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EDITED TRANSCRIPT

PFE - Q3 2019 Pfizer Inc Earnings Call

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OVERVIEW:

Co. reported 3Q19 results. Expects 2019 revenues to be \$51.2-52.2b and adjusted EPS to be \$2.94-3.00.



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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 - *Pfizer Inc. - SVP of IR*

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'll see here that Slide 3 covers our legal disclosures. Albert and Frank will now make prepared remarks, and then we'll move to a question-and-answer session.

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



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Albert Bourla - Pfizer Inc. - CEO & Director

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 2 expected events, the July loss of exclusivity in the U.S. for Lyrica and the July 31 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. This includes 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 U.S. and international markets. We believe the continued growth in the U.S. is the result of our effort to target specific physicians who have not been prescribing CDK inhibitors or had prescribed them to only a small set of patients.

For Xtandi, the alliance revenues in the U.S. 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 U.S. 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 U.S. and for ulcerative colitis in both the U.S. and certain 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 nonvalvular atrial fibrillation as well as oral anticoagulant market share gains.

Looking at our Rare Diseases business. VYNDAQEL continues to ramp up nicely in the U.S. 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 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 does 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 U.S. 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 advancement compared with the potential 15-valent by introducing all serotypes contained in PCV-15 plus 5 additional serotypes.

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In Sterile Injectables, we are seeing our focus on manufacturing recovery taking shape. Global revenues increased 3% operationally and U.S. 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 U.S. due to multisource 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 digits that we had predicted in our previous earnings call.

Consumer Healthcare. For third quarter 2019, revenues totaled \$377 million, down 54% operationally, reflecting the July 31, 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 29, we have 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 3 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 21, Pfizer announced jointly with our partner, OPKO, that the global Phase 3 trial evaluating somatropin dosed once weekly in pre-pubertal children with growth hormone deficiency met its primary endpoint of noninferiority 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 & 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 the certain cardiovascular and metabolic diseases. The therapy is currently being evaluated in a Phase 2 study in patients with type 2 diabetes, hypertriglyceridemia and nonalcoholic 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've presented interim analysis results from the Phase 3 BEACON trial of BRAFTOVI, MEKTOVI and cetuximab for the treatment of BRAF V600E mutant metastatic colorectal cancer. BRAFTOVI combinations saw 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 user practice, we will announce their decision regarding acceptance for review.



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And I am pleased to say that we now have U.S. launch days for 3 of our biosimilars recently approved by the FDA. ZIRABEV is expected to launch on December 31 of this year 2019, Ruxience in January of 2020 and TRAZIMERA on February 15, 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 bipartisan legislation on this issue is advancing. We also continue to work with policymakers and others in the health care 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 cap in Medicare Part D. 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 lifesaving 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 today as well as our confidence of 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 5-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-license 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 A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

Thanks, Albert. Good day, everyone. The charts I am 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 U.S.

Xeljanz globally, up 40% operationally, primarily driven by 34% growth in the U.S. 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 U.S., primarily driven by continued growth from anti-infective products in China and the November 2018 U.S. launch of PANZYGA.



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VYNDALIQ with sales of \$156 million in the quarter with \$79 million in the U.S. following the launch of cardiomyopathy; and Inlyta in the U.S. 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 U.S. 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 to 26% operationally, primarily driven by the expected significant volume declines from Lyrica in the U.S. associated with multisource generic competition that began in July of 2019. Excluding the unfavorable impact of Lyrica in the U.S., third quarter 2019 revenues for Upjohn declined 6% operationally due to continued generic competition for certain off-patent products.

These results were partially offset by revenues in China, up 2% operationally, primarily driven by volume growth for Lipitor and Norvasc in provinces where the 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 of 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 the Consumer Healthcare joint venture transaction with GlaxoSmithKline. This quarter's reporting reflects approximately 1 month of Consumer Healthcare domestic operations and approximately 2 months of Consumer Healthcare financial operations versus third quarter of 2018 revenues, which reflect the full 3 months of Consumer Healthcare global operations.

