Q3 2018 Earnings Call

Company Participants

- Albert Bourla, Chief Operating Officer & Director
- Angela Hwang, President-Pfizer Essential Health
- Charles E. Triano, Senior Vice President of Investor Relations,
- Frank A. D'Amelio, Executive Vice President, Business Operations & Chief Financial Officer
- Ian C. Read, Chairman & Chief Executive Officer
- John D. Young, Group President, Pfizer Innovative Health
- Mikael Dolsten, President, Worldwide Research and Development

Other Participants

- Alex Arfaei, Analyst
- Andrew S. Baum, Analyst
- Chris Schott, Analyst
- David R. Risinger, Analyst
- Geoff Meacham, Analyst
- Jami Rubin, Analyst
- Jason M. Gerberry, Analyst
- John T. Boris, Analyst
- Louise Chen, Analyst
- Steve Scala, Analyst
- Timothy Minton Anderson, Analyst
- Umer Raffat, Analyst
- Vamil K. Divan, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Good day, everyone, and welcome to Pfizer's Third Quarter 2018 Earnings Conference Call. Today's call is being recorded.

At this time, I would like to turn the call over to Mr. Chuck Triano, Senior Vice President of Investor Relations. Please go ahead, sir.

Charles E. Triano {BIO 3844941 <GO>}

Good morning and thank you for joining us today to review Pfizer's third quarter 2018 performance. I'm joined today by our Chairman and CEO, Ian Read; Albert Bourla, our Chief Operating Officer; Frank D'Amelio, our CFO; Mikael Dolsten, President of Worldwide Research and Development; Angela Hwang, Group President, Pfizer Essential Health; John Young, Group President, Pfizer Innovative Health; and Doug Lankler, our General Counsel.

The slides that will be presented on this call can be viewed on our website, pfizer.com/investors. Before we start, I'd like to remind you that our discussion during this call will include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements.

Additional information regarding these factors is discussed under the Disclosure Notice section in the earnings press release we issued this morning as well as in Pfizer's 2017 annual report on Form 10-K. The forward-looking statements during this call speak only as of the original date of this call. And we undertake no obligation to update or revise any of these statements.

During our call, we will also include certain financial measures that were not prepared in accordance with U.S. Generally Accepted Accounting Principles. Reconciliation of those non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in Pfizer's Form 8-K dated today, October 30, 2018.

Any non-GAAP measures presented are not, and should not be viewed as, substitutes for financial measures required by U.S. GAAP, have no standardized meaning prescribed by U.S. GAAP, and may not be comparable to the calculations of similar measures at other companies.

Ian, 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 Ian Read. Ian?

Ian C. Read {BIO 3358997 <GO>}

Thank you, Chuck, and good morning, everyone. During my remarks, I will discuss the progress we are making within each of our businesses and the latest advancements within our R&D pipeline. I will then ask Albert to discuss some of the steps we are taking to prepare the company to accelerate top line growth in the future.

In the third quarter, total company revenues were up 2% operationally, driven by a continued strength of key brands, biosimilars, and emerging markets. These growth drivers were partially offset by the loss of exclusivity of Viagra in the U.S. in December 2017, a decline in U.S. Legacy Established Products, driven by industry-wide pricing challenges, as well as product supply shortages and associated inventory reduction related to our legacy Hospira products.

I'll begin with a few words about each of our businesses, starting with Pfizer Innovative Health. This business had another solid quarter, growing its top line 5% operationally, thanks to the continued strength of several of our biggest selling medicines.

We remain very pleased with the performance of Ibrance, which has solidified its leadership position in the CDK 4/6 inhibitor class in the U.S., holding at just under a 90% share in terms of new prescription volume. Our current growth driver for Ibrance remains the international markets, particularly across Europe and Japan. And we had another quarter of solid growth there.

For Xtandi, alliance revenues in the U.S. were up 5% over the second quarter and a 20% year-over-year growth. We are seeing an increased number of urologists prescribing it.

There are positive early indicators with our PROSPER launch in the U.S. following the July approval, which made Xtandi the first and only FDA approved oral medication for both nonmetastatic and metastatic castration resistant prostate cancer.

And the European Commission has very recently approved Xtandi for the treatment of adult men with high risk nonmetastatic castration resistant prostate cancer, based on the PROSPER study data.

Eliquis continues to perform well. Pfizer's revenues for Eliquis were up 36% operationally to nearly $900 million. And it continues to maintain a strong leadership position in the NOAC class. Eliquis also overtook wore Warfarin to become the number one in OAC total brand, total prescription share in the U.S.

Xeljanz also continues to perform well with revenue up 26% operationally. This was bolstered by continued growth in rheumatoid arthritis revenues and some early contributions from the drug's recent expansion into psoriatic arthritis and ulcerative colitis.

Xeljanz scripts were up 31% compared with the third quarter of 2017. The main reason for the disconnect this quarter between volume growth and revenue growth in the U.S. market is that higher prescription demand was partially offset by a one-time year-to-date true-up in the quarter for access payments with one customer.

Sales of Prevnar 13 were up 12% in the U.S., largely due to the timing of government purchases. Sales were up 14% operationally in the emerging markets, driven by growth in the pediatric business, strong Gavi performance, and the 2017 launch in China.

