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Q4 2019 Earnings Call

Company Participants

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

Other Participants

- Andrew Baum, Analyst
- Chris Schott, Analyst
- David Risinger, Analyst
- Geoff Meacham, Analyst
- Louise Chen, Analyst
- Mani Foroohar, Analyst
- Navin Jacob, Analyst
- Randall Stanicky, Analyst
- Steve Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Umer Raffat, Analyst

Presentation

Operator

Good day, everyone, and welcome to Pfizer's Fourth 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 {BIO 3844941 <GO>}

Good morning and thank you for joining us today to review Pfizer's fourth quarter and full-year 2019 performance and 2020 financial guidance. I'm joined today by our CEO and Chairman, Albert Bourla; Frank D'Amelio, our CFO; Mikael Dolsten, President of

Worldwide Research and Development; Angela Wang, Group President Pfizer Biopharmaceuticals Group; John Young, our Chief Business Officer; and Doug Lankler General Counsel.

The slides that will be presented on this call were posted to our website earlier this morning and are available at pfizer.com/investors. You will see here that Slide 3 covers our legal disclosures. Albert and Frank will now make prepared remarks, and then, we will move to a question-and-answer session.

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

Albert Bourla {BIO 18495385 <GO>}

Thank you, Chuck, and good morning. everyone. This morning I will speak about our performance for the year, the continued advancement of our pipeline and the steps we are taking to position Pfizer for accelerated growth, following the expected separation of Upjohn from Pfizer later this year. Frank will then provide details regarding our fourth quarter performance and our 2020 financial guidance.

2019 was a productive and transformational year for Pfizer, in which we generated solid full year financial results. These results were highlighted by exceptional 8% operational revenue growth for the year and 9% in the fourth quarter for our Biopharma business, which will become the New Pfizer, following the expected separation of Upjohn.

Once again, our Biopharmaceuticals Group outstanding growth was driven primarily by the continued strong performance from all our key growth drivers. These include Ibrance, Xtandi, Eliquis, Xeljanz, Vyndaqel among others. Biopharma also generated 14% operational growth in emerging markets in 2019. I would point out that Biopharma's 2019 growth came from volume increases not pricing. In fact, pricing had a negative 2% impact in Biopharma's results.

For full year 2019, global Ibrance revenues increased 23% operationally to become a nearly $5 billion a year product. In the US, Ibrance realized robust growth and retained it's strong leadership position in the CDK class with a nearly 90% share. Ibrance's performance outside of the US was also very strong and we still see significant opportunities in countries where the use of CDK inhibitors has not yet reached the levels seen in the US. Overall, Ibrance is approved in more than 90 countries, is the number one prescribed CDK 4/6 inhibitor globally and has reached more than 250,000 places.

For Xtandi, alliance revenues in the US were up 20% for the full year and when combined with our royalty income on ex-US sales, totaled nearly $1.2 billion in 2019. Xtandi is the leading branded novel hormone therapy in an increasingly competitive but growing class, with 37% market share in total prescriptions. The robust year-over-year growth was due to continued uptake of the non-metastatic castration-resistant prostate cancer indication as well as prescriber confidence in the recognition of extend strong data across CRPC.

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With the recent launch of our extended indication in metastatic castration-sensitive prostate cancer in the US, Xtandi is now the first and only oral treatment approved by the FDA in three distinct types of prostate cancer.

Eliquis continued to perform well. Pfizer share in the global revenues was up 26% operationally to $4.2 billion. This growth was driven primarily by continued increased adoption in non-valvular

Atrial fibrillation, as well as oral anti-coagulant market share gains. Eliquis is now the oral anti-coagulant leader in 12 markets across the globe.

Xeljanz had a strong performance, with global revenues increasing 29% operationally to $2.2 billion. We are very pleased with the continued positive uptake across all indications, rheumatoid arthritis, psoriatic arthritis and ulcerative colitis and we continue to launch psoriatic arthritis and ulcerative colitis in new markets.

Looking at our rare disease business, Vyndaqel continues to ramp up nicely in the US, following the May 2019 approval and launch for the treatment of ATTR cardiomyopathy. Overall, this first of its kind medicine contributed $473 million in revenue in 2019. Our disease awareness efforts helped drive the diagnosis rates to 9% by the end of the fourth quarter compared with 1% prior to launch. As of the end of 2019, more than 9,000 patients have been diagnosed, more than 5,500 patients had received a prescription for Vyndaqel and more than 3,000 patients had received the drug. These numbers do not include approximately 100 patients who are still in the early access program.

Global Prevnar 13 revenues were up 3% operationally to $5.8 billion. The US CDC also published its updated recommendation for immuno competent adults aged 65 and older to start clinical decision-making in the November morbidity and mortality weekly report, highlighting that a patient can share the decision to vaccinate with PCV 13 with a physician, physician's assistant, nurse practitioner or pharmacists.

Looking at our sterile injectables portfolio, our focus on manufacturing recovery is taking shape and beginning to have a positive impact on the top-line in the US. We have made solid progress with remediation and modernization and expect continued improvement throughout 2020. Of note, while global revenue from our sterile injectables portfolio declined 1% operationally for the full year, it increased 5% operationally during the fourth quarter. Additionally, more than 80% of our injectables portfolio is in stock today. And we anticipate this percentage will continue to increase in 2020.

Our global Biosimilars portfolio grew 22% operationally to $911 million for the full year. This was driven largely by 70% growth in the US, thanks to the launch of Retacrit and a gradual uptake of Inflectra. The growth in the US was partially offset by a decline in International markets, driven mainly by Inflectra. We expect an additional contribution from Biosimilars in 2020, with the launch of three oncology monoclonal antibody biosimilars. Last week we announced the launches of Zirabev and Ruxience in the US market and next month we expect to launch Trazimera. All three products will be available at a substantially discounted price compared with their originator products.

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Full year revenues for our Upjohn business were down 16% operationally to $10.2 billion. The key headwind during the year was the advent of generic competition on Lyrica in the US, which was partially offset by 7% operational growth in China. The growth in China was driven primarily by Viagra and Celebrex as well as Lipitor in non-reimbursed channels, which constitute significant market share in China.

We are making good progress with the pre-integration planning for Upjohn's proposed combination with Mylan, which remains on track for mid-2020. In December, we announced that former Pfizer Chairman, Ian Read, and Current Pfizer Director James Kilts will join the Viatris Board of Directors upon completion of the transaction. We are also working closely with our counterparts of Mylan on the CFO selection process. We expect to announce the appointments of both the CFO and the third Director by the end of this quarter. We have great confidence in Viatris which will combine Upjohn's strong commercial capabilities and iconic brands with Mylan's terrific pipeline.

Turning now to R&D, we remain very pleased with the progress we are making with our pipeline. We are expecting key clinical results in 2020, several of which have the potential to make this an exciting year for patients hoping for new treatment options. We anticipate sharing data from up to 15 proof-of-concept readouts with contributions from all our therapeutic areas, as well as up to 10 pivotal study starts and five key pivotal study readouts.

I will now highlight some of those expected events. We continue to expect our two event-driven Ibrance early-breast cancer programs, PENELOPE-B and PALLAS to read out in late 2020 and early 2021, respectively. If successful, and following regulatory approval, these programs could double the number of patients eligible to benefit from Ibrance.

The Phase 2 open label, single-arm ANCHOR-CRC study evaluating the efficacy and safety of the combination of Braftovi and Mektovi and cetuximab in patients with previously untreated BRAFV600E-mutant metastatic colorectal cancer is currently ongoing. Results from the study will be submitted for presentation at a medical congress in the second half of 2020.

For Abrocitinib, our investigational JAK1 inhibitor for the treatment of moderate to severe atopic dermatitis. We look forward to sharing topline findings from the Phase 3 JADE compare trial in the coming months. Pending successful conclusion of the core Phase 3 studies, regulatory submission in the US is projected for the third quarter of 2020, with subsequent markets following later in the year.

