redomeciles company back to the U.S. in the most shareholder friendly jurisdiction, which is Delaware. And we do that with no meaningful dissynergy impacts. So there will be no tax dissynergies. And, of course, we have a strong performing governance.

Now this is what our shareholders received from us. In addition they will receive a 57% on the value of synergies of this combination will create, and of course they will receive \$12 billion in cash.

But what is more important for our shareholders, it is what -- how the remaining company Pfizer will look like. The company will be singularly focused on innovative biopharma with valuable growth assets in a strong pipeline.

Our product portfolio and pipeline will more easily move the needle in terms of growth impact given the smaller size, which will also make the growth more sustainable.

We anticipate remaining Pfizer's revenue CAGR on a five-year basis will improve to the high end of mid-single-digit and this will happen the moment that we close the transaction.

We also as I said believe that the growth will be much more sustainable, given the small size and given the fact that the size goes down but all the growth assets and all the R&D remains in the main company.

And finally we will continue, of course, to have a very strong balance sheet with a solid credit rating. We believe that when you see this transaction in the context of the previous three -- actually all transactions are closing in this week or next week, which is the Therachon acquisition, we expect to close very soon the Array acquisition, we expect to

close very soon the formation of the JV and we announced today this create a very different Pfizer that will be in the leadership of growth profile in top and much more bottom line. So thank you for all your questions and have a nice afternoon.

Chuck Triano

Thank you everybody. This will conclude our call.

Operator

Ladies and gentlemen, this does conclude Pfizer's second quarter 2019 earnings conference call. You may now disconnect.