In addition, Pfizer recognized an \$8.1 billion pretax 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 the 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 in adjusted cost of sales and positively impacted adjusted SI&A and adjusted R&D expenses. In aggregate, foreign exchange had a \$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 the 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 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 and 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 program is currently expected to offset the reduction of shares associated with these share repurchases by approximately half.



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Our 2019 guidance for adjusted other income deducts and the effective tax rate on adjusted income did not change. We continue to expect adjusted operating 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 for 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 - Pfizer Inc. - SVP of IR

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.

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

I guess just 2 here. First, I know you're not giving 2020 guidance at this point. But relative to your initial 2020 comments maybe in Upjohn, maybe just give us any -- just flavor of terms of business trends or any franchises that are performing ahead or behind maybe some of the initial expectations?

And my second question was about kind of the next wave of pipeline opportunities. It -- 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 particular -- a gap relative to, I guess, what we're thinking versus your expectations as we kind of focus in on some of these updates over the next few years?

Albert Bourla - Pfizer Inc. - CEO & Director

Well, 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 we'll ask Mikael Dolsten to speak about pipeline.

Let me start with the 2020 guidance. We don't give guidance up before our Board approves our operating plan. And this every year happens in the mid of December of 20-- of every year. And usually, we do it in the next earnings call that happen 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's going to be awkward if we do not give also some financial targets for 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.

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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 -- in the black box that we received, in the change in the 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 [are offering], and -- but have given very good results in the second quarter. We'll continue as we go into the third quarter. 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 Xtandi new indications will perform and also how the new product, which is our VYNDALIN in cardiomyopathy, eventually will do. As a fact of the matter, all 6 of them did much better than what we were expecting. And this is extremely, extremely positive, of course. We are not going provide now a guidance for next year, but definitely, things have improved compared to what we thought in the second quarter.

Moving to Upjohn. Also, the same sentiment. We have provided \$7.5 billion to \$8 billion for next year, and we have said that we've spent 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 -- but we'll try our growth in China in general to be low to single digits growth for China -- digits for China.

In fact, we're upgrading that now. And we are saying that for this year, our growth will be mid- to high digits growth in China portion of the Upjohn business. And again, we are not going to provide guidance for 2020 for Upjohn, but we will do that together with the total company in -- after our Board approves in mid-December. But we have updated the guidance for this year obviously because of the very good results for the third quarter. Frank, anything to add, please?

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

I would just add 2 things. One, our current expectations 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've previously issued that we talked about that we're appropriately cautious for the reasons that Albert discussed.

Albert Bourla - Pfizer Inc. - CEO & Director

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.

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Thank you, Albert. So let me say a few words. First, we have a large and strong pipeline with 98 projects from Phase 1 through registration, and the uptick is contribution from all of our 5 therapeutic areas. And it is driven by multiple science franchises and not dependent on 1 or 2 vulnerable compounds.

Number two, our R&D productivity have 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 benchmark. We estimate that [early] 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-5 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 rates are high and robust in also this most valuable compound.



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Now I wanted to conclude and give you more of near-term opportunities for our pipeline. So between now and 2020, you may want to remember the metrics, 15 plus 10 plus 5 plus 5. 15 relates to 15 POC readouts, up to 15 POC readouts; 10 to -- 10 Phase 3 starts; and then 5 for 5 Phase 3 readout and 5 key approvals.

Let me give you a few examples on the POCs that you can keep an eye on. We have 5 different POC -- up to 5 different POC readouts in our JAK franchise, including 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 a 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 the Phase 3 plans are underway.

In Internal Medicine, I want to punctuate the 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 P&G pediatric (inaudible) 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 readout 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 ENCORE BRAF/MEK fast line. We have data coming from our next-generation CDKs and from a 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, 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 the Xeljanz, ankylosing spondylitis, JAK1 in the comparator atopic dermatitis studies that is the final data set for them, moving to potential submission. And of course, the P&G adult. And I'm sorry for -- it's somewhat lengthy, but it actually reflected the many exciting things to happen from now to end of 2020.

