Q3 2019 Earnings Call

Company Participants

- Albert Bourla, Chief Executive Officer
- Angela Hwang, Group President, Pfizer Biopharmaceuticals Group
- Charles E. Triano, Senior Vice President, Investor Relations
- Frank D'Amelio, Chief Financial Officer & Executive Vice President of Global Supply & Business Operations
- Mikael Dolsten, Chief Scientific Officer and President, Worldwide Research, Development and Medical

Other Participants

- Andrew Baum, Analyst
- Christopher Schott, Analyst
- David Risinger, Analyst
- Geoff Meacham, Analyst
- Louise Chen, Analyst
- Navin Jacob, Analyst
- Stephen Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Umer Raffat, Analyst

Presentation

Operator

Good day, everyone, and welcome to Pfizer's Third 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.

Charles E. Triano {BIO 3844941 <GO>}

Good morning and thank you for joining us today to review Pfizer's third quarter 2019 performance and updated 2019 financial guidance. 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, 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 will see here that Slide 3 covers our legal disclosures. Albert and Frank, will now make prepared remarks and then we will move to a question and answer session.

With that I will now turn the call over to Albert Bourla. Albert?

Albert Bourla {BIO 18495385 <GO>}

Thank you, Chuck, and good morning, everyone. During my remarks, I will discuss our quarterly business performance, the latest updates from our pipeline and our plans for Pfizer following the anticipated completion of the Upjohn-Mylan combination, which we continue to expect to occur in mid-2020. During the quarter, we delivered a strong performance highlighted by 9% operational revenue growth in our Pfizer Biopharmaceuticals Group, which will be the business that remains at Pfizer following the anticipated closing of the Upjohn transaction.

We also saw revenue impacted by two expected events; the July Loss of Exclusivity in the US for Lyrica and the July 31st completion of the Consumer Healthcare Joint Venture transaction with GSK. For Biopharmaceuticals, once again this group's outstanding growth was driven primarily by strong performance from our key growth drivers. These include Ibrance, Xtandi, Xeljanz, Eliquis, Vyndaqel and Inlyta, as well as 15% operational growth in emerging markets, including 42% operational growth in China. Our Biopharmaceutical business in China generated higher revenue this quarter than the Upjohn business in the country.

Our Oncology business was particularly strong, up 30% operationally, compared with the year ago quarter. Global revenues for Ibrance were up 27% operationally in the quarter to $1.3 billion. We saw strong revenue growth in both US and international markets. We believe the continued growth in the US 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.

For Xtandi, the alliance revenues in the US grew 25% to $225 million. In August, the FDA granted Xtandi a priority review designation for the treatment of men with metastatic hormone-sensitive prostate cancer with a PDUFA date in December. If approved, this represents yet another potential growth driver for the brand. Inlyta revenues increased 98% operationally to $139 million. This included 240% growth in the US, where Inlyta has benefited from recent FDA approvals for the combination of Inlyta plus Bavencio and Inlyta plus Keytruda, in first-line treatment of advanced renal cell carcinoma patients.

Beyond Oncology, we had several other strong product performances. Global revenues for Xeljanz were up 40% operationally to $599 million. We saw continued volume growth in the rheumatoid arthritis indication and the recent launches for psoriatic arthritis in the US and for ulcerative colitis in both the US and several other developed markets also significantly contributed to the growth. Eliquis, also continued to perform well. Global revenues were up 20% operationally to $1 billion. This growth was driven primarily by

continued increased adoption in non-valvular atrial fibrillation as well as oral anti-coagulant market share gains.

Looking at our rare diseases business. Vyndaqel, continues to ramp up nicely in the US, following the May 2019 approval and launch. Our early disease awareness efforts have helped drive the diagnosis rates to greater than 4% in the quarter compared with 1% prior to the launch. As of end of August, approximately 4,100 patients had been diagnosed, approximately 2,600 patients had received the prescription for Vyndaqel and approximately 1,300 patients had received the drug. This number, do not include the early access program. If you include this, the number of patients receiving the drug increases to approximately 1,500.

Regarding Prevnar 13, revenues were down slightly across the global franchise. ACIP's updated recommendation in the US for the vaccine for adults 65 and older, which is not effective until the publication of the morbidity and mortality weekly report, reinforces that Prevnar 13 is considered safe and effective by both the FDA and ACIP. We look forward to successfully completing the Phase 3 studies for our investigational 20-Valent Pneumococcal Conjugate vaccine candidate. This candidate represents a potential significant advancements compared with a potential 15-Valent by introducing all serotypes contained in PCV15 plus 5 additional serotypes.

In sterile injectables, we are seeing our focus on manufacturing recovery taking shape. Global revenues increased 3% operationally and US revenues increased 1% operationally. We continue to expect this business to be a solid growth contributor in the future.

Now let me move to Upjohn. Revenues for our Upjohn business were down 26% operationally in the quarter. The decline was driven primarily by the expected significant volume declines in Lyrica in the US due to multi-source generic competition that began in July 2019. Excluding the Lyrica impact, the decline would have been only 6% operationally. Upjohn's China revenues increased 2% operationally, despite the volume-based procurement program in the 11 cities. Given this, we now expect Upjohn's full-year 2019 revenues in China to grow by mid-to-high single digits compared with full-year 2018, instead of low-to-mid single digit that we had predicted in our previous earnings call. Consumer Healthcare, the third quarter 2019 revenues totaled $377 million, down 54% operationally, reflecting the July 31st, 2019 completion of the Consumer Healthcare Joint Venture transaction with GSK.

Turning now 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 the science. Since our last earnings call on July 29th, we had seen some exciting milestones. In vaccines, we announced positive preliminary results from a proof of concept Phase 2 study of our investigational 20-Valent Pneumococcal Conjugate Vaccine under investigation for the prevention of invasive disease and Otitis Media in Healthy Infants. Once data with the fourth dose are available, we intend to discuss Phase 3 plans with regulators. We also have completed enrollment in our three Phase 3 pivotal clinical trials evaluating our investigational 20-Valent vaccine for the prevention of invasive disease and pneumonia in adults, 18 years and older.

In rare diseases, we completed the transfer from Sangamo to Pfizer of the manufacturing processes for the investigational SB-525 gene therapy for severe hemophilia A. This month we have enrolled the first patient in the lead-in trial of the Phase 3 clinical program. We expect to begin dosing patients for that trial in the first half of 2020. On October 21st, Pfizer announced jointly with our partner OPKO for the global Phase 3 trial evaluating somatrogon dosed once-weekly in pre-pubertal children with growth hormone deficiency met its primary endpoint of non-inferiority to daily injectable Genotropin. We are very pleased with the results because this potential once-weekly solution may offer significant benefits to patients. We are looking forward to presenting detailed data in a scientific conference and discussing them with the FDA and other regulators.