Finally, our Consumer Healthcare business posted strong growth internationally, while U.S. revenues were down slightly due to the LOE impact of Nexium 24HR, we continue to review options and expect a decision regarding strategic alternatives for this business will be made by the end of the calendar year.

Turning now to Pfizer Essential Health. We once again saw strong operational growth in emerging markets and in biosimilars. Overall, Essential Health revenues for the quarter declined, however, due in large part to the ongoing product supply shortages in the sterile injectable business, continuing product LOEs, namely Lyrica in developed Europe, and a decline in the Legacy Established Products portfolio in developed markets.

Emerging markets revenue within the Essential Health business grew 11% operationally for the quarter, primarily reflecting growth across the Legacy Established Products and sterile injectable pharmaceuticals portfolio in China.

Revenues from our biosimilars business grew 46% operationally in developed markets during the quarter, driven primarily by continued growth for Inflectra in certain U.S. channels as well as in developed Europe.

We continue to bring new biosimilars to the market and began shipping Nivestim, a biosimilar to Neupogen. to wholesalers in the U.S. at the end of September.

In our U.S. sterile injectables business, manufacturing supply constraints continue to impact our top line. We expect these issues to be significantly improved by the end of 2019. And we continue to expect this business to be a solid growth contributor in the future.

We continue to strengthen and advance our R&D pipeline. Let me touch on some of our more promising recent developments.

In Rare Diseases, our tafamidis Phase 3 ATTR-ACT study results were very positive. The data showed that tafamidis significantly reduced a combination of all-cause mortality and cardiovascular-related hospitalizations in patients with ATTR-CM. Given the nature of this disease, the exact prevalence is currently unknown, though we estimate less than 1% of the patients have been diagnosed.

There currently are no approved treatments for ATTR-CM, making it a tremendously underserved market. Tafamidis holds the fast track and breakthrough therapy designations. And we plan a rolling submission for ATTR-CM with a formal NDA being submitted during the current quarter.

In Internal Medicine, along with our partners Eli Lilly, recently presented positive results for our tanezumab Study 1056 at the American College of Rheumatology Annual Meeting. This was the first readout of the tanezumab global clinical development program. Additional Phase 3 readouts, which will more fully characterize tanezumab's clinical profile, are expected in the first half of 2019.

In Oncology, the FDA recently approved two of our innovative medicines. In September, we received approval for Vizimpro, or dacomitinib, for first line treatment of patients with EGFR mutated metastatic non-small cell lung cancer. Earlier this month, we received

approval for Talzenna, or talazoparib, for the treatment of the most common types of a rare-to-treat breast cancer.

Two other Oncology candidates, lorlatinib and glasdegib, are under priority review with the FDA. We expect to receive decisions for both before the end of the year.

We also recently presented at ESMO Phase 3 data for Bavencio plus Inlyta for patients with advanced renal cell carcinoma. We're excited about this potential opportunity. And we've been discussing these interim results with regulators to determine an appropriate path forward.

We are also encouraged by other recent data reinforcing Inlyta as the TKI of choice in combination with a checkpoint inhibitor for this condition.

In Inflammation and Immunology, two of our JAK inhibitors have received breakthrough designations this year, our JAK1 inhibitor for the treatment of patients with moderate to severe atopic dermatitis and our JAK3 inhibitor for the treatment of patients with moderate to severe alopecia areata, an immune disease that currently has no approved treatments. The JAK1 candidate is now being studied across four Phase 3 trials that are actively recruiting. The JAK3 candidate has been advanced to Phase 2b/3 trial, which will start in the upcoming months for alopecia areata.

In Vaccines, we announced in September that our 20-valiant pneumococcal conjugate vaccine candidate has received breakthrough therapy designation from the U.S.A. FDA. We expect to start Phase 3 trials in a few months.

Our Phase 3 Clover study in C. Difficile continues to enroll ahead of schedule and is now 88% enrolled with more than 14,000 subjects. We believe we remain positioned to have a potential first-in-class vaccine for this infection.

We are advancing a Phase 2 tetravalent vaccine candidate for Staphylococcus aureus with fast track designation. And we are in discussions with the FDA to potentially expand the study to become a Phase 3 pivotal study.

Overall, we continue to see the potential for approximately 25 to 30 approvals through 2022, of which up to half have the potential to be blockbusters.

We're also working to ensure these medicines will be launched in an environment where they can help the maximum number of people who need them. We continue to work with the President on his blueprint for strengthening the health care system, providing more access, and relieving the burden on patients at the point of sale.

For example, we recently responded to the administration's request for information on reviving the competitive acquisition program in Medicare Part B. We are supportive of developing a market-based alternative to the current buy and bill system, one that

includes voluntary participation by physicians and robust competition facilitated by many vendors, not just one or two PDMs (13:07).

In summary, we continue to deliver on our strategy and believe we remain well positioned to deliver new medicines for patients, prepare the company for accelerated growth in the future, and create enhanced shareholder value. In fact, we have continued to repurchase our shares over the past few months, as we believe our shares remain undervalued.

Earlier this month, we announced that Albert Bourla will succeed me as CEO on January 1. Albert's extensive knowledge of our business, firm grasp of the issues, and deep caring for patients will help Pfizer continue to build on the outstanding foundations we have put in place. And I am confident that he is putting in place a structure and leadership team that will maximize the company's growth opportunities.