Operator

Your next question comes from Umer Raffat from Evercore.

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

I want to touch upon 3 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 wanted to ask where you shake out on that, the first one.

Secondly, on Upjohn, I noticed there was a 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 7, 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 4,800 patients. And my question is, is it inconceivable that Pfizer could hit more than 40,000 patients diagnosed at peak?

Albert Bourla - Pfizer Inc. - CEO & Director

Excellent questions, Umer. So let me start with the M&A. Frank can cover the Upjohn forecast. And then of course, Angela will speak about tafamidis.



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On the M&A strategy, look, since the July of 2018, when I -- as Chief Operating Officer of 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 to be, on a 5 years CAGR, 6%. I know the analysts' expectation is even higher.

This number, even this 6%, compared to the analyst expectations likely will position -- it's not likely, it's positioning us compared to the data and our peer set, let's say, the top 10 to 15 companies in the industry, it'll be the second largest in terms -- the second fastest-growing company in the next 5 years with a 6% in terms of rate. And actually, the largest in terms of producing growth 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, I have 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 destructive 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 that will 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, ready Phase 2, ready Phase 3 assets that -- like the ones that we did in the last four business development activities that will provide revenues at the post -26, -27 period when we start feeling again some of the LOEs. And we want to make sure that the 6% growth is sustainable over the decade, the whole decade rather than only for the first 6, 7 years of this decade.

So this is our strategy, and we are not looking for a large M&A right now. And with that, I will move to Frank to speak a little bit about the Upjohn projections and what we had in our Board presentation, which I think is pretty much in line with what we gave as guidance for next year.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

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 expansion going from 11 cities, to all provinces, 50% share to 70% share, that, 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 first, think about this quarter. Upjohn in China this quarter-to-quarter grew 2%. How did it grow 2%? It basically 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's opportunities for that business in Emerging Markets outside of China and continuing opportunities for that business and the rest of the world, given the breadth of the portfolio is 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 the S-4.

Albert Bourla - Pfizer Inc. - CEO & Director

And then, Angela, please, about tafamidis.

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

So thanks for the question. Certainly, we are extremely pleased with the diagnosis rates of ATTR-CM that we have seen to date, which is about 4% to 5%. But even with that, it's important to remember that it is still a severely underdiagnosed disease, and we have a long way to go in terms of achieving what we believe our patients deserve.

There are 2 aspects of 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



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suspect the disease. And this has been helped by the recently published red flag symptoms, which make 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 the scintigraphy as a noninvasive 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 U.S. 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 until now, and that is what drove our peak estimate. 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.

Operator

Your next question comes from David Risinger from Morgan Stanley.

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

I have 2 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.

Albert Bourla - *Pfizer Inc. - CEO & Director*

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

Mikael Dolsten - *Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical*

Yes. As -- 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 even supported by real-world evidence data that was very favorable towards different aspects of progression-free survival and also robust on overall survival actually having hazard ratio of less than 0.6, which probably is the strongest hazard ratio provided so far. And we will update that hazard ratio as the study matures. Thank you very much.

Albert Bourla - *Pfizer Inc. - CEO & Director*

Thank you, Michael.

Frank A. D'Amelio - *Pfizer Inc. - CFO & EVP of Global Supply & Business Operations*

So Dave, I'll answer the gross margin question. 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 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.



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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 have 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 rhythm will be the revenue growth. So obviously, we're saying now that we think 6% operational revenue growth going forward, that will clearly help our operating margins on a going-forward basis relative to what we have said back in July because we'll leverage that to the bottom line. And so 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.

Operator

Your next question comes from Tim Anderson from Wolfe Research.

Timothy Minton Anderson - Wolfe Research, LLC - MD of Equity Research

A couple of questions. On your revenue guidance of a 5-year CAGR of 6%, consensus is not at that level, and I'm wondering if there's any big areas that jump out at you specifically as being mismodeled by the analyst community in 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.