This study is designed to assess the efficacy and safety of abrocitinib or dupilumab placebo in adults on background medicated therapy with moderate to severe atopic dermatitis. The study also has a key secondary endpoint but it is designed to assess the effect on each severity of abrocitinib compared with dupilumab in adults with moderate to severe atopic dermatitis on background topical therapy. There are up to five proof-of-concept readouts expected in 2020 from our industry-leading immuno kinase pipeline. Our hope is to advance several of these in to Phase 3 trials.

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This include TYK2/JAK1 with potential POC readouts for psoriatic arthritis and for a topical formulation for psoriasis and atopic dermatitis, as well as an oral JAK3/TEC for vitiligo and TYK2 for psoriasis. This is a great example of our unique strategy to purposefully match a molecule to a disease where we think it has the potential to make the most difference,a as well as a formulation that we believe has the potential to treat milder forms of disease.

Our gene therapy platform is advancing with promising Phase 1/2 to hemophilia A data that is expected to support a Phase 3 start this year. This would be our second gene therapy pivotal study following the ongoing hemophilia B Phase 3 study. In addition, our DMD gene therapy program is gathering additional robust patient data building on the progress we shared at the parent project muscular dystrophy conference last June. We are preparing for an expected POC in the first half of 2020 and a Phase 3 pivotal study start in second half of this year.

We look forward to successfully completing the Phase 3 studies for our investigational 20-

Valent pneumococcal conjugate vaccine candidate in adults and remain on track to submit the biologics license application to the FDA by the end of this year. Pfizer's candidate represents a potential significant advancement compared with the potential of 15-valent. If successful in Phase 3 and approved, the five additional serotypes may provide coverage against approximately 33% more strains that cause invasive pneumococcal disease in adults and 42% more strains causing the disease in infants in the United States.

For our maternal vaccine for respiratory syncytial virus, RSV, we are preparing for an expected POC in the second quarter of 2020, followed by a potentially swift progression to Phase 3. We look forward to sharing more updates on our pipeline during our upcoming Investor Day on March 31.

In summary, we finished 2019 with strong momentum and we look forward to continuing that momentum in 2020. During the year, we generated a solid financial performance, further advanced our strong R&D pipeline and took bold actions to reshape Pfizer into an innovation powerhouse, that will build on our legacy of delivering breakthroughs that change patients' lives.

Now, I will turn it over to Frank to provide details on the quarter and our outlook for the remainder of 2020. Frank?

Frank D'Amelio

Thanks, Albert. Good day, everyone. Now moving on to the financials, fourth quarter 2019 revenues, were $12.7 billion down 8% operationally versus the year ago quarter. Excluding the impact of the Consumer Healthcare business, revenue was down 1% operationally.

Our Biopharmaceuticals Group business revenues were $10.5 billion, up 9% operationally versus the year ago quarter, with strong operational growth in Ibrance, Eliquis, Xeljanz and Vyndaqel and a second straight quarter of operational growth for our Hospital business, including our sterile injectables.

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Revenues for our Upjohn business in the fourth quarter decreased 32% operationally to $2.2 billion, with the primary year-over-year impact again being generic competition for Lyrica in the US that began in July of 2019. Excluding the unfavorable impact of Lyrica in the US and other recent product losses of exclusivity, fourth quarter 2019 revenues for Upjohn declined 6% operationally.

I know UpJohn's business in China has been an area of focus, and fourth quarter revenues for Upjohn declined 1% operationally. We saw the expected revenue declines for Lipitor and Norvasc in provinces where the volume based procurement program has been implemented and these declines were mostly offset by operational growth from products not impacted by the VBP program including Celebrex and Viagra.

Adjusted cost of sales as a percentage of revenue was favorably impacted by the July completion of the Consumer Healthcare joint venture transaction with GSK, partially offset by the negative impact of foreign exchange and the Lyrica loss of exclusivity.

In the fourth quarter, we recorded a $0.06 loss per share on a GAAP basis, which -- primarily due to a $2.6 billion asset impairment charge for Eucrisa and restructuring purchase accounting and legal charges.

Adjusted diluted EPS for the fourth quarter was $0.55 versus $0.63 in the year ago quarter. The decrease was primarily due to lower revenues, again, mainly due to the Lyrica LOE in the US, and higher operating expenses.

I want to point out that diluted weighted average shares outstanding declined by 281 million shares compared to the year ago quarter, reflecting the impact of shares repurchased during 2018 and 2019, and partially offset by dilution related to share-based employee compensation programs.

Finally, foreign exchange had a negative impact of $158 million, or 1%, on fourth quarter 2019 revenues and a $0.03 negative impact on adjusted diluted EPS compared to the year ago quarter.

And as you can see on the chart, our 9% operational growth in the Biopharma business was driven by strong performance by Ibrance, Eliquis, Xeljanz, Xtandi, Vyndaqel and Inlyta.

Moving on to 2019 financial guidance, as you can see on the chart, we met or exceeded all components of our 2019 financial guidance.

Now I want to highlight how our 2020 guidance compares to 2019 revenue and adjusted diluted EPS. Starting on the left side of this slide, our 2019 results reflect partial year contributions from the Consumer Healthcare business segment, which we deconsolidated in the third quarter of 2019.

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Excluding $2.1 billion in revenues generated from the Consumer Healthcare business segment, total Company 2019 revenues were $49.7 billion, and 2019 adjusted diluted EPS is $2.95. For 2020, the adjusted diluted EPS guidance range reflects Pfizer's share of the Consumer Healthcare's joint ventures earnings that were generated in fourth quarter 2019 and will be reported in the first quarter 2020 along with Pfizer's share of the JVs' anticipated earnings for the first three quarters of 2020.

As you can see, the mid-point of our 2020 guidance range for revenues implies comparable performance to 2019 revenues after excluding the partial year contribution from Consumer Healthcare, as well as an anticipated $200 million favorable impact from foreign exchange based on mid-January 2020 rates compared to last year. Despite an anticipated $2.4 billion in LOE headwinds in 2020. We expect the mid-point of the revenue range to remain flat operationally, excluding Consumer Healthcare.

Now, let's go through the full details of our 2020 financial guidance for total Company. As we've said, we are expecting the close of the transaction between our Upjohn business and Mylan to be completed in mid-2020. So we are providing three sets of guidance: first, total Company, which reflects our current construct of the Biopharma and Upjohn businesses and excludes any impact from the pending Upjohn combination with Mylan; second new Pfizer, which is a full-year pro forma view that reflects the impact of the pending Viatris transaction by removing Upjohn and including $12 billion in cash proceeds from Upjohn to new Pfizer and other transaction related factors such as transitional service agreement revenue; and third, Upjohn is a standalone business. All of these scenarios are based on a full year of revenues and expenses in 2020.

Beginning with total Company, 2020 revenue guidance of $48.5 billion to $50.5 billion, reflects anticipated continued strong momentum in our Biopharma business, primarily offset by the continued negative impact of product losses of exclusivity in our Upjohn business, primarily Lyrica in the US.

Moving on to other elements of our 2020 financial guidance for total Company, compared with 2019 actual results, the mid-points of these ranges imply: higher adjusted cost of sales as a percentage of revenues due to the continued impact from the Lyrica LOE; higher adjusted R&D expenses; and higher adjusted other income, which reflects earnings from the Consumer Healthcare joint venture; and lower adjusted SI&A expenses and adjusted diluted EPS.

In 2020, financial guidance for adjusted EPS assumes no new share repurchases and we will focus instead on increasing the dividend and investing in the business during this period of growth. As a result, our guidance for adjusted diluted EPS assumes diluted weighted average shares outstanding of approximately 5.65 billion shares, which is approximately the same as 2019.

Moving on to financial guidance for New Pfizer for the full year 2020, we now anticipate full year 2020 revenues between $40.7 billion and $42.3 billion, with the mid-point of the guidance range representing 8% operational growth as compared to 2019 Biopharma

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revenues, excluding Meridian and Mylan Japan, and an improvement from our initial July targets.