Now I will turn it over to Albert, who will share some thoughts about what he will be focusing on when he assumes the role of CEO. Albert?

Albert Bourla {BIO 18495385 <GO>}

Thank you, Ian, and good morning, everyone. After prolonged periods of revenue decline and then stability, due to significant and unprecedented loss of exclusivity impacts, Pfizer is preparing for what we expect to be an era of sustained growth, following the impact of the Lyrica LOE that will negatively impact our growth in the next two years.

We now have a wide range of opportunities to continue to grow our core brands and a strong, deep R&D pipeline that has become a competitive advantage. Taken together, this provides us with important breadth both in terms of in-market and future opportunities. We are working quickly to make the natural adjustments that are needed when a company pivots to grow. And we have already begun this evolution.

As you know, back in the summer we announced that we will be organizing the company into three businesses. We believe each will be well positioned to take advantage of new growth opportunities, driven by the evolving and unique dynamics of their individual markets.

Our science-based Innovative Medicines business will be our primary and most substantial business. We believe our growth prospects in this segment are strong. And Pfizer is well positioned to deliver several potential new breakthrough innovative medicines in the next five years.

In order to maximize this unique opportunity, we need to make the right capital allocation decisions to drive both scientific and commercial innovation. As our pipeline matures, with the progression of current and the initiation of new pivotal trials, we will need to increase our R&D investments. And as our pipeline potentially delivers new commercialization opportunities, we will need to increase our investments in new market creation activities.

To partially offset these incremental cost increases, we will generate cost reduction opportunities, particularly in indirect SI&A. We are taking steps to simplify the organization, increase spans of control, and reduce organizational layers. By doing so, we expect not only to generate partially offsetting savings, but, more importantly, to reduce bureaucracy and expedite decision making.

We believe that our Established Medicines business, which will include the majority of our off-patent solid oral dose legacy brands, has the potential to generate sustainable modest revenue growth. Urbanization in emerging markets, particularly in Asia, is creating additional access opportunities for these medicines for hundreds of millions of people.

As the leading pharmaceutical company in Asia, and particularly in China, we believe we are well positioned to be a leader in this significant and rapidly growing market. We currently are focused on standing up this organization, enhancing its autonomy, and positioning to operate as a true stand-alone division within Pfizer.

Finally, with an increasing focus on healthy living, patients are seeking wellness and prevention solutions that are easier to access over the counter. With a strong portfolio of global brands that span health and wellness, our Consumer Healthcare business is well positioned to continue its growth. As Ian said, we continue exploring options for this business, and we expect to make a decision by year-end.

Earlier this month, we announced changes to the executive leadership team. These adjustments were designed to create a more effective structure that further strengthens our ability to deliver important medicines and vaccines to patients.

As a result of a smooth and very thoughtful succession process, when we transition leadership on January 1, we will have in place a clear strategy, a new organization, and a strong executive team.

Today, we believe that we have the best pipeline in our history. To ensure we capitalize this incredible opportunity, we must remain highly focused on successful execution. In this context, I would reiterate that we continue not to see the need for any large-scale M&A activity at this time.

Under Ian's leadership, we have set the right course. As a result, we have an opportunity over the next 5 to 10 years to have a profound impact on patients and global health, with the benefits of this impact extending to shareholders and other stakeholders.

I look forward to working with my mentor Ian in his new capacity as Executive Chairman, with the board, and with my leadership team to lead Pfizer in this new era and, of course, to working more closely with all of you in my new role.

Now I will turn it over to Frank to provide details on the quarterly financials and our financial outlook for 2018.

Frank A. D'Amelio

Thanks, Albert. Good day, everyone. As always, the charts I'm going to be reviewing today are included in our webcast. Now moving on to the financials.

Third quarter 2018 revenues were approximately $13.3 billion, which reflects operational growth of $243 million or 2%, and the unfavorable impact of foreign exchange, $113 million or 1%.

Our Innovative Health business recorded 5% operational revenue growth in the third quarter, driven primarily by Eliquis and Xeljanz globally, Ibrance in international markets, and Prevnar 13 and Xtandi in the U.S., all of which were partially offset by the loss of exclusivity of Viagra in the U.S. in December of 2017 and decreased revenues for Enbrel in most developed Europe markets, mainly due to continued biosimilar competition.

Revenues for our Essential Health business in the third quarter decreased 4% operationally, primarily due to a 14% operational decline in Legacy Established Products portfolio in developed markets, driven by industry-wide pricing challenges in the U.S. and generic competition, and a 9% operational decline in the sterile injectables portfolio in developed markets, primarily due to continued legacy Hospira product shortages in the U.S., all of which were partially offset mainly by the inclusion of Viagra revenues in the U.S. and Canada, 11% operational growth in emerging markets, primarily reflecting growth in the Legacy Established Products and sterile injectables portfolios in China, and a 46% operational growth in biosimilars in developed markets, mainly driven by Inflectra in certain channels in the U.S. and in developed Europe.

Third quarter reported diluted EPS was $0.69, compared with $0.47 in the year-ago quarter, primarily due to a lower effective tax rate, higher other income, and higher revenues.