In Inflammation and Immunology, we recently announced positive top line results from JADE MONO-2. This was the second Phase 3 pivotal study, evaluating the efficacy and safety of our oral JAK1 inhibitor, Abrocitinib in patients with moderate-to-severe atopic dermatitis. These findings are in addition to the positive results for our first Phase 3 study with Abrocitinib in this indication where the full data were presented earlier this month at a medical conference.

In Internal Medicine, we recently entered into a worldwide exclusive licensing agreement with Akcea Therapeutics for AKCEA ANGPTL3-LRx, an investigational antisense therapy being developed to treat patients with certain cardiovascular and metabolic diseases. The therapies currently being evaluated in a Phase 2 study in patients with type 2 diabetes, hypertriglyceridemia and non-alcoholic fatty liver disease. We believe this novel therapy will complement our clinical mid-stage Internal Medicine pipeline and that our deep expertise in cardiovascular and metabolic diseases will help allow this program to reach its maximum potential for patients.

Lastly in Oncology, from our recent acquisition of Array, we presented interim analysis results from the Phase 3 BEACON trial of Braftovi/Mektovi and cetuximab for the treatment of patients with BRAF V600E-mutant metastatic colorectal cancer. Braftovi combinations showed statistically significant improvements in overall survival and objective response rates versus control. We recently submitted to the FDA a Supplementary New Drug Application with this data and as per our usual practice, we will announce their decision regarding acceptance for review. And I'm pleased to serve what we now have US launch days for three of our biosimilars recently approved by the FDA. Zirabev, is expected to launch on December 31st of this year, 2019; Ruxience in January of 2020 and Trazimera on February 15th of 2020. So, all in the near future.

Of course, 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 patient affordability. We are making progress in certain areas. For example, our proposals regarding biosimilars have been well received and by partisan legislation on this issue is advancing. We also continue to work with policymakers and others in the healthcare system to find ways to reduce out-of-pocket costs at the pharmacy counter, especially for seniors.

We are particularly encouraged that lawmakers recognize the need for an annual out-of-pocket comp in Medicare Part B. And we are aggressively pursuing value-based arrangements that tie reimbursement to the ability of our medicines to produce positive outcomes for patients. While there has been a lot of discussion around less constructive proposals, it's difficult to imagine Congress supporting policies, that will explicitly stand in the way of life-saving medicines being developed and made available to American patients. Therefore, we remain confident that common sense solutions can be found that will drive continued innovation and benefit patients.

In summary, we turned in another solid quarter, and our pipeline continues to be a source of great hope and excitement for our company, our shareholders and the patients who rely on our innovative medicines and vaccines. We also raised the midpoints for our 2019 revenue and adjusted diluted EPS guidance ranges to reflect our strong performance to date as well as our confidence in the business going forward. Frank, will provide more details on this in a moment. Following the expected close of the Upjohn-Mylan transaction next year, Pfizer will be a smaller, science-based company with a singular focus on innovative biopharma. All our current growth drivers and pipeline will remain with Pfizer for this reason. And we expect Pfizer's five-year revenue CAGR to be approximately 6% and for that growth to begin immediately upon the close of the transaction.

Our Biopharmaceuticals Group is already growing at a similar pace. Starting in 2026, we will have a new set of LOEs, but we expect the new wave of compounds currently in the pipeline, along with the acquisitions of Therachon and Array Therapeutics, our equity interest in Vivet Therapeutics and the in-licensed investigational therapy from Akcea, to help mitigate the impact of these LOEs. These agreements represent the types of targeted BD initiatives, we will continue to pursue to help strengthen our substrate for the second half of the next decade. These are deliberate moves we are making because of the confidence we have in our science, in our ability to commercialize important new medicines and vaccines and in our ability to continue to invest in growth while returning capital to investors.

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

Frank D'Amelio

Thanks, Albert. Good day everyone. The charts I'm reviewing today are available on our website. Now moving on to business performance. Our Biopharmaceuticals Group business recorded 9% operational revenue growth in the third quarter of 2019, driven primarily by Ibrance globally, which recorded revenues of nearly $1.3 billion, an operational increase of 27%. This was composed of 48% operational growth in international markets and 18% growth in the US. Xeljanz globally up 40% operationally, primarily driven by 34% growth in the US as well as 61% operational growth in international markets.

Eliquis globally up 20% operationally. The hospital business, up 9% operationally in emerging markets and the US, primarily driven by continued growth from anti-infective

products in China and the November 2018 US launch of Panzyga. Vyndaqel, with sales of $156 million in the quarter, with $79 million in the US following the launch for cardiomyopathy and then later in the US, where revenues increased to $139 million, primarily driven by increased utilization in combination with certain checkpoint inhibitors for the first-line treatment of patients with advanced renal cell carcinoma, partially offset primarily by lower revenues for Enbrel internationally, down 19% operationally, primarily reflecting continued biosimilar competition in most developed European markets; and Prevnar 13 in the US, down 7% due to lower government pediatric purchases in the third quarter of 2019, and continued decline in revenues for the adult indication.

Revenues for our Upjohn business in the third quarter decreased 26% operationally, primarily driven by the expected significant volume declines for Lyrica in the US associated with multi-source generic competition that began in July of 2019. Excluding the unfavorable impact of Lyrica in the US, third quarter 2019 revenues for Upjohn declined 6% operationally due to continued generic competition for certain off-patented products. These results were partially offset by revenues in China, up 2% operationally, primarily driven by volume growth for Lipitor and Norvasc in provinces with a volume-based procurement program has not yet been implemented as well as operational growth from Viagra and partially offset primarily by volume declines and unfavorable pricing impact in cities where the VBP program was implemented in March of 2019.

Pfizer now expects Upjohn revenues in China to grow operationally by mid-to-high single digits for the full-year 2019 compared with 2018. Revenues for the consumer healthcare business in the third quarter are not comparable with the third quarter of last year due to the completion of Consumer Healthcare Joint Venture transaction with GlaxoSmithKline. This quarters reporting reflects approximately one month of consumer healthcare domestic operations and approximately two months of consumer healthcare international operations. First is third quarter of 2018 revenues, which reflect the full three months of consumer healthcare global operations. In addition, Pfizer recognized an $8.1 billion pre-tax gain upon the completion of the Consumer Healthcare Joint Venture transaction, which reflects the difference in the fair value of Pfizer's 32% equity stake in the joint venture compared to the carrying value of its Consumer Healthcare business.