Albert Bourla - Pfizer Inc. - CEO & Director

Yes. I think the -- again, the R&D question, I think, will go to Mikael. Just a brief comment, but, 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. We want to make sure that 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 that we will achieve. I have seen a lot of reports of analysts that they are having higher numbers than that. That's why I referred to that. 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 are doing our job. We feel very comfortable on the 6%. Mikael?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

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 aggregate safety data. It is a head-to-head against Dupixent -- 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 skin. And we have specifically an endpoint on itch 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, although 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 integers.



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Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

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, RemainCo keeps all of the growth drivers that we currently talked about on this call. So that portfolio, the momentum of that portfolio carries into the new Pfizer.

Albert Bourla - Pfizer Inc. - CEO & Director

Very good points, Frank.

Operator

Your next question comes from Steve Scala from Cowen.

Stephen Michael Scala - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

I have a couple. First, for Mikael, the press release says that after 3 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 3 doses in terms of immune response due to 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 a 4-dose regimen, but you must have data after 3 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 required to protect the bottom line. Could a 20% reduction in operating expenses be delivered? And if yes, would it take 6 months, 12 months or would it take much longer?

Albert Bourla - Pfizer Inc. - CEO & Director

Mikael?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. We shared data on 3 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 titer against all 20 serotypes. And at this stage, they look very similar to the PCV13 when you look at totality of data. And the immune titers also are supplemented by functional antibody responses that we're now obtaining that, again, look very robust for the PCV20 across all serotypes.

I wanted also to say that increasingly available epidemiology data strengthened the notion that the PCV20 has a very broad coverage, far exceeding PCV15 developed by a competitor, whether you look at the infant population, the adult population, U.S. or European major countries and whether you look at IPD and CAP. So we're very pleased with emerging data and increased insights into epidemiology that indicates this vaccine has the potential to provide the broadest ever coverage for a pneumococcal disease.

Frank A. D'Amelio - Pfizer Inc. - CFO & EVP of Global Supply & Business Operations

And then, Steve, if there was some draconian action that resulted in a 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 could do it, how quickly we would do it, quite frankly, we'd



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have to work our way through that. But the short answer is we would clearly review our cost structure, every element of the cost structure, by the way, which we do all the time anyway, and then see what we have to do to deal with -- quite frankly, what the model is -- what the business model is going forward. A 10% decline in our revenues is a change in our business model. And then we'd have to obviously look at that in terms of how we run our business on a going-forward basis.

Operator

Your next question comes from Navin Jacob from UBS.

Navin Cyriac Jacob - *UBS Investment Bank, Research Division - Equity Research Analyst of Specialty Pharmaceuticals and Large Cap Pharmaceutic*

Two questions, if I may. Number one, 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" over the last 2 years that would -- you may have been able to have if Hospira had been at full capacity? And 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.

Albert Bourla - *Pfizer Inc. - CEO & Director*

Right. I think Angela can answer the Hospira question. Just to say something, for us, the manufacturing issues and supply issues for Hospira created, I would say, a loss 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 have the relations that we had before built 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 transparency. Obviously, there is business that we lost, and we hope that we will recover most of it. Angela, what do you think?

Angela Hwang - *Pfizer Inc. - Group President of Biopharmaceuticals Group*

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's 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 portfolio today, our continuous launches both from a presentation and a device perspective as well as from a molecule perspective.

I think 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 or 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're venturing into.

Albert Bourla - *Pfizer Inc. - CEO & Director*

Yes, Mikael.



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Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

On the C. diff, yes, we're pleased with the aspect that safety and tolerability was regarded as favorable at the interim analysis. And clearly, the fertility analysis indicated that the study should continue. While we try to target high-risk patients for C. difficile infection, by looking at increased risk for contact with health care 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 learned 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 the study as soon as possible. And, of course, there's an urgency with 450,000 C. diff infections every year in U.S. and close to 30,000 of death, and we'll do everything possible to accelerate the readout of this study and get events. We clearly do accumulate events, although somewhat slower than we initially hoped. But rest assured that we will do everything we can to make sure the readout is coming as soon as possible, and we will later update you with more firm aspects of that.