This guidance range excludes $600 million of contributions from Meridian, Pfizer subsidiary and manufacturer of EpiPen and other autoinjector products, as well as from the strategic collaboration with Mylan in Japan for the development, manufacturing, and marketing of generic medicines. Due to an organization realignment, both of these assets have shifted to Upjohn effective at the start of 2020. Both Meridian and Mylan Japan will be reported in Pfizer's Upjohn business beginning in first quarter 2020.

We now anticipate full year 2020 adjusted IBT as a percentage of revenue of approximately 37%, also, an improvement from July. We anticipate the mid-point of the guidance range for adjusted diluted EPS to be $2.30. The operating cash flow guidance range remains approximately $11 billion to $12 billion. This EPS guidance reflects the $12 billion cash that Pfizer will receive upon the close of the combination of Upjohn with Mylan, which will be used to pay down debt during 2020.

As you can see the mid-points for new Pfizer's 2020 revenue and adjusted IBT margin guidance have improved materially since our preliminary 2020 projections were presented in July in conjunction with the announcement of the proposed Mylan and Upjohn combination. We have provided a bridge from our initial July targets to this current guidance on the bottom of the chart for clarity.

Upon the close of the Mylan/Upjohn combination and once we become New Pfizer, you can expect the same level of detail on 2020 guidance that we provided today for total Company.

Moving on to 2020 financial guidance for Upjohn for the full year 2020, we anticipate revenues of $8 billion, $8.5 billion, reflecting the continued negative impact of losses of exclusivity for products such as Lyrica in US, which began facing multi-source generic competition in July 2019, and the expansion of the volume-based procurement program in China, and reflecting the inclusion of revenues and expenses associated with Meridian and Mylan Japan.

We anticipate full year 2020 adjusted EBITDA for the Upjohn business of $3.8 billion to $4.2 billion. Other than the inclusion of revenues and expenses associated with Meridian in Mylan Japan, there are no operational changes to Upjohn's 2020 financial guidance compared with preliminary financial targets provided in July of 2019. Again, we have provided a bridge from our initial July targets to this current guidance at the bottom of the chart.

Moving on to key takeaways, regarding 2019, we delivered a strong fourth quarter with our Biopharma business growing 9% operationally, which represents our go-forward business after the pending combination of Upjohn and Mylan. We provide a 2020 guidance ranges for total Company, New Pfizer and Upjohn. Importantly, we are projecting strong organic revenue growth for New Pfizer in 2020.

We accomplished key product and pipeline milestones since our previous quarterly update and we returned $16.9 billion to shareholders in 2019 through a combination of dividends and share repurchases. Looking ahead, we remain committed to delivering attractive shareholder returns in 2020 and beyond.

Now, I'll turn it back to Chuck.

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Chuck Triano {BIO 3844941 <GO>}

Thanks, Frank and Albert, for those remarks. At this time operator, can we please poll for questions.

Questions And Answers

Operator

(Operator Instructions) Your first question comes from Randall Stanicky from RBC Capital Markets.

Q - Randall Stanicky {BIO 6967011 <GO>}

Great. Thanks guys for the questions. I have two, one for Albert and one for Angela. Albert, a couple of weeks ago, you called out $4.5 billion in enabling cost in SI&A, with an opportunity to simplify. So how do we think of all the cost savings opportunity after you close Upjohn in terms of: number one, how much incremental cost savings do you see beyond what is built into the 37% margin: and then, number two, how much of that could hit back half 2020 versus 2021? And then, I have a follow-up after that for Angela.

A - Albert Bourla {BIO 18495385 <GO>}

Okay. I think you should -- how can he ask the questions to Angela now. And we can back. So, indeed we have this year approximately $14.3 billion of SI&A and I will ask Frank to run the numbers in more details. And as I said, $4.5 billion approximately of that is what we call enabling functions. So these are functions like finance, legal, HR, facilities that they are facilitating and enabling the core functions for our business to perform. Core functions, I mean R&D that is discovering the products; manufacturing, that is making them happen; and commercial, that it is making them available to the patients.

We do believe that this $4.5 billion and actually approximately 10,000 people can be improved. And we have plans to do so. In the current guidance and I will ask Frank to comment, there is a part, a small part of that cost opportunity saving already incorporated. And in 2021, will be a much bigger part, So Frank.

A - Frank D'Amelio

So Randall, just let me run the numbers, which is, if you look at 2019 actual SI&A for example, we spent about $14 billion as a company, obviously, that $4.5 billion that Albert alluded to in that $14 billion. If you look at our 2020 guidance for SI&A, the range is $12

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billion to $13 billion, mid-point $12.5 billion. $12.5 billion from $14 billion is a decline of $1.5 billion. Now, roughly half of that is Consumer, because we went from consolidating Consumer -- equity accounting on Consumer once the deal closed in July 31, 2019.

The remaining half is really operational savings across the Company, including a part of the -- including some of the $4.5 billion that Albert alluded to. And that, obviously, helped contribute to the IBT as a percentage of revenue improving from 35% -- from the mid-30%s to 37%. And then to Albert's point, obviously, what we're doing now is working on further improvements that would obviously positively impact the SI&A and that will flow to the bottom line.

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A - Chuck Triano {BIO 3844941 <GO>}

Great. Thanks, Albert and Frank. Next question please.

Operator

Your next question comes from Chris Schott from JPMorgan.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much for the question. Just had a three quick product ones. The first was on Vyndaqel. Seems like a nice step-up in all your patient metrics, seems like all of those basically doubled or tripled from 3Q. Can you help bridge those figures with the sequential sales ramp we saw which wasn't quite as dramatic?

The second question I had was on Ibrance. Just aberration there in terms of what drove the revised timelines for PALLAS, and have you taken another interim look at the data at this point? And then, finally, on to tanezumab. Just an update in terms of what the status and outlook is for that product at this point? Thanks so much.

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A - Albert Bourla {BIO 18495385 <GO>}

Very good. Thank you very much. I will ask Angela to address the Vyndaqel and tanezumab questions and then I will say few words about Ibrance and may maybe I will ask Mikael to chime in.

A - Angela Hwang {BIO 20415694 <GO>}

Yeah. So, thanks for the question. And certainly, we are pleased with the increased diagnosis, prescription, as well as the numbers of patients that are receiving Vyndaqel. As you said, our diagnosis now is up to about 9%. The ability for patients to receive prescriptions up to about 64% of those that are diagnosed and those that are receiving medications are around 35% of those that are diagnosed. And every quarter, since we've been reporting this, we've been seeing some nice increases. So we're certainly pleased with that.

I think in terms of just the commensurate alignment with the actual net sales numbers, I think, that there are obviously -- every single day, this is a dynamic situation. And the

number and the proportion of patients, whether they are Medicare and commercial lives, those are changing, and so the gross to nets of those are going to effect, I think, what you see on a net sales basis. So I think that we are watching and really focused on driving diagnosis and ensuring that as many patients can get on these drugs as possible and we're starting to see some really nice pickup. But I think, that is still a very dynamic situation because we're really relatively new in this process. So we'll continue to monitor and should expect to see some quarter-to-quarter changes in terms of net sales.

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A - Albert Bourla {BIO 18495385 <GO>}

And obviously the new patients, they are contributing disproportionately because they are in fewer months of treatment in terms of sales.

A - Angela Hwang {BIO 20415694 <GO>}

And then, your second question was on tanezumab. So we're really pleased that in December of 2019, we completed our US submission of tanezumab and we are also pursuing regulatory submissions in the EU and in Japan. This submission was done in close collaboration with the FDA and it includes the 2.5 milligram in moderate to severe osteoarthritis patients. So at this moment in time, we're awaiting acceptance of this filing. But we see significant potential of tanezumab in osteoarthritis. So we're really excited about this filing and particularly, because we're in a time where non-opioid solutions are very, very much needed for these patients.