Finally, diluted weighted average shares outstanding declined by approximately 337 million shares to 5.65 billion versus the year ago quarter, primarily due to Pfizer's ongoing share repurchase program, reflecting the impact of share repurchases during 2018 and 2019, partially offset by dilution related to share-based employee compensation programs. Foreign exchange negatively impacted third quarter 2019 revenues by approximately $215 million and adjusted cost of sales and positively impacted adjusted SI&A and adjusted R&D expenses. In aggregate foreign exchange had $0.02 per share negative impact on adjusted diluted EPS compared to the year ago quarter.

Moving on to 2019 financial guidance. We raised the midpoint of our 2019 guidance range for revenues by $200 million to $51.2 billion to $52.2 billion composed of $400 million of operational revenue growth partially offset by a $200 million unfavorable impact from changes in foreign exchange. (technical difficulty)

Sorry for the technical problems, everyone. So let me continue it's Frank. In addition, we now expect adjusted cost of sales to be in the range of 19.3% to 19.8%, adjusted SI&A expenses to be in the range of $13.5 billion to $14 billion, adjusted R&D expenses to be in the range of $7.7 billion to $8.1 billion, and adjusted EPS to be in the range of $2.94 to $3.00 from $2.76 to $2.86, an increase of $0.16 since the previous quarter, reflecting an $0.18 operational improvement, partially offset by a $0.02 unfavorable impact from recent changes in foreign exchange rates. This guidance assumes diluted weighted average shares outstanding of approximately 5.7 billion shares, which reflects the weighted average impact of share repurchases, totaling $8.9 billion executed in 2019. Dilution related to share-based employee compensation programs is currently expected to offset the reduction in shares associated with these share repurchases by approximately half. Our 2019 guidance for adjusted other income deducts in the effective tax rate on adjusted income did not change. We continue to expect adjusted other income deducts to be $200 million of income and the effective tax rate to be approximately 16%.

Now moving on to key takeaways. We delivered a strong quarter. Revenues with the Pfizer Biopharmaceuticals Group grew 9% operationally versus the year ago quarter, driven by Ibrance, Xeljanz, Eliquis, Vyndaqel, Inlyta and Xtandi. We updated our 2019 financial guidance, increasing the midpoint of our adjusted EPS guidance range by $0.18 operationally. We accomplished multiple product and pipeline milestones since our previous quarterly update and we returned $14.9 billion to shareholders through the third quarter, through a combination of dividends and share repurchases. Finally, we remain committed to delivering attractive shareholder returns in 2019 and beyond.

Now, I'll turn it back to Chuck.

Charles E. Triano {BIO 3844941 <GO>}

Thank you. Albert and Frank for the prepared comments. Operator, can we please move to the Q&A session.

Questions And Answers

Operator

(Operator Instructions) Your first question comes from Chris Schott with JPMorgan.

Q - Christopher Schott {BIO 6299911 <GO>}

Great, thanks very much for the questions. I guess just two here. First, I know you're not giving 2020 guidance at this point, but relative to your initial 2020 comments made with Upjohn, maybe just give us any -- just flavor in terms of business trends or any franchises that are performing ahead or behind, maybe some of the initial expectations? And my second question was, was about kind of the next wave of pipeline opportunities. Because it seems to me, when I hear the enthusiasm you have about that pipeline that there is a bit of a disconnect between Street expectations and Pfizer expectations on the pipeline. So when you look at that portfolio, are there assets in particular where you see a particularly -

- a gap relative to I guess what we're thinking versus your expectations as we kind of focusing on some of these updates over the next few years? Thanks so much.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Thank you, Chris. Let me try to speak a little bit about your question on guidance of next year and then I will ask also Frank to help me on that. And then I will ask Michael Dawson to speak about pipeline. Let me start with the 2020 guidance. We don't give guidance, before our Board approves our operating plan. And this every year happens in the mid of December of 2000 -- of every year and usually we do it in the next earnings call, which happens in January. This year in the mid of the year in July, because of the transaction, we had to provide some financial targets for Upjohn. As a result, we felt that it is going to be awkward if we do not give also some financial targets for all of the RemainCo in 2020.

But of course, we did that with a lot of unknowns and with great distance from the year of 2020, so we were appropriately cautious I would say. Since then, a lot of things happened and happened in the areas that we wanted to see how things could perform. For example, we were not certain how the ACIP recommendation for Prevnar would affect the adult business. We were not certain how the label for Xeljanz, the black box that we received in the change in label for Xeljanz, how that would affect the prescription habits of physicians. We were not sure how Ibrance effort that started in the beginning of this year to increase the market size rather than focus on increasing our own markets around it and that had given very good results in the second quarter will continue as we go into the third quarter, but we were not certain how the newly approved Inlyta compared to Bavencio together with Bavencio and together with Keytruda indication will transform into performance into the market, and we were not certain how expanding new indications were before and also how the new products, which is our Vyndaqel in cardiomyopathy eventually will do. As a fact of the matter, all six of them did much better than what we were expecting. And this is extremely, extremely positive of course. We are not going to provide now the guidance for next year, but definitely, things have improved compared to what we sold in the second quarter.

Moving to Upjohn, also the same sentiment. We had provided $7.5 billion to $8 billion for next year and we had said, that -- which by the way significantly lower than what Upjohn is doing now, because we wanted to make sure that we incorporate the impact predominantly in China of the volume-based procurement system. And for the same reasons, we said that the second half of this year will be lower and that will drive our growth in China in general it could be low-to-mid single digit for China. In fact we're upgrading that now and we are saying that for this year, our growth will be mid-to-high digit growth in China portion of the Upjohn business and again we're not going to provide guidance for 2020 for Upjohn, but we will do that together with the total company after our Board approves in mid-December, but we have updated the guidance for this year obviously, because of the very good results of the third quarter.

Frank, anything to add to that please.

A - Frank D'Amelio

I would just add two things, one, our current expectation is we would provide guidance for 2020 like we typically do on our fourth quarter earnings call. But the only other thing I would add is -- but please understand that we intend to improve upon the 2020 numbers that we previously issued that we talked about that we're appropriately cautious for the reasons that Albert discussed.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Now from the financials, let's go to things that are driving the financials, which is our strength of our pipeline. So Mikael Dolsten, please, go ahead.

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you, Albert. So let me say a few words. First, we have a large and strong pipeline with 98 projects from Phase 1 to registration and its contribution from all of our five therapeutic areas and it is driven by multiple science franchises, and not dependent on one or two vulnerable compounds. Number 2, our R&D productivity had improved consistently over the last few years. Let me exemplify with our Phase 2 success rates have now been exceeding 40% for a number of years well above the benchmark.