Operator

Your next question comes from Andrew Baum from Citi.

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

Your portfolio is heavily exposed to high list price, heavy Part D 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 spend under Medicare Part D, but within the same finance committee proposal, there is also an obligation for you to fund catastrophic coverage to the tune of 20%, an 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 CDK4/6s the obligation on the plan providers to fund catastrophic coverage is going to further increase price competition in the segment?

And then the second question very quickly is, historically, I've railed against some of your competitors, for basically holding Xeljanz into very treatment refractory settings, given exposition 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 JAKs given drugs like Dupixent are going to be generating significant rebates for the PBMs in the commercial book of business by the time you hit the market?

Albert Bourla - Pfizer Inc. - CEO & Director

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 there are things that we do not agree. But I will tell you that we are fanatically in favor of reducing out-of-pocket costs to patients. Because right now, the fundamental issue that drives this polarization in the political environment around health care. It is a real problem. And the problem is that the Americans are paying for their medicines. Like if they are not insured, although they are having insurance, when they go to collect them from the counter of the pharmacy. This is not happening with hospital. This is not happening with diagnostics. This is not happening with other medical interventions, at least to the degree that it's happening with medicines. And this is why the drug pricing is so high in the debate, although they represent only 10%, 12% of the total health care costs. So that needs to be addressed.

Now the way that the Senate, for example, is proposing to address it, or even worse to the House, they are going to increase the contribution of the pharmaceutical companies. And of course, this will hurt, but this is the least of my problems overall because at least, what hurts us helps the patients.



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My issue with this bill, it is that a lot of other measures that they are suggesting that hurt us even more. They are not moving the savings to the patients, which is the fundamental issue that, right now, society 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 health care system to reduce the cap, to reduce the out-of-pocket expenses either with rebate reform or, if that's not on the picture right now, by reducing the --by implementing a cap for out-of-pocket. It's of paramount importance even if we have to pay for it. And Xeljanz, Angela?

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

So it is true that when we 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 PBMs 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 I think that we have demonstrated our ability to be a real solution in this space of great unmet need. And as evidence, 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 PBMs to bring the totality of our data and our experience to bear, filling an area of great unmet need.

Operator

Your next question comes from Terence Flynn from Goldman Sachs.

Terence C. Flynn - Goldman Sachs Group Inc., Research Division - MD

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 biosimilar market in the U.S.?

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?

Albert Bourla - Pfizer Inc. - CEO & Director

Let me speak a little bit about -- generally about biosimilars, and then I will ask Angela to answer the second question and also specifics of the biosimilars potential that we are going to launch.

I think in the U.S., 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 trap. But payers, although they do see the benefit of using the biosimilars solution that physicians would like to prescribe and that the FDA's 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 that the originator is offering.

And I think, frankly, that unless 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 world is 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 health care system can see real lives. Significant savings can only happen if we find a solution to that. We have also suggested other measures like the savings should be served by providers, et cetera, et cetera, but I think that's the fundamental one.



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Now all biosimilars are not the same because -- and not all markets are the same. Whether you have closed systems like the Kaiser, for example, the penetration of biosimilars 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.

And also, oncology is very different. Also, biosimilars from, I&I biosimilars because the I&I, they are giving for very extensive period of time, so you need to switch. New patients aren't coming very often. Oncology is very different because it's more limited the period that they are -- that therapists use. 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 an answer to the second question.

Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

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 U.S. 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. Like to date, it has a 16% market share, which is the highest that we have seen of any biosimilar here in the U.S. 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 3 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 neurologists and medical oncologists, are having with Xtandi.

We have leading market share at 37% branded in a growing class. And the class 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 2 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 starts since the PROSPER approval. And just as a measure of PROSPER, urologists are generally the prescribers in an earlier disease setting. And here, our urology prescribing is growing at 44%.

And so we're continuing to see the proportion of our business from PROSPER grow 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 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 not only have the #1 share of voice with oncologists, but our prescribing with oncology, medical oncology continues to grow significantly as well in this quarter at 21%.