If you look at the market potential, today, there are about 27 million Americans that suffer from osteoarthritis and 11 million of those have moderate to severe OA. 80% of those 11 million people have tried and failed three or more analgesics. So that tells us that there is just a huge amount of unmet need in this patient population. Patients are cycling through a number of pain medications and there just is an incredible need for new options, and this is where we think tanezumab can really fill an unmet need. It has the potential to become the first-in-class non-opioid treatment for these patients and we eagerly await the acceptance of this file from the FDA.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you. Now let me address the question on Ibrance. The expected completion of the study slipped a little bit few weeks actually. It was at the end of the '19 -- excuse me, at the end of '20 and now it's moved in the very beginning of '21. The only reason of these is that the events are not coming at the pace that we had forecasted and expected. So it rather means people are not progressing into their disease. I don't think we can draw any conclusions if that means good news or bad news, I think it's just structure of the data. We don't know if the people aren't progressing equally in the two arms or they are not progressing in their treatment arm, that remains to be seen when we unblind the data.

As regards to your question, if there was an interim analysis. There was not an interim analysis. So we haven't seen any interim analysis. There will be an interim analysis, but we do not expect that -- the most likely scenario is that the study will continue when this interim analysis comes. The study was designed to come to full completion and the criteria that we had set to stop for efficacy in the interim study are very, very high. So it's

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not impossible, but this will happen. But most likely scenario, it is that as we had planned at the start it will come to a completion, at the end of it this is what will happen. But we are very -- we still remain very, very encouraged and optimistic about Ibrance. Of course, it's a Phase 3, you never know what would be, but all the science behind it is, supporting that we could have a positive outcome. And I will ask actually Micheal, to make a few comments on the science and what does this mean.

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A - Mikael Dolsten {BIO 16368411 <GO>}

I'll just punctuate a few things that Albert described so well. Four aspect of why we are very excited and optimistic about the science and clinical data to predict a potential positive outcome for the discussed PALLAS study, as you know, first of all that the CDK 4/6 inhibitor Ibrance converge with estrogen receptor drugs to stop cancer cells or breast cancer cells to divide. We have shown that in the PALOMA-2 and 3 studies and more recently we reported that we could reproduce a data direction in real world evidence based on real world data from Flatiron and other databases. And this noteworthy, including also overall survival data, again showing in medical practice the importance of this drug.

Three, the PALLAS study that looked at the ability of palbociclib Ibrance to stop dividing of estrogen-receptor positive primary breast cancer showed that this mechanism was very well operating in a powerful way. And finally, let me remind you that other agents that act on estrogen-receptor positive primary breast cancers and converge with palbociclib such as tamoxifen and aromatase inhibitors all were initially developed in metastatic cancer, indeed very well in adjuvant treatment in early breast cancer. So these four observations and others makes us continue to be excited and very optimistic.

And as Albert alluded to, relatively small change in projected trial is based on the trial that actually started four and half years ago and it is quite common that in the final 12 months or so minor changes in enrollment rate and process planning for study reports can affect a trial. But with all of these, you can hear, we remain encouraged, enthusiastic about what Ibrance can offer for adjuvant treatment of breast cancer.

A - Chuck Triano {BIO 3844941 <GO>}

Great. Thanks for the helpful context, Mikael. Next question please.

Operator

Your next question comes from Terence Flynn from Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the questions. Maybe just two product ones from me. I was wondering if you can talk about Ibrance rest of world dynamics, any specific headwinds this quarter and how to think about the trajectory into this year? And then, for Xeljanz, I was wondering if you can give us the split of sales by indication and if you're seeing any impact in RA from the launch of AbbVie's Rinvoq on either share or price? Thank you.

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A - Albert Bourla {BIO 18495385 <GO>}

Thank you very, very much. So, Angela.

A - Angela Hwang {BIO 20415694 <GO>}

Sure. So first of all on Ibrance, we continue to see good growth and strong growth ex-US, but probably two factors that are tempering the net sales as you saw in Q4. The first is pricing and that continues to be something that we work hard at, especially in EU, to gain access for our product in Europe. And the second is class growth. So you look at the class growth of the CDK class through the quarters, that has increased, but over the last quarter it has tempered. And it's sitting at around 35% CDK class growth right now in class share, but within that the Ibrance still has a very, very high product share in the 80%s. So I think it's pointing out to us the fact that there is still opportunity for us to grow and that growing the CDK class is going to be an area of our tremendous focus for us ex-US in 2020 and beyond.

Your second question was around Xeljanz, and so on Xeljanz, again, we continue to see excellent growth in Xeljanz. In fact, despite the fact that you only see the 1% net sales growth in Q4, I will point out that, globally, full year, we had 29% growth of Xeljanz, which is one of the highest of all of our core brands here at Pfizer and our entire portfolio. Q4, we saw 23% prescription growth and this prescription growth was driven by extremely strong performance in rheumatoid arthritis, which really was not impacted by the label changes. And we still continue to see strong growth in ulcerative colitis, even though here was the biggest label change, and so physicians did have to adjust the way that they were prescribing Xeljanz. But we expect this growth to continue because we have excellent momentum and confidence in prescribing from our physicians, we have significant unmet need, and we have greatly improved access. And this access is, in fact, what drove the 1% net sales in Q4.

There was a -- in Q4 of '18, we saw an inventory build at the end of the year, which didn't happen in Q4 of '19. So that was one of the reasons that affected our Q4 performance in '19. And then, also, and more importantly, throughout the course of 2019, we gained significant access. In fact, we added 59 million incremental lives through contracting. And it's because of the timing of when these contracts were signed or renewed that drove the subsequent impact of rebates. And this came to ahead and disproportionately affected us in Q4 of '19.

So I think, stepping back, we're really pleased with the access that we do have in Xeljanz. And since it was launched eight years ago, this is the most favorable access situation that we've ever had, which is very important when it comes to our ability to compete with Rinvoq. You asked a question around Rinvoq. Just to put into perspective, I think, that we are excited about having another competitor help drive the growth of the JAK class in all of our indications. That being said, Xeljanz still enjoys a leading market share, especially in RA, where we have more than 15% of the market share of the entire class.

A - Chuck Triano {BIO 3844941 <GO>}

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

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Operator

Your next question comes from Umer Raffat from Evercore.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my question. First, Albert, if I may, what are you hearing on a possible upcoming rule on IPI? There's a lot of press that companies have been notified by White House. I was curious what you know about it and if there's something we should be very concerned about?

Mikael, two quick one. One quick one for you on the DMD gene therapy for a minute. You mentioned there is a proof-of-concept coming. My question is, have there been additional protocol driven pauses and enrollment? And I asked because recall when the first SAU [ph] in acute kidney injury happened the trial was paused and I'm curious, has anything like that happened again?

And then finally, Frank, maybe just quickly on SI&A line. I know it's a little higher than consensus, but technically, year-over-year versus 4Q '18, it wasn't that much higher. But I also realized 4Q '18 had some Consumer. Maybe if you could just tell us about your holiday party? Thank you very much.

A - Frank D'Amelio

All right. So let me start with the IPI. We have not received any notification on that. So there is no news from our side other than what we read on the newspaper. So, Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Just to remind you, we shared at the PBMD conference mid of last year, update on six patients dosed with our DMD gene therapy that showed encouraging data on expression in muscle fibers among the micro-dystrophin and on some of the patients we had also an opportunity to report the encouraging trends on functional outcomes. We have dosed additional patients since then and we continue to gather experience and efficacy, safety and clinical management that are incorporated in the procedures how we manage these patients going forward. We plan to conclude Phase 2 this spring. And based on current data and insights, we are planning to start Phase 3, of course pending regulatory dialogues later this year as indicated in Albert's opening remarks.

A - Albert Bourla {BIO 18495385 <GO>}

All right. Frank, maybe you want to tell us about the holiday party. I was not invited.

