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# Pfizer's (PFE) CEO Albert Bourla on Q3 2019 Results - Earnings Call **Transcript**

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Q3: 10-29-19 Earnings Summary



Press Release



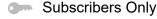
SEC 10-Q



Slides

EPS of \$0.75 beats by \$0.13 | Revenue of \$12.68B (-4.65% Y/Y) beats by \$314.75M

# **Earning Call Audio**



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Pfizer, Inc. (NYSE:PFE) Q3 2019 Earnings Conference Call October 29, 2019 10:00 AM ET

# **Company Participants**

Chuck Triano – Senior Vice President of Investor Relations

Albert Bourla – Chief Executive Officer

Frank D'Amelio – Chief Financial Officer

Mikael Dolsten – President of Worldwide Research and Development

Angela Hwang – Group President, Pfizer Biopharmaceuticals Group

# **Conference Call Participants**

Chris Schott - JP Morgan

Umer Raffat - Evercore

David Risinger - Morgan Stanley

Tim Anderson - Wolfe Research

Steve Scala - Cowen

Navin Jacob – UBS

Andrew Baum - Citi

Terence Flynn - Goldman Sachs

Louise Chen – Cantor Fitzgerald

Geoff Meacham - Bank of America

# 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.

#### **Chuck Triano**

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 will move to a question-and-answer session

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

#### Albert Bourla

Thank you, Chuck, and good morning, everyone. During my remarks, I will discuss our quarterly business performance, 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 care in meet 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 anticipate closing of the Upjohn transaction. We also saw revenue impacted by two 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, these groups outstanding growth was driven primarily by strong performance from our key growth drivers. This include Ibrance, Xtandi, Xeljanz, Eliquis, Vyndaqel end Inlyta, as well as 15% operational growth in emerging markets including 42% operational growth in China. Our biopharmaceutical business in China generated higher revenues this quarter than the Upjohn business in the country.

Our oncology business was particularly strong up 30% operationally compared with a 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 efforts 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 U.S. grew 25% to \$225 million. In August, the FDA granted Xtandi priority review designation for the treatment of men with metastatic hormone sensitive prostate cancer with a PDUFA date in December. If approved, this represents get another potential growth driver for the brand.

Inlyta revenues increased 98% operationally to \$139 million. This included 240% growth in the U.S. or 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 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 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 could receive 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 these, 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 of 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 U.S. revenues increased 1% operationally. We continue to expect this business to be a solid growth contributor in the future.

Now let me moving 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 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 these, 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 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 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 21, Pfizer announced jointly with our partner OPKO that the global Phase 3 trial evaluating Somatrogon dose 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 BRAFV600E-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.

And I am pleased to serve what we now have U.S. launch days for three 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 of 2020. So all 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 patients' 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 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 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 the 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, but will drive continued innovation and benefit patients.

In summary, we turn 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 from this in a moment. Following the expected close of the Upjohn-Mylan transaction next year, Pfizer will be 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 bio-pharmaceuticals group is already growing at a similar pace.

Starting in 2026, we will have a new set of LOEs, but we expect that 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 this 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 and 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 of 20% operationally, the hospital business up 9% operationally in emerging markets in the U.S., primarily driven by continued growth from anti-infective products in China in the November 2018 U.S. launch of Panzyga.

Vyndaqel with sales of \$156 million in the quarter with \$79 million in the U.S. following the launch for 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 26% operationally, primarily driven by the expected significant volume declines for Lyrica in the U.S. associated with multi-source 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 and 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 in 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 a consumer healthcare joint venture transaction with GlaxoSmithKline.

This quote is reporting reflects approximately one month of consumer healthcare domestic operations and approximately two months of consumer healthcare international operations versus 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.

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 from \$2.76 to \$2.86, an increase of \$0.16 since the previous quarter, reflecting an \$0.18 operational improvement, partially offset by \$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.

#### **Chuck Triano**

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

#### **Question-and-Answer Session**

#### Operator

[Operator Instructions] Your first question comes from Chris Schott with JP Morgan.

# **Chris Schott**

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 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? Thanks so much.

# **Albert Bourla**

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 2000 – 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. Since then, a lot of things happened and happened in the areas that 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 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 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 to that, please?

#### Frank D'Amelio

I would just add two 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**

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

Thank you, Albert. So let me say a few words. First, we have a large and strong pipeline with [indiscernible] projects from Phase 1 through registration, and the uptick is 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 two, our R&D productivity have improved consistently over the last two 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 rates are high and robust in also this most valuable compound.

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 five different POC – up to five 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 [indiscernible] 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, 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.

#### **Chris Schott**

Thank you, Mikael.

#### **Chuck Triano**

Great, thank you. Can we move to the next question please, operator?

#### **Operator**

Your next question comes from Umer Raffat from Evercore.

#### **Umer Raffat**

Hi, thanks so much for taking my questions and congrats on a quarter. I want 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 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 in 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? Thank you very much.