And so when you bring all of this together and you add into that the approval and/or the positive Phase 3 results we got from Ezimet and the submissions that we have for additional indications in both the non-metastatic, the 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.

Operator

Your next question comes from Louise Chen from Cantor Fitzgerald.

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

So my first question is that in consensus, there's a meaningful step-up in Ibrance sales through 2023. And do you think you can grow Ibrance double digits without an adjuvant or NEA adjuvant approval?



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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 JAKs we've seen in the industry? And the last question I have 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.

Albert Bourla - Pfizer Inc. - CEO & Director

Yes. A quick answer on the Ibrance, and then I think abrocitinib and DMD will be covered by Mikael. Again, in the spirit that I don't want to comment what is the analysts' expectations, I know what they are, and I know what are our expectations. And we are projecting that we will grow Ibrance to double digit, and, therefore, also expecting that we will receive the -- that we will have, let's say, a positive PALLAS study, which is the main study that is 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 because the ratio on all of that is not based on 1 or 2, but is based on risk adjustment of multiple. So we are feeling very comfortable that, overall, we will not say bad because if another fails, another one would succeed. And that one will derisk the revenue. So we'll be much higher. Mikael?

Mikael Dolsten - Pfizer Inc. - Chief Scientific Officer and President of Worldwide Research, Development & Medical

Yes. So starting with abrocitinib. 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 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 have seen in our reported trials, efficacy has been very persuasive and 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 dialogue 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 mini-dystrophin at 30% of normal that we think is in the range that -- where you should see benefit. Interestingly, we also shared with you, you seeing the Northstar Ambulatory activities game, that we had 2 patients where we saw benefit in increased performance. And please remember, these patients were older than patients reported by other players in the field. And the older the patients are, the harder it is to show benefit, as their natural history is to decline. So we are concluding we hope to study 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 this type of therapy can transform patient lives for these poor boys.

Operator

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

Geoffrey Christopher Meacham - BofA Merrill Lynch, Research Division - Research Analyst

I just had a few. Angela, for VYNDAQEL, I just want to get a little bit more detail on the rollout in the U.S. Obviously, I know it's early, but from the field, how would you characterize reimbursement and access? And are there 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 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?

Albert Bourla - Pfizer Inc. - CEO & Director

Angela?



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Angela Hwang - Pfizer Inc. - Group President of Biopharmaceuticals Group

Great. 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 be in the Medicare bucket, about 12% in the commercial lives bucket and then 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 are 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's always a portion of patients that are on our 3 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 Pfizer's 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 their prior authorizations. And I think that this service has been hugely helpful in helping us to clear prior auths and get our patients on drug as soon as possible.

Albert Bourla - Pfizer Inc. - CEO & Director

And Geoff, to your question about if we believe that this growth can be sustainable in the post 25, 26 period, the answer is yes. Look, it is normal for companies to have LOEs. What is abnormal is to not have LOEs, okay? But it is normal for companies to have LOEs. And ourselves, we will come back to normality. Actually, not even in 26. 26 is a 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 everything that we know right now, normal in 27.

So this is 8 years from now, right? So I feel very comfortable that we will have enough time and we have a pipeline that is very diversified, and we have a strategy that is doubled down on these to develop a substrate that would deliver on that.

So when the company's on a normality, we'll be able to continue growing at the same rate that we are growing right now.

So I think that's the end, right? It's like, unfortunately, we don't have time. We exceeded our time. So I want to thank you all for joining us today. I liked a lot this call. There were fewer questions on financials because they were stellar, of course. And we devoted most of the time to the pipeline, which is exactly what we want to do, and to the growth drivers of the business, which is exactly what an earnings call of a successful pharmaceuticals company should look like.

Now 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 to remain positioned to deliver top and bottom line growth, that it's among the industry leaders. And you know us. We want to be the leader, so we will aim for that. And by bringing together Mylan's growth products into Upjohn's growth markets, we are creating the leading off-patent drug company with a strong financial profile and true global reach.