A - Frank D'Amelio

Sure. Yes. I wasn't invited either. So, maybe you will visit the party. Let me run the numbers, and I'll explain what happened. So for the quarter, SI&A line was about $4.1 billion, it was up about 4% operationally, a $100 million give or take from the prior year quarter. What really drove that was increased investment behind some of our brands, some of our oncology products, some of our launch products like Vyndaqel, and some

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increased investment in emerging markets. But it was really investment in terms of supporting our brands.

A - Albert Bourla {BIO 18495385 <GO>}

Yeah. Thank you, Mikael. And just to make a comment, we are very, very diligent in the way that we allocate capital. And when we have opportunities to put in promotional money, so we can get a very strong start, we do it. And we take those money usually by being very diligent in the way that we control the indirect expense. I have been very clear that within direct there is a very clear distinction in our mind. So when it comes to things that there are overheads and things that they are not affecting directly the business results, we are very, very tough. And when it comes to areas that the investments can affect business results, we are creative and generous. So that's what you just saw here.

A - Frank D'Amelio

And these are clearly direct expense --

A - Albert Bourla {BIO 18495385 <GO>}

And these are direct expenses. And the same -- by the way, although, you didn't ask -- comes to R&D, right now, we are increasing R&D investments, but we are increasing R&D investments only for programs, only for projects. We are not increasing infrastructure, we are not increasing research centers, at labs [ph], we maintain a very strong presence there and we keep that very strong. But what is driving the increased R&D, it is more Phase 3 or Phase 2 studies. It is very clear.

A - Chuck Triano {BIO 3844941 <GO>}

Great. Thank you. Next question please, operator?

Operator

Your next question comes from David Risinger from Morgan Stanley.

Q - David Risinger {BIO 1504228 <GO>}

Yes. Thanks very much. So I have three questions please. First Albert, could you discuss why Pfizer decided not to repurchase shares in 2020? And then, maybe, Frank, you can comment on how we should think about the EPS implications when we consider your guidance relative to consensus which had assumed some share repurchase?

Second, regarding the opportunity to rationalize the $4.5 billion in costs. Could you just give us a sense for what percentage reduction is reasonable to assume a few years out? I was guessing maybe 20%, but I just don't know what's reasonable. And then, third, regarding the transfer of $600 million in revenue to Upjohn, does that change the economics that Pfizer will receive as part of the exit to Mylan? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

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Yes. And I think basically all question can be answered by Frank. I would just make some introductory comments. The reason why in our capital allocation we are allocating right now money to increase the dividend and also to invest in our business, or the OpEx to modernize our facilities, the reason why we don't do right now -- purchase it is, because we want to make sure that we maintain very strong, high power to invest in the business. The past was a very different Pfizer. The past of the last decade had to deal with declining of revenues, constant declining of revenues. And we had to do what we had to do, even if that was finance a (inaudible) or purchasing back our sales. We couldn't invest them and create higher value.

Now, it's a very different situation. We are a very different Company. The Company is going to have best-in-class top-line growth, revenue story, starting from now from the separation of Upjohn in the middle of the year -- from the expected separation of Upjohn in the middle of the year. And we do not need -- we can organically grow EPS. As you can see all our projections on EPS this year are organically, no (inaudible), but we can use the capital to invest in good Phase 2, Phase 3 assets that could build our pipeline. So this is the strategy behind it.

Now, let me ask, Frank, to run the numbers.

A - Frank D'Amelio

So David, all I'll do is, I don't want to duplicate anything Albert said. I'll just add a couple of things on the share repurchases. One, we also announced a dividend increase in December. So obviously, we continue to deploy capital in the area of dividends, which we think is important to our investment thesis and that's something obviously as we go forward, we'll continue to look at. And then obviously, our 2020 guidance assumes no repurchases. So when you look at the improvement, which is material in terms of the mid-point versus what we did back in July, none of that is coming from share repurchases.

Now, let me answer your other couple of questions. On the $600 million transfer to Upjohn and does that change any of the economics? Let me give some context on this, which is; one, nothing has been decided yet. We are still in negotiations with Mylan on those two businesses and whether or not they will transfer to Viatris upon close. If we don't come to an agreement, those businesses would remain with New Pfizer. And so, we're still in negotiations. And so in terms of the economics, I'd say, more to come, still to be determined. And if and when we complete that, obviously, I'll be in a better position to answer that.

On the $4.5 billion of indirect spend and directionally what do we think we can do there, I don't want to give a specific percentage, because we're still working our way through the process, but I think I alluded to this earlier, which is, we've already made some nice headway. I think we can make additional headway. That additional headway will show up in SI&A, and obviously, our intent would be for that to show up the IBT as a percentage of revenue line. So that's what we're working to do. Our intent is to improve upon those numbers and as we work our way through the process and as we have more to report, we'll make sure we do so.

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A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Frank. And also, a comment on the reasons why we transfer those business to Upjohn. So both of these businesses first of all, they fit more under Upjohn in terms of the dynamics that they have, so that they can be manage much better. And secondly, I think they fit very nicely with Mylan because; one, it is the EpiPen predominantly business that right now is shared between Mylan, we are providing for them. And the second it is, a partnership that we have with Mylan, that was established years back and with generics in Japan. So both of them fit much better in Viatris and that's the reason why we separated. And also that will allow you to have, in case that this happens, a much more clearer view of the growth trajectory of the Company because now you know exactly what would be the P&L of the remaining Company.

A - Chuck Triano {BIO 3844941 <GO>}

Thank you. Next question please, operator.

Operator

Your next question comes from Louise Chen from Cantor.

Q - Louise Chen {BIO 6990156 <GO>}

Hi. Thanks for taking my questions here. So I had a few. My first question is, is the approximately 6.5% five-year sales CAGR for standalone Pfizer the New Pfizer is still holds? Second question I had is, how much of a priority is M&A for you under the New Pfizer and what kind of size of deals or types of deals are you most interested in? And last question I have is on the PCV dataset that's coming through. You and a competitor also have a whole set of PCV data. I'm just curious how you see that landscape evolving over time? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Yeah. Thank you very, very much Louise. Let me start with 6% CAGR if it still holds up. Absolutely, it still holds. Actually as you can see, if anything else, this business what we are projecting five years CAGR -- all the way to '25 actually CAGR of 6%, this year performed at 8%, 9% for the quarter and we are projecting 8% for 2020. So definitely we are on good way to achieve that.

As regards to the M&A, yes, the M&A is a very important part of our strategy, and as I just alluded before, this is why also we are not diluting our firepower with stock purchasing right now because we do believe that we can create significant value with a right strategic move. Now, we never say never to anything, but strategically we have made very clear that we are not interesting for a big M&A, but we will have a cost synergies as value driver, because, first of all, that would be like diluted in our top-line growth. I don't think there are many companies that they can have this type of growth trajectory what we have in the next few years.

Second, we could be distracted, because having a big M&A means that thousands of people will have to work on integrations rather than supporting all these products that we

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just show, that are growing in 20%s and 30%s, and also all this pipeline that is coming up. So we never say never, but this is not our strategy. Our strategy for M&A, it is to be able to have Phase 2, Phase 3 programs, all right, Phase 2, Phase 3, which could become potential medicines in the period '25, '26, '27, '28, so that we can augment our internal pipeline and we are able that we maintain the 6% growth for the long term, actually, for the very, very long term because right now, five years I would say is a long-term.

And the other thing that I want to emphasize it is that, the 6% CAGR, it is risk adjusted. I repeat, it is risk adjusted. Let me answer that. In our projections, we are adjusting all the non-read studies right now appropriately. Now, if all the Phase 3 goals are on the right way and they are all successful, it's not going to be 6%, it's going to be double-digits, it is going to be 13%, 14%, 15%. Now, if everything fails, also, it would not be 6%. It will be very low. But if statistics works and the studies, let's say, 50% more or less are successful, that means that we will achieve 6%. That's why I want to emphasize that there is no binary event in our projections. Binary event would be if that 6% was dependent on two or three major readouts, that if they could go one way or another, could affect. Right now, they are dependent on 15, 16, 17 blockbusters. And then many other, but they are much smaller.