We estimate that earlier between 2018 and 2022, 25 to 30 approvals from 2018 to year-to-date, we're already at 11. Within that approval wave, let me exemplify our focus on the 15 in five strategy to deliver blockbuster approvals. And within that cohort as you have seen, we have had really good progress and both Phase 2 and Phase 3 success rate or high and robust and also it is most valuable compound. Now I wanted to conclude and give you more of near-term opportunities for our pipeline. So between now and end-2020, you may want to remember the metrics 15 plus 10 plus 5 plus 5, 15 relates to 15 POC readouts -- upto 15 POC readouts, 10 to -- 10 Phase 3 starts and then 5 for 5 Phase 3 readout and 5 key approvals.

Let me give a few example on the POCs that you can keep an eye on. We have five different POC -- upto five different POC readout in our JAK franchise including an indications across topical atopic dermatitis, psoriasis, vitiligo and also psoriatic arthritis for an oral drug. We have a strong momentum in our gene therapy platform. Albert mentioned in his introduction, our Factor 18 therapy where we are expecting soon POC readout and have started to enroll for baseline characteristics in Phase 3. We are progressing well with our DMD gene therapy, and we have reached proof-of-concept for our tissue factor pathway inhibitor monoclonal antibody. We're also going to strengthen our hemophilia and Phase 3 plans are underway.

In Internal Medicine, I want to punctuate angiopoietin L3 deal pending close that we expect to have a POC readout early next year. Our vaccine franchise also has a number of intriguing data sets to be shared. Obviously, the [ph]PNG pediatric plus faustus , RSV maternal Phase 2 data next year, followed by Phase 3 start pending data. And also in our meningococcal pentavalent vaccine, we have actually reached very promising Phase 2 readouts and are reviewing them to be shared for a potential Phase 3 start.

Finally, in our Oncology franchise, we have the readout next year expected for our anchor BRAF/MEK first line, we have data coming from our next generation CDKs and from HER2 breast cancer ADC. So as you can see I exemplified some out of the many POC readouts coming from now to next year, and just punctuate that of course the late-stage pipeline to which you are more familiar with, have major interesting things in 2020. High on everyone's agenda is the Ibrance early breast cancer, which we strongly look forward to. And I feel encouraged and optimistic about that salience ankylosing spondylitis JAK1 in the comparator atopic dermatitis study that is the final data set for then moving to potential submission. And of course then PNG adult. I'm sorry for somewhat lengthy, but it's actually reflected the many exciting things to happen from now to end of 2020.

Q - Christopher Schott {BIO 6299911 <GO>}

Thank you, Mikael.

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

Great, thank you. We move to the next question please, operator.

Operator

Your next question comes from Umer Raffat from Evercore.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my questions and congrats on the quarter. I wanted to touch upon three things today, if I may. First, Albert, there's been a lot of investor questions on whether Pfizer could potentially be interested in M&A to recover the EPS dilution because of Upjohn. I just -- I just wanted to ask where you shake out on that? The first one. Secondly on Upjohn, I noticed there was an S-4 filed yesterday where Pfizer's internal forecast was that Upjohn stays at $7.8 billion to $8 billion post 2020 even though there would have been a Lyrica patent expiry worth $800 million in Japan and even though China 4 plus then would have intensified. So my question is what's driving this potential $1.5 billion to $2 billion worth of revenue shortfall to keep Upjohn stable at close to $8 billion post 2020? And finally on Tafamidis, it's very encouraging to see you're already at 40,800 patients and my question is, is it conceivable -- is it inconceivable that Pfizer could hit more than 40,000 patients diagnosed at peak? Thank you very much.

A - Albert Bourla {BIO 18495385 <GO>}

Excellent question Umer. So let me start with an M&A. Frank can cover the Upjohn forecast and then of course, Angela could speak about Tafamidis. On the M&A strategy, look, since the July of 2018, when I as Chief Operating Officer at that time I articulated the strategy going forward on several items including M&A strategy. We are very consistent. Right now we are poised for organic growth. Our organic growth, we forecast will be on a five years CAGR, 6%. I know the analyst expectation is even higher.

This number, even the 6%, compared to the analyst expectations likely will position -- if not likely is positioning us compared to the data and our peer set, let's say, the top 10 to 15 companies in the industry will be the second largest in terms -- the second fastest

growing company in the next five years with a 6% in terms of rate. And actually the largest in terms of producing gross dollars, because we are going to of course, of our size, of course. So any efforts, that we're going to do, I'm not going to jeopardize that. So we are not the name of the game for us, like I said it many times, it is top line growth.

And M&A of scale, they have the tendency, one, very difficult to find someone that will not be accretive given that we are the second fastest in our growth. And secondly, it is very disruptive operationally and we can always do a large M&A, but we have a very clear window of opportunity now to get it right with our pipeline, to get it right with our launches. As you can see we are doing very well. I don't want to put that at risk. Our business development strategy will continue to be bolt-on, but we'll have a focus on R&D. And when I speak about R&D, again as I said before, I want to be very clear, we are looking for Phase 2 assets, [ph]ready Phase 2, ready Phase 3 assets that likely the ones that we did in the last four business development activities that will provide revenues at the post '26, '27 period, when we started feeling again some of the [ph]wins and we want make sure that the 6% growth is sustainable for the decade,

the whole decade, rather than only for the first six, seven years would indicate. So this is our strategy. We are not looking for a large M&A right now. And with that I'll move to Frank to speak a little bit about of the Upjohn projections and what we said in our Board presentation, which I think is pretty much in line with what we gave as a guidance for next year.

A - Frank D'Amelio

Yes, so for Upjohn the 2020 revenue number that we put out there was $7.5 billion to $8 billion. By the way, that number reflected the Lyrica LOE and it reflected the China VBP. In fact we anticipated the expansion of the China VBP in that number in terms of going expansion for 11 cities, 12 provinces, 50% share to 70% share, that range anticipated the impact of VBP in China. So a couple of comments on how do we get to the rhythm of the numbers that you alluded to. So I think about this quarter, Upjohn China, this quarter grew 2%. How do we grow 2%? Basically, it was able to mitigate the impact of the procurement program with geographic expansion within the country.

We believe that that's an opportunity that continues on a going forward basis. We also believe that there is opportunities for that business in emerging markets outside of China and continuing opportunities for that business in the rest of the world given the breadth of the portfolio, it's going to have and quite frankly the pipeline that the new company has on a going forward basis. So that's why you get to the numbers that were put into S-4.

A - Albert Bourla {BIO 18495385 <GO>}

And then, Angela please about Tafamidis.