All these reasons, it is an exciting time for our company, and we will remain highly focused on executing against these strategies. So thank you very much. Have a great rest of the day.

OCTOBER 29, 2019 / 2:00PM, PFE - Q3 2019 Pfizer Inc Earnings Call**Operator**

Ladies and gentlemen, this does conclude Pfizer's Third Quarter 2019 Earnings Conference Call. Thank you for your participation. You may now disconnect.

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FORWARD LOOKING STATEMENTS

This communication contains “forward-looking statements”. Such forward-looking statements may include, without limitation, statements about the proposed transaction, the expected timetable for completing the proposed transaction, the benefits and synergies of the proposed transaction, future opportunities for the combined company and products and any other statements regarding Pfizer’s, Mylan’s, the Upjohn Business’s or the combined company’s future operations, financial or operating results, capital allocation, dividend policy, debt ratio, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competitions, and other expectations and targets for future periods. Forward-looking statements may often be identified by the use of words such as “will”, “may”, “could”, “should”, “would”, “project”, “believe”, “anticipate”, “expect”, “plan”, “estimate”, “forecast”, “potential”, “pipeline”, “intend”, “continue”, “target”, “seek” and variations of these words or comparable words. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include,

but are not limited to: the parties' ability to meet expectations regarding the timing, completion and accounting and tax treatments of the proposed transaction; changes in relevant tax and other laws; the parties' ability to consummate the proposed transaction; the conditions to the completion of the proposed transaction, including receipt of approval of Mylan's shareholders, not being satisfied or waived on the anticipated timeframe or at all; the regulatory approvals required for the proposed transaction not being obtained on the terms expected or on the anticipated schedule or at all; inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements and the providing of estimates of financial measures, in accordance with accounting principles generally accepted in the United States of America and related standards, or on an adjusted basis; the integration of Mylan and Newco being more difficult, time consuming or costly than expected; Mylan's, the Upjohn Business's and the combined company's failure to achieve expected or targeted future financial and operating performance and results; the possibility that the combined company may be unable to achieve expected benefits, synergies and operating efficiencies in connection with the proposed transaction within the expected time frames or at all or to successfully integrate Mylan and Newco; customer loss and business disruption being greater than expected following the proposed transaction; the retention of key employees being more difficult following the proposed transaction; any regulatory, legal or other impediments to Mylan's, the Upjohn Business's or the combined company's ability to bring new products to market, including but not limited to where Mylan, the Upjohn Business or the combined company uses its business judgment and decides to manufacture, market and/or sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an "at-risk launch"); success of clinical trials and Mylan's, the Upjohn Business's or the combined company's ability to execute on new product opportunities; any changes in or difficulties with Mylan's, the Upjohn Business's or the combined company's manufacturing facilities, including with respect to remediation and restructuring activities, supply chain or inventory or the ability to meet anticipated demand; the scope, timing and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on Mylan's, the Upjohn Business's or the combined company's consolidated financial condition, results of operations and/or cash flows; Mylan's, the Upjohn Business's and the combined company's ability to protect their respective intellectual property and preserve their respective intellectual property rights; the effect of any changes in customer and supplier relationships and customer purchasing patterns; the ability to attract and retain key personnel; changes in third-party relationships; actions and decisions of healthcare and pharmaceutical regulators; the impacts of competition; changes in the economic and financial conditions of the Upjohn Business or the business of Mylan or the combined company; uncertainties regarding future demand, pricing and reimbursement for Mylan's, the Upjohn Business's or the combined company's products; and uncertainties and matters beyond the control of management and other factors described under "Risk Factors" in each of Pfizer's and Mylan's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other filings with the SEC. These risks, as well as other risks associated with Mylan, the Upjohn Business, the combined company and the proposed transaction are also more fully discussed in the Form S-4 and the Form 10. You can access Pfizer's, Mylan's or Newco's filings with the SEC through the SEC website at www.sec.gov or through Pfizer's or Mylan's website, as applicable, and Pfizer and Mylan strongly encourage you to do so. Except as required by applicable law, Pfizer, Mylan and Newco

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