Adjusted diluted EPS for the third quarter was $0.78 versus $0.67 in the year-ago quarter. The increase was primarily due to a lower effective tax rate, higher revenues, higher other income, and foreign exchange. I want to point out that diluted weighted average shares outstanding declined by 54 million shares versus the year-ago quarter, due primarily to our ongoing share repurchase program, reflecting the impact of shares repurchased during 2018, partially offset by dilution related to share-based employee compensation programs.

As I previously mentioned, foreign exchange negatively impacted third quarter 2018 revenues by approximately $113 million and positively impacted adjusted cost of sales, adjusted SI&A expenses, and adjusted R&D expenses in the aggregate by $236 million. As a result, foreign exchange favorably impacted third quarter 2018 adjusted diluted EPS by approximately $0.01 versus the year-ago quarter.

As you can see, we narrowed our 2018 revenue guidance range to $53 billion to $53.7 billion, reducing the midpoint by $650 million, which was largely related to lower-than-anticipated Essential Health revenues, primarily due to continued legacy Hospira sterile

injectable product shortages in the U.S. and recent unfavorable changes in foreign exchange rates.

In addition, we now expect adjusted cost of sales as a percentage of revenues to be in the range of 20.8% to 21.3%, adjusted SI&A expenses to be in the range of $14 billion to $14.5 billion, adjusted other income to be approximately $1.3 billion, and the adjusted diluted EPS to be in the range of $2.98 to $3.02 per share, the midpoint of which hasn't changed, implying 13% growth year over year.

This guidance assumes anticipated share repurchases of approximately $12 billion in 2018, of which $9 billion has been completed to date. As of today, we have $7.4 billion remaining under our current share repurchase authorization.

Our 2018 guidance for R&D expenses and effective tax rate on adjusted income did not change. We continue to expect R&D expenses to be in the range of $7.7 billion and $8.1 billion, and the effective tax rate to be approximately 16%.

Turning to other income, I'd like to provide some additional commentary. First, the increase in guidance was mainly due to two factors, increased income from collaborations, licensing agreements, and milestone payments; and to a lesser extent, further realized gains on equity securities through the end of the third quarter 2018. It's important to note that other income will continue to be highly variable this year because of the new mark-to-market accounting changes for potential gains and losses on our equity ownership of ICU Medical and Allergene (25:11).

I also want to remind you that our current guidance for other income does not include a forecast for any further potential changes in value for our unrealized gains and losses on equity investments for the remainder of the year.

Looking forward to 2019, I want to give you the core components of other income deductions that we could reasonably estimate at this time to provide an anticipated baseline prior to the inclusion of newer one-time factors, such as market-to-market gains or losses.

Interest expense of approximately $1.5 billion, interest income of approximately $300 million, pension credit and other items of approximately $500 million, and royalty income from products such as Xtandi, neratinib and Prezista, as well as dividend income from our ViiV partnership, which are running at a combined annual rate of approximately $700 million.

At this point, the puts and takes of these core components net to a roughly flat starting point for 2019 versus our original expectations of $400 million for 2018. As has been our practice, we will provide our 2019 annual guidance in conjunction with our fourth quarter financial results.

Moving on to key takeaways. We delivered solid financial results in the third quarter of 2018 with 2% operational revenue growth and a 16% increase in adjusted diluted EPS versus the prior-year quarter. We updated and narrowed certain components of our 2018 financial guidance. The midpoint of our adjusted diluted EPS range has not changed. We accomplished several key product and pipeline milestones.

We returned $15 billion to shareholders as of October 30, 2018, through dividends and share repurchases. And we expect to return approximately $20 billion directly to shareholders this year. Finally, we remain committed to delivering attractive shareholder returns in 2018 and beyond.

Now I'll turn it back to Chuck.

Charles E. Triano {BIO 3844941 <GO>}

Thank you, Frank. Operator, at this point can we please poll for questions?

Q&A

Operator

Your first question comes from Alex Arfaei from BMO.

Q - Alex Arfaei {BIO 15433937 <GO>}

Oh, great. Thank you very much. Folks, you've now repeatedly mentioned steady growth prospects after 2020. I think you have characterized it as mid-single digits growth on the revenue side. What are the key growth drivers of that from your perspective? And I'm specifically interested in the ones that you think are not well appreciated by the Street, given your stock's current strong performance.

And then on tafamidis, our research suggests that we're starting to see more centers using this new nonbiopsy test for diagnosing patients. Given that reimbursement doesn't seem to be a barrier, I'm just wondering what are your expectations about potential improvement in the diagnosis rate? Do you see it as gradually improvement or – improving, or could we actually see a step-wise increase, given that doctors have a very good reason to actually identify these patients now? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Alex. I'll ask Albert to answer the question on the growth drivers post-2020. And then perhaps John will answer the question on tafamidis.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Alex. And as you know, beginning of the new financial year we have reorganized our company into three distinct business units, and each one of them has distinct growth drivers. So let me give you some idea of them.

In our primary and fundamental Innovative Medicines business, it is very clear that the driving forces are an aging population and our introduction of significant innovation. We have, as you know, 15 potential blockbusters in five years.

And they are – the ones that excite me the most, if I can pick just a few examples, we do have in Xtandi already launched the PROSPER and are expecting to present result for ARCHES, and which is another metastatic setting. We are very excited in immuno-oncology with our combinations with Inlyta and Bavencio. We are excited that we have launched, or we are expected to launch, four new molecular entities by the end of the year in oncology. Although they are smaller in size collectively, they inform (29:43) a blockbuster.