A - Angela Hwang {BIO 20415694 <GO>}

Thanks for the question. Certainly, we are extremely pleased with the diagnosis rate of ATTR-CM that we have seen to date, which was about 4% to 5%. But even with that, it's important to remember that it is still severely under-diagnosed disease and we have a

long way to go in terms of achieving what we believe our patients deserve. There are two aspects to this diagnosis. The first is, suspicion or suspecting the disease and the second is the ability to detect the disease. As you know because we've spoken about this over the last several quarters, we have been intensely focused on our educational efforts to help physicians suspect the disease and this has been helped by the recently published reds [phonetic] like symptoms, which makes it easier for physicians to see the possible clinical symptoms of ATTR-CM and helping them to drive suspicion of this disease.

From there, we have been educating around the use of scintigraphy as a non-invasive means to diagnose ATTR-CM. And we're pleased to see that to date, about 90% of our diagnosis is now being driven through scintigraphy. Scintigraphy, as you know is a well-established imaging technique and it's widely available across the US in cardiology practices. Actually we estimate about 15,000 of these diseases are available in cardiology practices throughout the country. And we're seeing then this willingness and the readiness of physicians to adopt ATTR-CM diagnosis through this mechanism. I know that benchmarks that we have quoted in the past, show that a diagnosis rate of about 30% to 50% is what most rare diseases have achieved up till now and that is what drove our peak estimates. However, we are learning a tremendous amount every single day about this particular disease, about what it takes to diagnose it and certainly we are focused on making sure that we can do better than that for our patients.

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

Thank you, Angela. Next question please.

Operator

Your next question comes from David Risinger from Morgan Stanley.

Q - David Risinger {BIO 1504228 <GO>}

Yes, thanks very much. I have two questions. First, could you just update us on the timing of the Ibrance adjuvant interim efficacy look? And second, I was hoping you could speak to the gross margin upside in the quarter in a little bit more detail and comment on the sustainability of strong gross margins? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Very interesting questions, David. I think again, Michael, can provide an update on the timing of Ibrance and of course for margins, the master of margins improvements, Mr. Frank D'Amelio. Micheal?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes. We tend, in general, not to be specific about interim analysis in any programs. We expect the program to run to completion in 2020. There is an interim analysis a little bit earlier in 2020, but most likely it will run to completion. And we remain optimistic about the outcome of the study based on Ibrance's very strong performance. More recently event supported by real world evidence data that was very favorable across the different aspects of progression fees survival and also robust on overall survival, actually having

hazard ratio of less than 0.6, which probably the strongest hazard ratio provided so far and we will update the hazard ratio as the study matures. Thank you very much.

Q - David Risinger {BIO 1504228 <GO>}

Thank you, Michael.

A - Frank D'Amelio

So, David, I'll answer the gross margin question and I think I'll also just add in even though you didn't ask a little bit about operating margins too. So on gross margins, let's do it based on cost of sales. If you look at our own cost of sales year-over-year, Q3, 2018, 20.1%; Q3, 2019, 19.4%, so directionally correct right, down on a year-over-year basis. What drove the improvement? Really a couple of things, one is some cost improvements that we were able to implement in our global supply chain organization, obviously, our manufacturing plants and the like. And then secondly we had some very favorable product mix, right. If you look at where our revenue growth was, alliance revenues were up 18% year-over-year, Ibrance grew so -- and then Vyndaqel. So we had some very favorable product mix.

If you look at our operating margin for the quarter, high-30s, approximately 30%. So if you look at the trending and then you think about going forward, one key on that operating margin with them will be the revenue growth. So obviously, we're saying now, we think 6% operational revenue growth going forward that will clearly help our operating margins on a going forward basis, relative to what we had said back in July, because we'll leverage that to the bottom line. As I mentioned earlier, clearly our intent is to improve upon the numbers that we provided previously that we're cautious, appropriately cautious back in July. So net-net, we think we can improve upon the numbers we provided and we'll give you all an update on that when we give our 2020 guidance.

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

Thanks, Frank. Next question please, operator.

Operator

Your next question comes from Tim Anderson from Wolfe Research. Thank you.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. A couple of questions. On your revenue guidance of five-year CAGR of 6%, consensus is not at that level. And I'm wondering if there is any big areas that jump out at you, specifically as being mis-modeled by the analyst community and as much as you've looked at that sort of thing? And then on Abrocitinib, your JAK inhibitor, you're running a trial called JADE Compare head-to-head versus Dupixent always bold to take on a product head-to-head. It looks like this trial should be reading out in December of this year. So coming up. I'm wondering what we should realistically expect from that both in terms of efficacy and safety. It seems that, at least on safety and tolerability, it almost can't look as good as Dupi because it's a small molecule JAK inhibitor, but maybe you can kind of tell us what you expect that trial will show?

A - Albert Bourla {BIO 18495385 <GO>}

Yes, I think again the R&D question, I think we'll go to Michael, just a brief comment. Look we speak about our numbers right. And the 6% that we're providing for our numbers, we are very, very comfortable with this number. Always we want to make sure what we say, what we do and we do what we say. So I don't want to jeopardize that. So I'm giving numbers that we feel very comfortable to achieve. I have seen a lot of reports of analysts that they are having higher numbers than that that's why I refer to that and I'm going to check what is the consensus on that, but, as I said, I don't want to comment on other people's -- you are doing your job and we're doing our job. We feel very comfortable on the 6%. Michael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes, thank you very much for shedding light on the Compare study. So we are very excited about that study as it concludes our potential filing material including then aggregator safety data. It is a head-to-head against the dupilumab Dupixent and we felt that, it's an important trial in the sense we expect both drugs to show tolerability and safety that are favorable. We expect Abrocitinib based on current historical comparison to do very well on efficacy, on clearance of scheme. And we have specifically an endpoint on its relief pruritus reduction, which is one of the critical most patient friendly centered endpoints and we expect, and I believe that Abrocitinib would outperform Dupixent in a very clinical meaningful manner as it has a strong fast onset and data available althought not head-to-head showed that the JAK1 class not just performed better clinically so far and head-to-head is the reason why we wanted to document that hypothesis. But there is also science behind it. It inhibits the Interleukin-31, that is a major itch mediator which is not covered by Dupixent. So I hope that gave you some insight into our enthusiasm.

A - Frank D'Amelio

And Tim, it's Frank. I just wanted to add to what Albert said, remember when the new company is formed between our Upjohn business and Mylan, RemainCo, our new Pfizer is our Pfizer Biopharma business. Our Biopharma business this quarter grew 9%. The last couple of quarters, grew 6%, 7%. So that approximately 6% that Albert gave, we've been printing now literally for the last few quarters. And remember when newco was formed, new Pfizer or RemainCo keeps all of the growth drivers that we currently talked about on this call. So that portfolio -- the momentum that portfolio carries into the new Pfizer.