#### **Albert Bourla**

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. On the M&A strategy, look, since the July of 2018, when I – as Chief Operating Officer of that time, I think I related this 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 five years CAGR, 6%. I know the average expectation is even higher. This number, even this 6% of us, 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, they'll 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, there are a lot of this 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 can say this 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 instructive operationally. And we can always do in 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 fall. These are development activities that will provide revenues at the post 2026, 2027 period, when we start filling 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 six, seven 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 D'Amelio

Yes. So for so 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, 12 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

And then, Angela, please, about tafamidis.

#### Angela Hwang

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 and our patients deserve. There are two 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 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.

#### **Umer Raffat**

Great.

#### **Chuck Triano**

Thank you, Angela. Next question please.

### Operator

Your next question comes from David Risinger from Morgan Stanley.

# **David Risinger**

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.

#### Albert Bourla

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

Yes. As – we tell 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 towards different

aspects of progression-free survival and also robust on overall survival actually having hazard ration 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

Thank you, Mikael.

#### Frank D'Amelio

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. 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.

#### **Chuck Triano**

Thanks, Frank. Next question please, operator.

#### **Operator**

Your next question comes from Tim Anderson from Wolfe Research.

#### **Tim Anderson**

Thank you. A couple of questions. On your revenue guidance of a five-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 mis-modeled 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**

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 going do your job and we are doing our job. We feel very comfortable on the 6%. Mikael?

#### Mikael Dolsten

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.

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

### **Albert Bourla**

Very good points, Frank.

#### Frank D'Amelio

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

### Operator

Your next question comes from Steve Scala from Cowen.

#### **Steve Scala**

Thank you. I have a couple. First, for Mikael, 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 due to 13 valents that they have in common. Can you comment on that point and the response to the additional seven valents? I know Prevnar 13 is a four-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 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? Thank you.

#### Albert Bourla

Mikael?

#### Mikael Dolsten

Yes. We shared data on 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 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, where do 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 D'Amelio

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 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.

#### **Chuck Triano**

Thanks, Frank. Next question please.

### Operator

Your next question comes from Navin Jacob from UBS.

#### **Navin Jacob**

Hi. Two questions if I may. Number one on Hospira, as you have stabilized that business in the manufacturing capabilities there. Wondering if you could help us understand to what extent there have been "lost revenues" over the last two years that would – that 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.

#### Albert Bourla

Right. I think, Angela can answer the Hospira questions to say something for us, the manufacturing issues and the supply 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 and make them very strong. And I have to say that we were very successful and what the customers appreciate the most was across products. Obviously there is business that we lost and we hope that we will recover most of it. Angela, what do you think?

#### **Angela Hwang**

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 hear 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 the 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 – 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.

#### Albert Bourla

Yes, Michael.

#### Mikael Dolsten

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 450,000 C. diff infections every year in U.S. and close to 30,000 of this 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 assure 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.

#### **Chuck Triano**

Thanks Michael. Next question please, operator.

#### **Operator**

Your next question comes from Andrew Baum from Citi.

#### **Andrew Baum**

Thank you. Your portfolio is heavily exposed to high list price, heavy Part B expose drugs. I'm obviously thinking about Ibrance, Inlyta, Xtandi 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 funds 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, the obligation on the plan providers to fund catastrophic coverage is going to further increased price competition in the segment?

And then the second question, if I quickly, historically in veiled against some of your competitors for basically holding Xeljanz into very treatment refractory settings, given sufficient of that 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? Many thanks.

#### Albert Bourla

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 fanatically 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 intervention, at least to the degree, what was happening with medicines and this is why that drug pricing is so high in the debate, although they represents only 10%, 12% of the total healthcare cost. So that needs to be addressed.

Now the way that the Senate for example is proposing for aggressive or even worse through 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 overall, because at least what hurts us helps the patients. My issue with this bill, it is that a lot of other measures, but they're 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 healthcare system 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.

# **Angela Hwang**

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 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 PBMs to bring the totality of our data and our experience to bear. I'm filling an area of great unmet need.

#### **Chuck Triano**

Great. Thanks, Angela. Next question please.

## Operator

Your next question comes from Terence Flynn from Goldman Sachs.

# **Terence Flynn**

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 U.S. And then Angela, just wondering any more color you can provide on the extended dynamics in terms of either share among the different segments or maybe mix of the prescriber base? Thank you.

#### Albert Bourla

Let me speak a little bit about – generally about biosimilars, and then I will ask Angela to answer the second question and also specifics in the biosimilars potential of what we are going through. 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 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 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 agree, 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.

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 are very similar 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**

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.

To date, it has a 16% market share, which is the highest that we've 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 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 neurologists 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 starts since the PROSPER approval.

And just as a measure of PROSPER, urologists are generally the prescribers in an 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 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 number one 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 inbox 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.

# **Chuck Triano**

Excellent, thanks Angela. Next question please.

### Operator

Your next question comes from Louise Chen from Cantor Fitzgerald.

#### **Louise Chen**

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.

#### **Albert Bourla**

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 they're 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 PALACE 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 one or two, 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

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 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 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 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.

## **Chuck Triano**

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

### Operator

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

### **Geoff Meacham**

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 U.S. 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.

#### Albert Bourla

Angela?

# **Angela Hwang**

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 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 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 that 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

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 abnormal 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 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, but we will have enough time and we have a pipeline that is very diversified and we have a strategy that is doubled 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.

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.

# Operator

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