In our vaccines, we are very excited to continue working on Staph. aureus and our Clostridium difficile vaccines, as well as our next generation pneumococcal vaccines.

In inflammation, we have launched new indications for Xeljanz, particularly I think exciting, it is the UC indication that we have just launched. And we have pivotal studies that are running in what I think is one of the best JAK portfolio in the industry.

And of course, in the rare diseases, we are about to launch tafamidis. And in internal medicines we will hopefully launch, pending the data, tanezumab. So as you can see, there is significant of strength to drive the growth in this type of a business.

When it comes to the Established Medicines business, over there also we believe that we can have sustainable, modest low growth, but the drivers are very different over urbanization. At this time, right now, you see we have already 24% growth in China. This means $700 million we have generated more or less in nine months.

So the growth potential over there is substantial. And we will continue investing, particularly by relocating our management team and providing autonomy to this business to operate from China.

And last but not least, our Consumer business will continue growing based on the trends that existed with consumers.

A - Ian C. Read {BIO 3358997 <GO>}

John? Thank you, Albert.

A - John D. Young {BIO 17639257 <GO>}

Thanks for the question, Alex. So let me just say we're obviously very excited about the opportunity that Vyndaqel presents to help patients. And the process of educating cardiologists on our data is underway.

ATTR-CM is significantly underdiagnosed. There's only about 1% of cases today detected prior to death. So it's a highly underdiagnosed disease.

Given that there are no approved treatment options today, the education of physicians and patients on what we would think of as red-flag symptoms and availability of the treatment itself will obviously play a big role improving disease awareness. And changes to treatment guidelines should also drive utilization over time.

To your point, diagnosing ATTR-CM has evolved significantly in recent years. Patients previously required a biopsy to confirm diagnosis. But now it's become much easier to diagnose patients using a non-invasive imaging technology called scintigraphy. There are around about 15,000 machines and 32 centers of excellence in the U.S. already using this technology. Training is not burdensome. And that is going to be a real focus of our activities as we bring this medicine to patients and to physicians sometime next year.

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

Thanks, John. Next question, please, operator.

Operator

Your next question comes from Vamil Divan from Credit Suisse.

Q - Vamil K. Divan {BIO 15748296 <GO>}

Hi. Great. Thanks so much for taking the question. So first one I guess is for Ian and Albert. Congrats, Albert, by the way on the new appointment. So the last quarter, Ian, you had mentioned you believed the administration has the intention of removing safe harbor for rebates. And that we're moving to a marketplace where we won't have rebates over time.

Over the last few weeks and months it feels like more of the commentary has been focused on potentially point of sale rebates and also obviously the reform around Part B. So I'm just wondering if you remain as confident as you were three months ago on the U.S. moving away from a system that's based on rebates?

And then my second question is just on Ibrance. And I know there's a lot of excitement and potential around the adjuvant opportunity if we look out a few years. But the growth in the midterm I think could be a little bit more challenging.

So I'm just wondering if you can give us some perspective on what's going to drive that product over the next couple years before we get the additional data in the adjuvant setting. Thanks so much.

A - Ian C. Read {BIO 3358997 <GO>}

Well, thank you, Vamil. I mean I think we're still waiting the guidance to come out from Secretary [Alex] Azar on the rebate situation. I do believe it continues to be a point of interest for the administration.

It is the most effective way that the administration can lower prices for patients at the point of purchase. I mean, discounts at the point of sale are also effective. They achieve

the same thing. The mechanisms of achieving this lowering of prices for the patient could be varied. I still think the administration is focused on that.

The new Part B rule, or the new part – suggested rule in Part B is – I don't think it's in the best interest of patients to effectively enforce price controls from abroad into the U.S. And would hope that the administration would reconsider its position on that.

And in general, I still expect to see activity between now and the end of the year on rebates. With that, I'll pass it over to John to talk about Ibrance.

A - John D. Young {BIO 17639257 <GO>}

Okay. Thanks for the question, Vamil. So in terms of the growth trajectory for Ibrance, we have always viewed it as having three main phases.

Phase 1 was obviously the U.S. launch and maximizing the market opportunity there. Since launch in the U.S., we have entrenched Ibrance as the new standard of care. We've treated over 90,000 patients. So significant progress in the U.S.

Phase 2 has obviously been the international launch with particular focus in Europe and Japan. And I'm very pleased with the progress that we've made here since establishing reimbursement in the E.U. last year. Over 69,000 patients have already been prescribed Ibrance. And we continue to view that as being a growth driver for Ibrance over the years ahead.

The third phase to your point is yet to come, and that really represents the adjuvant or early breast cancer opportunity. And that could address a population roughly double the size of the current metastatic population. We're still a few years away from potentially entering this phase of growth, should our clinical trials be successful. But we are very excited and positive about the opportunity that that potentially represents for Ibrance in its life cycle.

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

Thanks, John. Next question, please, operator.

Operator

Your next question comes from Chris Schott from JPMorgan.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks so much for the questions. Just my first one was, based on some of the investment needs you highlighted in the opening comments, should we be thinking about margin erosion for Pfizer in 2019 and 2020 as Lyrica goes away? Or could some of those cost cuts offset those pressures? And then maybe longer term, is it fair to think about operating margin expansion returning in 2021 and beyond?