So then Frank, maybe something to add on that before I ask Mikael to comment on PCV data?

A - Frank D'Amelio

And Louise, the only thing I wanted to add, just to punctuate everything Albert said is, and why are we focusing on Phase 2b Phase 3, it's because the LOEs really start to kick in in 2027. So if you think about we are in January of 2020, we literally have eight years to work our way through this problem. And by the way, given that kind of a timeframe, given the breadth and strength of our pipeline, given our balance sheet, our capacity, obviously, we feel confident we will be able to solve that.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. I'm pleased that you asked about our (inaudible) next generation. So, as you know, we have adult and pediatric studies ongoing. The adult study has been given breakthrough designation at September 28, based on our encouraging Phase 2 data. And we expect very soon to report Phase 3 outcome of the adult piece PCV20 trial. And obviously, we are optimistic about that outcome based on the Phase II and the breakthrough designation.

On the pediatric, we have now accumulated further post fourth dose data of the PCV20 Phase 3 study. These data from the fourth dose further substantiate the positive data reported in the press release after the third dose. And we expect initiation of Phase 3 soon for the infant vaccine pending discussions with regulators. The full dataset will be presented at the major vaccine related conference likely mid of this year.

Now, Albert commented also in his introduction very nicely on the improved relative coverage of the PCV20 from us versus a potential compared to the 15-valent and he mentioned 33% better coverage for adults and 42% better coverage in the US for infants.

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Obviously, very important significant better coverage. I just wanted to punctuate, when you look in the top European market, similar -- the improved coverage in adults is actually 60% to 100%, in infants 80 to 200%. This is all for invasive pneumococcal disease. Also in US, we have analyzed for community-acquired pneumonia where we see substantial that to cover it for the 20 versus a potential 15-valent.

So all in all, you can see, we look forward to datasets advancing the program and think it would be the premier 20-valent and premier pneumococcal vaccine for patients.

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A - Chuck Triano {BIO 3844941 <GO>}

Thank you. Next question please, operator?

Operator

Your next question comes from Steve Scala from Cowen.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have a few questions. An increase in the dividend was mentioned twice, but it sounds as though Upjohn will be spun not split, in which case, the dividend will be reduced. So I'm wondering, if you could clarify the dividend comment? And I assume the 2020 EPS guidance implies a spin, not a split.

Secondly, on the abrocitinib versus Dupixent study, given the fact that it is completed, Mikael, I'm wondering if the data met the very positive portrayal you provided on the Q3 call, which included Superior itch relief to Dupixent. And then, lastly, will the proof-of-concept DMD data be presented at the March 31st meeting? Thank you very much.

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A - Albert Bourla {BIO 18495385 <GO>}

Well, thank you very much, Steve. Very good questions. So Frank, why don't you clarify once more the dividend?

A - Frank D'Amelio

Sure. So Steve, in terms of the guidance, you are right. It assumes a spin not a split. And then in terms of the dividend, I think, you said in your question, there would be a reduction. I don't see it that way. What we've said is, the sum of Viatris dividend and our dividend would equal the current dividend that Pfizer show the receipts today. So I don't see a reduction in the dividend. The dividend income will be kept whole. I think we've been very clear about that all along.

A - Albert Bourla {BIO 18495385 <GO>}

And will continue growing, maybe not at the same pace, which we do now at $0.02 per quarter, but will continue growing.

A - Frank D'Amelio

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Right. And Steve I can quickly run the numbers for you, if you'd like. So, we think what Viatris has said is, their first full year of about $4 billion of free cash flow, they would pay about 25% of that in the dividend. So that's a $1 billion. Total Viatris will have about 1.2 billion shares, you put the 1 billion over 1.2 billion shares, it's about $0.83. The exchange ratio is 0.12, you put 100 shares of Pfizer, you get 12 shares of Viatris assuming a spin. That's roughly $10 a share. We would reduce our dividend on an annual basis by that $10, but the sum of our dividend plus that $0.10 would equal to what Pfizer share only gets today. In my thing, it's $10 not $0.10.

A - Chuck Triano {BIO 3844941 <GO>}

Abrocitinib?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes. So thank you for your interest in abrocitinib and we believe that it's going to be a new drug class for such a prevalent disease that affect tens of millions of Americans, atopic dermatitis and where an oral alternative seems to be a real patient and physician preference. We will soon report out the data from the important Compare study. So I haven't actually seen to data, so I can only punctured a little bit what we discussed at earlier investor meetings that, the historical comparison between abrocitinib and Dupixent suggest that we should expect to see a similar or better impact on clearing skin, and particularly, as Albert alluded to in his introduction, there is an important key secondary endpoint looking at each relief, starting with a readout already of two weeks and then following the study through 12 to 16 weeks.

And the historical data suggests that we should be very optimistic about abrocitinib, outperforming biological such as Dupixent on each relief at earlier time points and provide the potential benefits of early onset of relief for disease. Now we have to wait for the data to be able to obviously be absolutely confident in that outcome. But this is what I believe and look forward very much to see the data come shortly.

A - Chuck Triano {BIO 3844941 <GO>}

And on the DMD question.

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. We are finalizing I think the program for the R&D Day. So I can't absolutely promise you, but I think it's likely that such an interesting program as the DMD gene therapy will be one of the potential agenda items. And obviously we would like to then share updates from increased number of patients over a longer time period. So please welcome and take a front row seat. Thank you very much to both and by the way, Frank, as always was right. It is $10 for $0.12 for Mylan.

A - Chuck Triano {BIO 3844941 <GO>}

All right. We will move on to our next question, please.

Operator

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

Q - Geoff Meacham {BIO 21252662 <GO>}

Morning, guys. Thanks so much for the question. Just have a couple. Mikael, in gene therapy platform, with the advancement of hemophilia A and B, as well as DMD into Phase 3, what's the capacity to add additional indications to the portfolio? I mean you guys have been successful with partnering, but at this point, it does seem like you could expand the platform organically in a material way.

And then, for Angela, on Xtandi, just wanted to get your perspective on the inroads you've made in M0 prostate patients and where do you think could represent a tipping point commercially, especially given generic Zytiga available in the US? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yes. So, Jeff, we are -- share you enthusiasm for the gene therapy platform and what is particularly, I think, a strategic advantage for us is to end-to-end capability from discovery, clinical, manufacturing and of course, that capability is also linked to important external partners that gives us capacity to advance increasing number of internal as well as partner programs. And we have an option for the Vivet Wilson disease program that could in a relatively near-term future be available for clinical studies. And we expect from internal and external initiative to aspire to about bringing one new gene therapy into the clinic every year or so for the next period to come. And we think that should build up a very comprehensive gene therapy portfolio.

The three programs you alluded to are, of course, the frontier for us with Factor IX that we hope to be the first Company bringing that over the finish line in Phase 3 now, and to start additional two Phase 3s for HEM A, where we think we have a best-in-class profile so far. And then, we already spoke about DMD.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much. Angela?

A - Angela Hwang {BIO 20415694 <GO>}

Sure. So in terms of the M0, the non-metastatic CRPC, I mean, what we're seeing here is just tremendous growth and tremendous performance. Just broadly speaking, in terms of Xtandi, we had a great quarter, right. We grew 29% and this was driven by two things. One, was actually demand across both metastatic as well as non-metastatic, but also, what we saw was the continued expansion of the actual class, the novel hormone therapies. And in this class, Xtandi has the lion's share. We have about 35% share right now.

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So first of all, to answer your question vis-a-vis generic Zytiga, we really don't see a competition from a generic versus brand in this instance. I think the competition with Zytiga is really amongst generic Zytiga versus branded Zytiga, whereas what we're seeing here is a clear uptick in Xtandi. And specifically from the PROSPER trial in this M0 population, as you say, we are continuing to see, as I've talked about in all the previous quarters, really, really significant and very confident and uptake in urology prescribing and we do believe that this is underpinning the growth of our non-metastatic population. And the fact that these are patients also earlier in their disease is helpful in driving our growth in this population.