A - Albert Bourla {BIO 18495385 <GO>}

Very good points Frank.

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

Thank you. We move to our next question, please.

Operator

Your next question comes from Steve Scala from Cowen.

Q - Stephen Scala

Thank you. I have a couple, first for Michael. The press release says that after three doses in infants, the safety of 20-Valent Pneumococcal Vaccine is similar to Prevnar 13, but you don't say the efficacy is similar after three doses in terms of immune response to the 13-valents that they have in common. Can you comment on that point and the response to the additional 7 valents? I know Prevnar 13 is afford dose regimen, but you must have data after three doses? So that's the first question.

Second question for Frank, should something draconian come out of Washington that overnight cut revenue by 10%, a 20% reduction in operating expenses would appear require to protect the bottom line. Could a 20% reduction in operating expenses be delivered, and if yes , would it take six months, 12 months or would it take much longer? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Michael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes. You know, we share data on the three immunizations and it was a descriptive study not powered for efficacy, but I my take at this was as in the press release, we had very robust rise in immune titers against all 20 serotypes. And at this stage it look very similar to the PCV 13 when you look at the totality of data. And you know the immune titers also are supplemented by functional antibody responses that we're now obtaining that again look very robust for the PCV 20 across all serotypes. I wanted to also to say that know increasingly available epidemiology data strengthened the notion that the PCV 20 has a very broad coverage, far exceeding PCV 15 developed by a competitor where you look at the infant population to adult population, US or European major countries and where you look at IPD and CAPs. So we're very pleased with the emerging data and increased insights into epidemiology that indicates this vaccine has the potential to provide the broadest ever coverage for pneumococcal disease.

A - Frank D'Amelio

And then Steve, if there was some draconian action that resulted in 10% impact on our revenue, which is a big number, then clearly we would have to revisit our cost structure. I mean, how could we not? In terms of how much we can do with how quickly we would do it, quite frankly, we'd have to work our way through that. But the short answer is, we would clearly -- we view our cost structure -- every element of the cost structure by the way, which we do all the time anyway, and then see what we'd have to do to deal with -- quite frankly what the model is -- what the business model is going forward -- going forward. A 10% decline in our revenues is a change in our business model and we'd have to obviously, look at that in terms of how we run our business on a going forward basis.

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

Thanks, Frank. Next question please.

Operator

Your next question comes from Navin Jacob from UBS.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi. Two questions if I may. Number 1 on Hospira, as you have stabilized that business and the manufacturing capabilities there, wondering if you could help us understand to what extent there have been lost revenues quote-unquote over the last two years that would -- yet you may have been able to have if Hospira had been at full capacity and that basically, what I'm asking is, how much do you think you can recover going forward for Hospira and how quickly could that growth be achieved? And then on the C. difficile vaccine, I think the Phase 3 was supposed to read out in 2020, but I think you just went through an interim analysis in the DSMB or the monitoring board suggested to expand that study, wondering when the readout for that Phase 3 will be now? Thank you very much.

A - Albert Bourla {BIO 18495385 <GO>}

Right. I think, Angela can answer the Hospira question. I like to say something, for us, the manufacturing issues and the supply issues for Hospira created, I would say a lot of trust with our customer. This is for me the most important, okay. And that's why we took it very seriously and we were very transparent with them and we created also a hospital business unit because this is mostly hospital products, so that can be very customer focused only on the hospitals, so that we can make sure that we had the relations, that we had before field and make them very strong. And I have to say that we were very successful on that and what the customers appreciated the most was the transparence. Obviously, there is business that we lost and we hope that we will recover most of it. Angela, what do you think?

A - Angela Hwang {BIO 20415694 <GO>}

Sure. I think the way I would think about the future growth of the hospital business unit and even Hospira would be in the following way. I think there is a portion of the revenue that was lost as a result of the supply issues that we would recover. There is a portion that we wouldn't recover, but that isn't -- I guess that's not the only source of growth, I think the way to think about growth also is what we're doing to continue to diversify that portfolio and to bring in new launches. You heard Frank talk about Panzyga, as one of those and in our pipeline and in our -- in our portfolio today, our continuous launches, both from a presentation and a device perspective as well as from the molecule perspective.

I think the other -- the other element of the hospital business unit that we also need to consider is the strong anti-infective portfolio that is part of that business unit. Those are sterile injectables and in that unit -- in that portion of the business are a number of new launches that began a couple of years ago and are now launching globally. So that's how I would think about growth in that portfolio, is that it's not dependent purely on the replacement or the regaining of business. A portion of it is, but much more of it is dependent on new ventures and new spaces that we are venturing into.

A - Albert Bourla {BIO 18495385 <GO>}

Yes, Michael.

A - Mikael Dolsten {BIO 16368411 <GO>}

On the C. diff, yes, we were pleased with the aspect that safety and tolerability with regard as favorable at the interim analysis and clearly the futility analysis indicated that the study should continue. While we tried to target the high-risk patients for C. diff infection by looking at increased risk for contact with healthcare community or recent use of antibiotics, we are of course, pioneers in this area of developing a vaccine for this urgent need for preventing what can be fatal C. diff infections.

So we'll use all our insights to learn today to make sure that we can continue and expand enrollment to follow the advice from the monitoring committee to make sure we can conclude this study as soon as possible. And of course, there is an urgency with 50,000 C. diff infections every year in US and close to 30,000 of diff and we'll do everything possible to accelerate the readout of the study and get the events. We clearly do accumulated events, although somewhat slower than we initially hoped, but rest assured that we will do everything we can to make sure the readouts is coming as soon as possible and we will later update you with more firm aspects of that.

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

Thanks Michael. Next question please, operator.