My second question was just on a higher level. Can you talk a little bit about the growth of both your sterile injectable and biosimilar businesses going forward, as we think about those moving over into the Innovative portfolio going forward? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. Thank you, Chris. I'll ask Frank to address the margin question. And then Angela to talk about the growth prospects of sterile injectables and biosimilars.

A - Frank A. D'Amelio

So, Chris, on the operating margin going forward, the way to think about this is, once we clear the Lyrica LOE, so think about that as the base year being 2020 when we get the full year effect of Lyrica LOE, beyond that we clearly believe there's an opportunity to expand our margins.

We've talked about at that point the revenue growth in the mid-single digits. And ultimately, we've been able to demonstrate over the years, we grow the top line X, we'll grow the bottom line more than X.

So from my perspective, once we get past the Lyrica LOE, clear opportunity to expand our margin performance in the P&L. Between now and then, clearly with the Lyrica LOE, we'll have to work our way through this. We'll give guidance for 2019 on our next call relative to the specifics by line item. But beyond the Lyrica LOE, clearly we're optimistic about our ability to expand margins.

A - Ian C. Read {BIO 3358997 <GO>}

Angela, please.

A - Angela Hwang {BIO 20415694 <GO>}

Thanks for the question, Chris. I'm going to talk a little bit just about our prospect in growth in terms of sterile injectables and then just talk a little bit about biosimilars as well.

We see the global sterile injectables market as being a very attractive market. It's large, it's growing, it has high barriers to entry due to the complexity of manufacturing. And for that reason, we are very focused on our remediation efforts as a critical success factor in this market.

We are confident about our remediation plans. We expect our supply to improve significantly towards the end of 2019, after which we see this business as being a significant growth contributor to Pfizer. So we remain committed to this business. And we see a tremendous amount of potential and growth prospect here.

Likewise, with biosimilars, we see tremendous growth potential. You've seen that over this quarter, we grew 40% with our biosimilars portfolio, growth in Europe as well as in the U.S.

Our U.S. growth currently has seen some great progress in closed systems, in regional plans, as well as in Medicare. However, in the commercial plans, that is where we continue to be challenged with growth due to J&J's exclusionary contracting. So we remain focused on working with our customers and payers to see the long-term savings benefits that can be derived from the use of biosimilars over short-term rebates.

However, our portfolio is changing in that we are now venturing from just Inflectra alone to entering the oncology biosimilar space, where we see very different dynamics here and are also excited about this growth. This is a market that has already seen the entrance of biosimilars in the form of filgrastim. And there has already been really good uptake of filgrastim in the U.S.

We see different dynamics in that the treatment – the duration of treatment is shorter, therefore you're going to get new patients cycling through faster. That is going to enable payers and customers to transition patients from the originator molecule to biosimilars much more quickly, thereby allowing them to benefit from the savings.

So we're excited about our entrance into oncology biosimilars and look forward to not just this launch, but to realizing the five next biosimilars that we have in our pipeline.

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

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

Operator

Your next question comes from Jami Rubin from Goldman Sachs.

Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. First, I just want to say, Ian, it's been a real pleasure to work with you and learning from you over the years and in terms of all the value you've been able to unlock from the Wyeth acquisition and then some.

A question for you, Albert. The message today is that large-scale deals seem off the table. But with the biotech tape (40:48) coming under pressure, some of your key growth drivers looking like they're flattening out, and with your strong balance sheet and your higher P/E multiple since early last summer, it would seem to me that you have a lot more options today than you did six months ago.

Can you define what those options look like in your mind? And if a large-scale deal is off the table – how do you define a large-scale deal? I mean, I would assume that back in 2009 when you bought Wyeth, a $60 billion or $66 billion deal, that was a large-scale deal. But today, you're a much bigger company. It's a completely different market. That may not be considered a large-scale deal. So if you could please define what you mean by that.

And then, secondly, if you could talk about what sort of options that you see for your Essentials (sic) [Essential] Health business. Thanks very much.

A - Ian C. Read {BIO 3358997 <GO>}

Hey, Jami, thank you much for those kind comments. I'll then pass it over to Albert to answer the meats of your question.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Jami. Look, a $64 billion acquisition, it is a large M&A for any standards. But you are right, but for us, we have the ability and the balance sheet to execute basically whatever we would like to execute, if we see the value to customers.

The way that we see right now large M&As is not based on our ability to execute or not. It is based on how destructive they could be by integrating them. And this is the main concern right now.

We are going to enter into a period of growth post 2020. And we need to make sure that we execute right now on our pipeline, we execute right now on our commercial launches and market preparations. And a large M&A typically comes with big integration plans, but distracts operations during this integration. And this is what we would like to avoid.

Obviously, there are opportunities over there with biotechs that are going down, although price are going down for a reason usually. But the truth is that as we are looking in our capital allocation, we are planning to scan the market for both opportunities that will not bring the destruction, operational destruction that a large M&A could bring, but could enhance our growth trajectory or our pipeline.

Now on the second question on the – basically you're asking on the optionality, obviously external separation in the form that we had contemplated in the past is off the table because as you said and as you know, we are going to operate from the beginning of this financial year with a new operational construct.