I'll also mention that just from a market share perspective, though the non-metastatic, the M0 population has Xtandi leader as well as Nubeqa, Xtandi by far and away has the leading market share in this segment and has been from the time that it was launched.

A - Chuck Triano {BIO 3844941 <GO>}

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

Operator

Your next question comes from Tim Anderson from Wolfe Research.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. A couple of questions, one is on Prevnar in China. So sales have been ramping up there, but the regulatory authorities recently approved a domestically produced 13-valent product and the CEO of that company suggest they have capacity that's in the 10s of millions of doses and who knows if that's true or not, but I'm wondering, if you can give some perspective on how you see competitive dynamics in a situation like this going forward, not only in China, where a domestic producer could potentially benefit from favoritism, but also if that company were to take their product into other markets outside of China at a different price point? I think a lot of investors assume vaccines are durable, forever, but I'm wondering if this sort of thing could be disruptive and how you take this sort of potential competition into your forecast?

Second question is on M&A. So any M&A that you may engage with in 2020, should we assume at least during this first six-month window, while you still have Upjohn that that is probably put on hold? And the last question on Vyndaqel, might there be a low-hanging fruit phenomenon where we see initial nice uptake, but then it kind of flattens out suddenly or do you expect this will be continued strong linear growth?

A - Albert Bourla {BIO 18495385 <GO>}

Thank you very much. I will give a quick answer to your M&A question, Tim, and then, Angela can deal with Prevnar and probably that growth. On M&A, no. The answer is, no, absolutely not. We are very actively looking to invest capital on value creation opportunities. And then I assume that we will have several of them in the first half of 2020 before the close of the deal, again, across the lines that I have described. You know

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exactly what we're doing. We want to make sure that we sustain the growth beyond 2027 when the LOEs will have some impact. Angela, what about Prevnar, China?

A - Angela Hwang {BIO 20415694 <GO>}

Sure. So we acknowledge that there is a new competitor in the form of Walvax in PCV13. However, I want to recognize that there are some differences here. Though it is a 13-valent vaccine, the Walvax vaccine is made with a different conjugate. And this conjugate technology being an older technology, so quite different from what we see in PCV13. That being said, it is a competitor. However, if you step back and look at the opportunity that we have in the pneumococcal vaccinations, there are approximately 14 million new births every year in China and today only over, maybe 1% of those infants are being vaccinated. So regardless of the volumes that Walvax might have available, I think, the opportunity between us is just much larger than that.

And we have a tremendous amount of untapped potential in the marketplace and we are confident that with the quality, the reliability, as well as the tremendous experience that Pfizer has had globally with PCV13, but also the tremendous success that we've had in China, specifically for PCV13, that our growth will continue. And this is what we expect. We have a very robust footprint. As you know the vaccines and it will be the same for Walvax's PCV13, this is an out-of-pocket market and it will be the same for both of us. So this is where we'll be competing, which is why having a robust promotional engine and having a footprint of representatives that can really be available to support patients and caregivers at the points of vaccinations is really important. And I think in this regard, we have demonstrated great expertise and ability to grow this market. So that's how we see it. We acknowledge the competition, but we continue to see tremendous potential.

A - Albert Bourla {BIO 18495385 <GO>}

What about Vyndaqel?

A - Angela Hwang {BIO 20415694 <GO>}

All right. So in terms of Vyndaqel, so yes, of course, in the year of launch, one might expect to see a little bit of a bolus, a number of patients who have been identified and are awaiting diagnosis and treatment. That being said, we are confident about what we've learned in the marketplace in our first year of launch. We are confident that we have the right set of tools for helping physicians to suspect the patients that might have ATTR-CM. We have mobilized education around using non-invasive methods like scintigraphy to diagnose patients and we have also mobilized a patient support hub to help patients receive their medications. So I think doing more of that, as well as continuing to think about new methods to help diagnose and treat patients such as using artificial intelligence and increased number of tools, all of that will continue to support our ability to drive the important and rapid diagnosis of patients as well as their treatment.

A - Chuck Triano {BIO 3844941 <GO>}

Great. Thank you. Next question, please?

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Operator

Your next question comes from Andrew Baum from Citi.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. Couple of questions, please. Firstly on your pending oncology biosimilars rollout in the US, given the challenges historically with biosimilar penetration, could you talk to your expectations, particularly with these two drugs? There should be an economic incentives for payers given the pass-through, but yet there is issues in patients who are already on an established (inaudible) biosimilar to switch -- and it's a brand to switch to biosimilar. So if you could give us some kind of sense as to how much penetration and how quickly you may expect, that would be super helpful?

And then second, in terms of Tafamidis, Angela, you kindly gave some penetration figures at beginning, which I was struggling to keep up with and write-down. But just more broadly, could you outline how large you think the untapped patient population really is here and how far Pfizer is along in establishing that market? Many thanks.

A - Albert Bourla {BIO 18495385 <GO>}

Angela, lot of questions for you today. Please go ahead.

A - Angela Hwang {BIO 20415694 <GO>}

Okay. Sure. All right. So I think firstly, we see the dynamics in oncology biosimilars being very different from that of what we saw for inflammation in the form of Inflectra. So to your point about how will the dynamics change here and how quickly can payers as well as providers capture their savings, it's going to be much quicker. The use of oncology biosimilars are much more rapid, right. You see more patients cycling through, treatment times are much shorter. So that's going to enable payers and providers to capture savings much more quickly, which is a very different dynamic that you see in Inflectra where it's a chronic treatment and patients on that treatment for a very long time. So I think that's one big difference.

The second is that there is already some -- we already have some precedents. We saw this with Retacrit, where after a year of being in the market, though I know it's a supportive care in oncology, we already have 20% market share. This is still far cry from what we see in Europe, where there is much more rapid uptake that I think that it's a signal and an indicator of the differences you see in the various biosimilar markets. And we also have some early signals from competitor biosimilars that have already some good market share in oncology biosimilars. So I think that we have some good indicators that this is going to be a different.

I think the benefit that we see here is that we have a portfolio of three oncology biosimilars all coming out around the similar time, like around now. And I think what we have -- we have a robust pricing strategy, discount to the WAC of the originator, as well as I think strong relationships and networks built with both providers and payers that give us confidence that this will be an area of high growth for Pfizer.

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A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Angela.

A - Angela Hwang {BIO 20415694 <GO>}

And then your question was around Tafamidis. Sorry, can you just repeat that again?

A - Frank D'Amelio

It was the untapped population.

A - Angela Hwang {BIO 20415694 <GO>}

Got you. So as we have said in previous calls, we do believe that this is a rare disease and that in the US, there will be about 100,000 patients in total. Globally, 500,000, but in the US, 100,000. To date, we have diagnosed 9,000 patients. So that leads us to 9% of the population that we have diagnosed. So while this may feel like very significant progress from the time that we have launched, and it is, I think, you can also see that we have a long, long way to go to finding all 100,000 of these patients. And what I spoke earlier about in terms of the education, in terms of how do you suspect disease, how you diagnose the disease, and then, very quickly gaining access, so our patients can benefit from treatment of the disease, these are all three levers that we are intensely focused on.

A - Chuck Triano {BIO 3844941 <GO>}

Great. Thank you. Next question, please.

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Operator

Your next question comes from Navin Jacob from UBS.

Q - Navin Jacob {BIO 20931208 <GO>}

Hello. Thanks for taking my A couple if I may. Just on biosimilars following up with Angela, your comment about strong growth continuing on for the biosimilars. So wondering if you could give any color around how we should think about the trajectory over the next couple of years, is this a doubling or tripling of that now almost $1 billion business? And then, also, would love to understand how you're thinking about the tail of each of the individual assets? Are you seeing or should we be thinking of this as a ramp that goes up for a few years and then eventually starts tailing off like other generics or do you see this stabilizing and having a sustainable tail?