Operator

Your next question comes from Andrew Baum from Citi.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. Your portfolio is heavily exposed to high list price, heavy Part B exposed drugs. I'm obviously thinking about Ibrance, Inlyta, Xtandi and so on and so forth. You mentioned -- you welcomed the proposal to cap out of pocket spends under Medicare Part B, but within the same Finance Committee proposal, there is also an obligation for you to fund catastrophic coverage to the tune of 20% and even larger contribution from the plan sponsor. So my question is what is your comfort level with that part of the proposal and to what extent do you think, particularly in crowded classes like the CDK 4/6 is, the obligation on the plan providers to fund catastrophic -- catastrophic coverage is going to further increased price competition in the segment? And then the second question, if I quickly is, historically in veiled against some of your competitors for basically holding Xeljanz into very treatment refractory settings, given accession of their rebate power, I'm thinking particularly of Humira, what's your confidence level that you're going to be able to secure favorable market positions with JAK's given drugs like Dupixent that are going to be generating significant rebates for the PBMs in the commercial book of business by the time you hit the market? Many thanks.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much. Let me try to answer your question about the out of pocket and all these reforms in the Medicare that have been proposed. And then I will ask Angela to speak about Xeljanz. When it comes to price reforms there are things that we agree and are things that we do not agree. But I would tell you that we are fanatical in favor of reducing out-of-pocket cost for patients. Because right now the fundamental issue that drives this polarization in the political environment around healthcare, it is a real problem and the problem is that the Americans are paying for their medicines. Like if they are nothing short, although they are having insurance, when they go to collect them from the counter of the pharmacist. This is not happening with the hospital, this is not happening with diagnostics, this is not happening with other medical interventions, at least to the degree, what was happening with medicines and this is why the drug pricing is so high in the debate. Although, that they represent only 10%, 12% of the total healthcare cost. So that needs to be addressed.

Now that way that the Senate for example is proposing for aggressive or even worse to the House, they are going to increase the contribution of the pharmaceutical companies and of course, this will help. But this is -- the list of my problems [ph] over it because at least what hurts us helps the patients. My issue with this POC business, a lot of other measures that they're suggesting that hurt us even more. They are not moving the savings to the patients, which is the fundamental issue that's right now societies is dealing with and this is our efforts here. I believe that it is to the benefit of the industry, it is to the benefit of innovation, it is to the benefit of patients, it is to the benefit of the healthcare system to reduce the cap -- to reduce the out-of-pocket expenses, either with a rebate reform or if that's not on the picture right now, by reducing the -- by implementing a cap for out-of-pocket, it is of paramount importance, even if you have to pay for it. And Xeljanz, Angela.

A - Angela Hwang {BIO 20415694 <GO>}

So, it is true that we may look back the Xeljanz access has been challenging through time, but certainly, we over the last several years have worked hard with our payers as well as our PDMs as well as amassing, I think some really strong scientific and patient experience and evidence behind Xeljanz, that is creating momentum for this particular product. The I&I category generally is one that is the most heavily rebated and and I think that we have demonstrated our ability to be a real solution in this space of great unmet need. And as evidenced just compared to last year this time we now have 32 million more incremental lives in Medicare and commercial channels that have gained unrestricted access, and specifically in fact just this past May we gained an additional 8 million lives. So I think that this is sort of good evidence to show how we are working hand-in-hand with our payers, as well as our PDMs as to bring the totality of our data and our experience to bear and filling an area of great unmet need.

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

Great. Thanks, Angela. Next question please.

Operator

Your next question comes from Terence Flynn from Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the questions. Albert, you mentioned a few of your upcoming biosimilar launches, just wondering if you can help frame for us, the potential size of the opportunity as you think about the long-term there and maybe walk through some of the remaining hurdles in terms of establishing a robust biosimilars market in the US? And then Angela, just wondering any more color you can provide on the Xtandi dynamics in terms of either share among the different segments or maybe mix of the prescriber base? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Let me speak a little bit above generally about the biosimilars and then I will ask Angela who will answer the second question on the specifics in the biosimilars potential that we are going to launch. I think in the US, unlike other countries there is a problem with the system and the system is that there is -- the fundamental issue that there is this rebate trough, but payers overall they do see the benefit of using biosimilar solution of what physicians would like to prescribe and that the FDA, saying that has similar efficacy and safety, and it is much cheaper. Although they want to do that, they are trapped and they cannot because they are going to lose the benefits or the rebates what the originator is offering them.

And I think frankly, but unless if we resolve this big issue we will never be able to see tremendous progress on biosimilars. So this is something I think that the political work understanding. This is something that we are very vocal about it. This is something that we are discussing constantly with payers, who they want to move to new solutions, but they cannot. And I think that there is positive momentum on that, but still I repeat, to be able to see transformational change in the penetration of biosimilars. So the healthcare system can see realized significant savings can only happen if we find a solution to that. We have also suggested other measures like the savings to be served by providers etc., etc., but I think that's the fundamental one.

Now all biosimilars are not the same because -- and not all markets are the same. When you have close systems like the [ph]Kaizers for example the penetration question is very, very high, because they can see the benefit of doing something like that. But when you have intermediates being involved, but then big rebates in play, it's very difficult for them to do it. And also Oncology is very different also biosimilars from I&I biosimilars, because the I&I, they are giving, for very expensive periods of time. So you need the suites. New patients aren't coming very often. Oncology is very different because this is more limited the period that they are -- the therapies are used and then the patients are coming much more often -- new patients are coming much more often in higher proportion.

But, Angela maybe you want to add into that and then also provide and answer the second question.

A - Angela Hwang {BIO 20415694 <GO>}

Sure, I think Albert has said, much of it and maybe what I can add is the following. I think within the context of the fact that the US dynamics are very different from the European

dynamics, where you see a much greater adoption of biosimilars, what we have seen with our supportive care biosimilar, which is Retacrit, is that we've seen some nice growth there. To date it has a 16% market share, which is the highest that we've seen of any biosimilar here in the US and I think that that tells us -- and that's given us the opportunity to learn about what it will take to launch oncology biosimilars as well as what we can expect in this particular space. So I think with the three biosimilars coming within -- one after the other December, January, February of end of this year, we look forward to driving the growth of this portfolio of biosimilars in an area of high unmet need for patients.

As it pertains to Xtandi, you do see a tremendous growth here this quarter. We had a great quarter growing 25% year-over-year, and I think that this is evidence of the great confidence that our prescribers, both urologists and medical oncologists are having with Xtandi. We have leading market share at 37% branded in a growing class and the plus as well has been one that has grown 3 points from last quarter to this quarter. So when we look at our sources of patients for Xtandi, they come in two forms. First, it's the non-metastatic castrate-resistant prostate cancer, where we continue to see increases, both in total patients as well as new patient since the PROSPER approval. And just as a measure of PROSPER, urologists are generally the prescribers in earlier disease setting, and here urology prescribing is growing at 44%, and so we're continuing to see the proportion of our business from PROSPER growth very positively. Also to remember that these patients are earlier in terms of their course of disease and therefore have higher days of therapy. So this will drive -- this will drive the prescriptions and the revenues.