That being said, we constantly look our businesses and all parts of our businesses for fit internally and we will continue doing that.

As I said, let me tell you where we are right now. On the Innovative business, it is very clear that the focus is executing the pipeline and the new launches. In the Consumer Healthcare business, we already said that we are examining options to separate or not this business. And we will come to a decision by year-end.

In our newly-established Established Medicines business, the focus right now is to stand up this business. We need to make sure that we segregate it from Pfizer by providing them substantial autonomy. We need to make sure that we relocate the leadership to China where most of the growth is coming. And this is right now where we are.

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

Thank you, Albert. Next question, please, operator.

Operator

Your next question comes from John Boris from SunTrust Robinson Humphrey.

Q - John T. Boris {BIO 2563403 <GO>}

Thanks for taking the questions, and Albert, thanks for the great overview.

First question for Ian, just on pricing. I know you've indicated that you're going to obviously be pausing on taking any price increases through the end of this year. Just your thoughts on how you will attack pricing going into next year.

A question for Frank. What was the contribution of price and volume in the quarter?

And then on Xtandi, can you just give the split of sales that are in the metastatic versus nonmetastatic segment? And what is the risk that if a generic ZYTIGA launches at a significant discounts, if there's two approved but potentially 10 entrants and pricing possibly eroding there, what the impact might be on Xtandi going forward? Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. John, thank you for that three-part question. I'm going to address the pricing, and then we'll have Frank do your price versus volume. And then John will answer your question on – the questions you raise about Xtandi.

Look, our pricing – I don't think our pricing situation has changed. We remain – our pricing philosophy is to price to the value of the product and price inside a competitive marketplace. I expect that like most industries, we will look at our pricing situation in January and take decisions based on what the competitive set is and what our value proposition is in the new marketplace. I have at this moment in time no different view about how we will take price our increases as we did last year.

So with that, Frank, do you want to talk about pricing volume right now?

A - Frank A. D'Amelio

Sure. So, John, global basis price was minus 2%, volume was plus 4%, so operationally plus 2%. We were up $243 million operationally in revenue. FX was a minus 1%, $113 million. So net-net we reported plus 1%, $130 million in revenue.

And just a little color commentary on that minus 2% on price. If you look over the last 10 years, on average, that price number has been plus or minus low-single digits. So we're still in that range of plus or minus low-single digits.

A - Ian C. Read {BIO 3358997 <GO>}

John?

A - John D. Young {BIO 17639257 <GO>}

Okay. Thanks for the question, John. So we're still in the very early days following the nonmetastatic CRPC approval. And contributions from that indication were relatively modest in quarter three.

We expect the full impact of this opportunity will take a couple of years to realize, as much of the value from this indication is built through patient accumulation and the longer duration of therapy given its earlier stage of use.

We're continuing to leverage our relationships with urologists as we launch the indication. And we've seen a very encouraging uptick in our new-to-brand trends since the PROSPER approval. So we're very positive about the opportunity that this represents.

In relation to your question about generic ZYTIGA, we generally don't expect generic ZYTIGA to impact our business in a meaningful way. Market share erosion historically comes from the branded version of the same compound rather than a therapeutic substitution.

And Xtandi now has different indications than ZYTIGA for metastatic and nonmetastatic CRPC. We believe these agents are not likely to be viewed by physicians as interchangeable or substitutable. And ACP preference is not expected to be negatively impacted by the generic availability of a ZYTIGA.

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

Thanks, John. 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. First, relative to pneumococcal vaccines, what was your conclusion from the recent ACIP meeting? And will you have data on the 20-valent vaccine by their next meeting in February? So that's the first question.

Second, can you quantify the non-cash gain for Cerevel and its creation that was in Q3 other income?

And then lastly, how does Pfizer foresee Bavencio's prospects in first line renal cell carcinoma given the recent news from competitors? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. Thank you. We'll ask John to take two of the three questions, and then Frank will take the noncash question. John?

A - John D. Young {BIO 17639257 <GO>}

All right. So thanks for the question, Steve. So the ACIP obviously met last week. And their – purpose of their review was looking at the adult recommendation for adults 65 and over in the U.S.

It's important to state that this is relatively early in their process. The next stage for ACIP is to grade the data and then vote on the continuation of the 65-plus healthy age recommendation, which according to the CDC is likely to happen sometime in 2019.

Our belief is that given the effectiveness shown by Prevnar 13 in preventing vaccine-type community-acquired pneumonia in adults 65 and over, we continue to support a broad recommendation of 65-plus. And that direct vaccination remains the only sure form of protection against persistent vaccine type IPD and pneumonia. We will obviously continue to work with the CDC to generate data and communicate the burden of impact of pneumococcal disease.

And in relation to your question about Prevnar 20, obviously as you know, we've sort of indicated that we have received a positive breakthrough designation from the FDA. And we expect to start Phase 3 studies within the next few months. But we don't anticipate that we'll be submitting data on Prevnar 20, PCV20, to the ACIP for their forthcoming meeting.

In relation to your question about the prospects that we see in the immuno-therapy space, we are really very encouraged. We've always said that we believe that the true value of I-O is to be expected in effective combinations. And the results of our first Phase 3 I-O combination study support that view.