And then just on Vyndaqel, you received a positive CHMP opinion in the EU in December. Given that Vyndaqel is already approved probably in Europe, the indication, wondering how we should be thinking about the price with the addition of the cardiomyopathy indication? Is there any chance for moving that around? And then how we think about the ramp in the EU relative to the US? Thank you so much.

A - Angela Hwang {BIO 20415694 <GO>}

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So I will start with the last one first. So you're right, we just received EU approval for Vyndaqel. And as you know, there is quite a time lag between approval and then reimbursement in each of the countries. So all I can say is, right now, we are in active negotiations with the countries in terms of determining the price of Vyndaqel as well as its reimbursement. You referred to the fact that we already have the 20 milligram proof-of-polyneuropathy in Europe and we recognize that. That being said, we have -- first of all ATTR-CM is a completely different indication. The trials that were conducted as well as the significant mortality benefits that were demonstrated in our clinical trials for ATTR-CM are completely different and we have the clinical data to demonstrate the great patient benefit that that we have in ATTR-CM. And so that's the basis of our discussions with each of the countries in Europe for reimbursement.

Your second question was around Vyndaqel growth and the pace of it. I think, the way to think about it is the following. We have through analogs seen that only 30% to 50% of all rare diseases are ever diagnosed, but of course, we believe that based on the mortality data that we have and the patient benefit that can be derived, that it is critical that we meet that at least beat that. And so that's what we are intensely focused on. We have 10% of our patients or 9% in the US that are diagnosed today. We have a long way to go and that's what we need to do.

Your last question --

A - Chuck Triano {BIO 3844941 <GO>}

What's the rhythm on the biosimilars, so we've had strong growth, 22% this year for the year, what can we expect going forward?

A - Angela Hwang {BIO 20415694 <GO>}

That's right. So I think in terms of the biosimilars, again, this is an area of growth that we can anticipate. We have three biosimilars now in oncology, plus the two that we have in supportive care. And so we look forward to this being a significant growth contributor to our oncology portfolio, not just from a growth percentage perspective, but also from a revenue base perspective.

A - Mikael Dolsten {BIO 16368411 <GO>}

I just wanted to add that Vyndaqel cardiomyopathy has a positive EU recommendation. So we expect the approval to come soon and that links very nicely to really helpful outline you did Angela.

A - Angela Hwang {BIO 20415694 <GO>}

Thanks, Mikael.

A - Chuck Triano {BIO 3844941 <GO>}

And if we can take our last question please, operator.

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Operator

Your final question comes from the line of Mani Foroohar from SVB Leerink.

Q - Mani Foroohar {BIO 20015167 <GO>}

Hey, guys. Thanks for taking my question. A couple of little ones on the rare disease side. In terms of Tafamidis, we saw pretty attractive growth OUS, including some markets that don't necessarily have the cardiomyopathy indication yet. Is there some follow-on benefit in polyneuropathy from the increased promotional efforts in cardiomyopath in Europe and elsewhere?

As a second question, given the expansion of patient opportunity into polyneuropathy in the US, how do you think about the opportunity to pursue a supplemental NDA or similar strategy in the US based on the real world evidence guidelines laid out previously by the FDA? Or would that require a separate study?

And then, finally, on the gene therapy side, obviously, pretty interesting data, hemophilia at ASH moving forward in a couple of Phase 3s now. How do you think about that market in a universe where you have multiple therapies within curative intent in gene therapy alongside a number of fairly robust chronic therapies? Who are the patients who should receive an irreversible intervention in terms of gene therapy? And who do you think are more appropriate for chronic therapy such as your own BeneFIX? Thank you.

A - Albert Bourla {BIO 18495385 <GO>}

Yeah. I think I will ask Mikael to start with gene therapy and the ASH and all of this great portfolio assets that we have and how they fit together. Mikael?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah. Thank you very much. What I think is unique in our hemophilia portfolio, first, of course, we have a legacy being one of the pioneers for intravenous deliverer of Factor VIII and Factor IX. So we have a platform and experience on the business and R&D side. And as you so nicely alluded to, we also shared with our partner Sangamo some very much best-in-class data recently on Factor VIII gene therapy. Our current portfolio has Factor VIII and Factor IX gene therapy plus our TFPI antibody that has like Hemlibra an opportunity to provide subcu alternative but actually TFPI can be applicable for both Factor VIII and Factor IX deficiency. So the way we see it develop is that, I think, physicians will look at gene therapies that durability and good tolerability.

And that has really been the hallmark for the strategies when we developed Factor VIII and Factor IX best-in-class profile, because there are alternatives for these patients. So once they see the data for drugs -- the treatments that are approved that have durability and really good outcomes, which I think has been so far what we have seen with our gene therapies, those will be the one that can be adopted because there are alternatives that have less convenience, but will at least until strong data is available to be used. For patients that are early in their disease, diagnosed at earlier age, I think this will be a very important treatment as it saves them from the breakthrough bleedings that occur on

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lifelong treatment with infused factor and particularly for patients that are at early age that are a very physically active, it is important to have a solution for cure. So I think this will be a tremendous important patient populations.

But the availability of subcutaneous agents will supplement them and also allow for patients that may have antibodies to the gene therapies to use them until a sufficient number of gene therapies available that there is always one for each patient. And finally bringing it together, I think what's unique with us is the entire portfolio that can address these patients and we really much forward to be around 2021 and 2022 when we see this portfolio coming into registration phase. I think that was the main piece here.

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A - Albert Bourla {BIO 18495385 <GO>}

Yeah. And then, Angela, may be on Vyndaqel, we have seen some uptick in markets that cardiomyopathy was not approved, what's going on there and about supplemental filing on polyneuropathy?

A - Angela Hwang {BIO 20415694 <GO>}

Yeah, in terms of polyneuropathy, in the US, this is something that we're continuing to explore with the FDA --

A - Albert Bourla {BIO 18495385 <GO>}

No decisions have been made yet, but we are in discussions.

A - Angela Hwang {BIO 20415694 <GO>}

That's right. Exactly. And then in terms of the uptakes in polyneuropathy, I mean, I'm not sure that it's a cardiomyopathy effect. As you know, we are approved. It's an approved indication for us ex-US. So we continue to actively promote it and it's probably as a result of those activities.

A - Albert Bourla {BIO 18495385 <GO>}

Yeah, we will have, as we said, approval for that indication. And this is one we think we will see material impact on Vyndaqel in cardiomyopathy and these patients, who are not right now -- we are just promoting of course the indications that we have registered over there. So we don't do anything outside that.

All right. I think this concludes more or less our call. Just I wanted to make some comments because really I feel that we are at an exciting point in Pfizer's history. And If you take a big-picture view over the last decade, we have changed and refocused our approach to R&D. We have improved dramatically its productivity and we have developed the best pipeline we ever had and one of the best I believe in the industry.

As you've seen in 2019, it was a year that we took deliberate and powerful steps to strengthen each one of our businesses and eventually shred the current Pfizer into a new,

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smaller, high growth profile enterprise that will remain a powerhouse in marketing, but also has been converted into powerhouse of science.

Following, the expected close of the Upjohn and Mylan transaction later this year, of course, we will be a very different Company. And we will focus on continuing to execute our strategy. This includes, we will continue the commercial momentum and preparing our new product launches. You have all asked a lot of questions about those products that keep surprising with our growth profile. And also, you've seen what we are taking seriously and we are investing in new launches.

We are continue advancing our internal pipeline and we'll augment it with mid-stage R&D programs through targeted bolt-on business development opportunities. As I referenced before, we should continue seeing these type of activities in the first and second half of this year.

Of course, we are working very intensively to set up Upjohn to be in a strong position when it combines with Mylan to become Viatris and create a formidable company. And of course, we will continue leading the conversation in Washington as we work to address the affordability challenge facing patients. So these are the areas that we are focusing for next year.

Once again, we look forward to sharing more pipeline updates during our Investor Day on March 31. Have a great rest of your day.

Operator

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

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