In metastatic CRPC castrate-resistant prostate cancer, which is still the majority of our business. Our new patient share continues to increase there too. And here we had not only have the number one share of voice with oncologists, but our prescribing with oncology -- medical oncology continues to grow significantly as well and this quarter at 21%. And so when you bring all of this together and you add into that -- the approval, or the positive of the Phase 3 results, we got from from [ph]Asmed and the the submissions that we have for additional indications in both the non-metastatic hormone-sensitive setting as well as additional data from the EMBARK study. I think that what we have in Xtandi is a uniquely positioned NHT that is going to be able to treat multiple indications in both hormone-sensitive as well as castrate-resistant prostate cancer.

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

Excellent, thanks Angela. Next question please.

Operator

Your next question comes from Louise Chen from Cantor Fitzgerald.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thanks for taking my questions. So my first question is that in consensus there is a meaningful step up in Ibrance sales through 2023. And do you think you can grow Ibrance double digits without an adjuvant or neoadjuvant approval? And then second question I had is on Abrocitinib, based on the safety data that you've seen thus far, is

there a chance that you will not get a black box warning like other JAK15 in the industry? And then last question I had was if you could give an update on your DMD program, where you stand today, the competitiveness of your program versus some of the other ones out there, based on the data that you've seen thus far? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Just a quick answer on the Ibrance and then I think on Abrocitinib and DMD will be covered by Mikael. Again in the spirit, that I don't want to comment what is the analyst expectations. I know what are our expectations. And we are projecting that we will grow Ibrance double digit and are also expecting that we will receive the -- that we will have, let's say, positive PALLAS [ph] study, which is the main study about driving expansion of prescriptions and drivers. So of course everything is risk adjusted in our projections and some will be positive, some will be negative, but the 6% that we are taking with (inaudible) is not based on one or two, but is based on risk adjustment of mutliples. So we are feeling very comfortable, but overall we will let's say because we can face and other one would succeed and that one will derisk the revenues or will be much higher. And Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes. So starting with Abrocitinib, you know, I think it's a good question, you raised here that each JAK inhibitor are different and we designed our JAK inhibitors for optimal use depending on the condition, and it's hard for me to express a strong view here on the potential black box as it's really the decision of the FDA. I can only say that we have so far seen a very good safety profile and we have not seen any cardiovascular signals at all with this drug. And as you've seen in our reported trial, efficacy has been very strong. So we look forward to finalize the program, generate the compare data that could show potential advantages with faster onset versus standard of care Dupixent and then have a dialog with FDA. The DMD program we are continuing dosing patients and we reported at the PPMD Conference that we had transduced more than 70% of the muscle fibers and expressed mean dystrophin at 30% of normal that we think is in the range that where you should see benefit.

Interestingly, we also shared with you, using the North Star Ambulatory Activity Scale that we had two patients, where we saw a benefit in increased performance. And please remember, these patients were older than patient reported by other players in the field, and older patients are the harder is to show benefit as the natural history is to decline. So we are concluding, we hope to start in a relative short time frame and pending final data set, we are preparing for start of Phase 3 next year. And hope certainly that these type of therapy can transform patients' lives for these poor boys.

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

Thanks, Michael. And operator, can we take our last question please.

Operator

Your final question comes from Geoff Meacham from Bank of America.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good morning, guys, thanks for the question. Just had a few. Angela for Vyndaqel, I just want to get a little bit more detail on the rollout in the US? Obviously, I know it's early, but from the field, how would you characterize reimbursement and access and other commercial lessons to be learned from the EU? And then, Albert, just to put a finer point on your comments for long-term growth and deals. I mean, when you look at the LOE starting in 2026, you mentioned the pipeline readouts as a clearly an offset, but can that or smaller tuck-in deals be enough to still get you to growth over the course of the decade? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Angela?

A - Angela Hwang {BIO 20415694 <GO>}

Great. And so from a reimbursement perspective, I think that we are seeing things pan out exactly as we thought. As you know, the large majority of our patients would be Medicare patients because the -- just the age and the prevalence of the disease in this particular population. But currently, we're seeing about 80% of our patients in the Medicare bucket, about 12% in the commercial lives bucket and then of the remainder in Medicaid and others. And so anticipating that this would be sort of how the patient -- I guess the patient mix would look. We created at the launch of Vyndaqel, a number of programs to support the reimbursement of Vyndaqel. And, so for example, in the commercial patients, we have a co-pay card, a co-pay assistance program. For all patients, we have a bridge program to ensure that patients can receive access to Vyndaqel, while they're waiting for their reimbursement decisions. And for Medicare patients, we're exploring -- we're in the process of exploring a number of ways that we can help lower co-pay costs for Medicare patients including working with payers on innovative contracting approaches, which will then help to lower their co-pay. And then of course there is always a portion of patients that are on our free drug program.

But I think all in all, what we're learning from these early days in the market, is that the solutions that we have are definitely supporting our patients in the way that they need, and then not to forget, we still have the support from the Pfizers patient hub as well as a number of specialty pharmacies and hospitals that actually provide our patients with all the support they need to clear that prior authorizations. And I think that this service has been hugely helpful in helping us to clear (inaudible) and get our patients on drug as soon as possible.

A - Albert Bourla {BIO 18495385 <GO>}

And Geoff, to your question about if we believe that this growth going to be sustainable in the post '25, '26 period? The answer is yes. Look, it is normal for companies, who have LOEs. What is up is not to have LOEs, but it is normal for companies to have LOEs and ourselves, we will come back to normality, actually not even in 2026, 2026, with a very very small number of LOEs. From '27, we are coming back to normal LOEs as a percentage of sales. And then this we need to with better because as we know right now . Normal in '27. So this is eight years from us, right. So I feel very comfortable, but we will

have enough time and we have a pipeline that is very diversified and we have a strategy -- double down only to develop substrate that will deliver on that. So when the Company's on normality, we'll be able to continue growing at the same rate that we are growing right now. I think that's the end. I don't think we have time. We exceeding our time. So, I want to thank you all for joining us today. I like to lot this call. There were fewer questions from financials because they were still of course. And we devoted most of the time with the pipeline, which is exactly what we want to do in to growth drivers for the business, which is exactly what an earnings call -- what successful pharmaceutical company should look like. BNw as we move toward the expected close of the Upjohn-Mylan transaction next year, I expect that both businesses will be significantly strengthened. We expect Pfizer RemainCo to be positioned to deliver top and bottom line growth, but it's among the industry leaders and you know what, we want to be the leader and so we will improvise and by bringing together Mylan's growth products into Upjohn's growth markets, we are creating the leading off patent for our company with a strong financial profile and through global reach. For all these reasons, it is an exciting time for our company and we will remain highly focused on executing against this. So thank you very much. Have a great rest of the day.

Operator

Ladies and gentlemen, this does conclude Pfizer's third quarter 2019 earnings conference call. Thank you for participation. You may now disconnect.