So the JAVELIN Renal 101 trial that you're referring to, that combined Bavencio with Inlyta in previously untreated advanced renal cell carcinoma, demonstrated that the combination provided superior progression-free survival compared with Sutent.

The Bavencio and Inlyta combination demonstrated positive results across a broad RCC patient population in the first line setting, regardless of the prognostic risk group or PDL expression. And I think I would just add that obviously we noted the positive Inlyta and Keytruda results in RCC. And we think that that emphasizes the growing importance of Inlyta as a gold standard TKI inhibitor in the management of RCC.

A - Frank A. D'Amelio

And then, Steve, on your question on the non-cash gain. The gain was $343 million and it was in GAAP results only. It was not included in adjusted results.

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

Thanks, Frank. Operator, next question, please.

Operator

Your next question comes from Umer Raffat from Evercore.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my question. I guess, Ian, Albert, for both of you, so when the price increases were rolled back earlier this summer, there's an expectation that price increases could be instituted again in January, if no concrete steps are taken on rebate.

So I guess my question is, are you planning on putting them back on in January, your price increases? And has there been any dialogue or are you expecting any pushback from the administration when that happens? So that's first.

And then on tafamidis, my question really is, so you've mentioned 1% diagnosis. You've also mentioned it's a blockbuster opportunity. My question really is, do you see this as a $1 billion opportunity or as a $5 billion opportunity? Just trying to put book ends around how big this could be from your perspective, given all the investor debate around that.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Umer. Well, on pricing, what I'm trying to indicate is that we did voluntarily agree to defer price increases until the blueprint was implemented over the end of this year. We've been working with the President on parts of the blueprint. And I expect our approach by the end of year will be, what I would characterize as business as normal.

We price to the marketplace. We price competitively, and we will make those decisions towards the end of the year and early in January.

So thanks for your question on that. And then we'll turn to the scope of standards.

A - John D. Young {BIO 17639257 <GO>}

So thanks for the question, Umer. Obviously as you know, we don't give forecasts for inducing – or individual products.

Let me just sort of underscore what I mentioned already, that we're incredibly excited about the opportunity. Any time you have positive clinical data that demonstrates significant reduction in mortality and hospitalization in a patient population that doesn't have access to any alternative treatments, that has to be a significant opportunity.

Clearly as we said, highly underdiagnosed at the moment. Our focus is going to be sort of really making sure that we can accelerate the knowledge around how to diagnose appropriately and sharing our clinical data with physicians. So we're very excited about the opportunity that presents.

Certainly, it's premature for us to begin to frame the size of our revenue opportunity particularly. But we'll make sure that our expectations are obviously going to be part of our 2019 guidance when we give that in the first quarter next year.

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

Thank you, John. Next question, please.

Operator

Your next question comes from Louise Chen from Cantor Fitzgerald.

Q - Louise Chen {BIO 6990156 <GO>}

Hi. Thanks for taking my questions. I had a few on the pipeline. So first question here is on tanezumab. Would you expect to see a potential imbalance in RPOA in the chronic low back pain indication? And why or why not?

And then secondly for the ATTR-CM indication, how big do you think that population actually is, now that there is better diagnosis?

And the last question I had was on your DMD gene therapy program. What kind of data are you going to report next year? And what do you think the competitive advantages of your product are as it relates to promoter vector in gene and how do you think about this opportunity versus looking at CRISPR for DMD? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Well, I think we'll ask Mikael to answer your first and last question. The one in the middle, we'll refer back to what has been substantially answered already by John. And I believe we will give our indications of the – in our guidance in the first quarter about what we expect from tafamidis. Clearly, it's a substantial opportunity, but one that we're not ready yet to talk about until we give our guidance next year.

A - Mikael Dolsten {BIO 16368411 <GO>}

Thank you for your interest in tanezumab. And let me just punctuate that we were really excited about the data from our first study that showed that more than 50% of the patients got a 50% or greater reduction in OA pain and about 35% reported a 70% or greater improvement in pain. So these are real great benefits for patients.

Now concerning chronic lower back pain, those patients are generally younger. Most of them do not as advanced OA as a typical OA pain population. And we, in general, have excluded patients that have severe OA in the chronic low back pain, because we're using a higher dose for that study.

And we do not anticipate that there would be a major impact of rapidly progressing OA in that patient population.

Concerning DMD, we have a very, I think, strong DMD gene test set that we're using with a unique gene expression capsid and also our capsid has certain unique features that we think will optimize its delivery to mass zones.

And we have started treating patients and a part of a dose escalation, but thus far we are pleased to see the tolerability of the gene therapy product. And initial oxidations are encouraging. And we look forward to continuing this study.

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

Thank you, Mikael. Next question, please.

Operator

Your next question comes from David Risinger from Morgan Stanley.

Q - David R. Risinger {BIO 1504228 <GO>}

Thanks very much. And, Ian, let me add my congratulations and best wishes to you after a very successful career and value creation at Pfizer.

My two questions are, could you please discuss your discussions with commercial payers to evolve rebate contracts in the commercial sector?

And then, second, going back to the high level, Albert, I'm hoping that you could rearticulate the purpose of the new operational construct and the incremental value that you expect to drive potentially, including additional strategic action. You had referenced the separation decision, and I just wanted to get a little bit clearer picture on the opportunity you see for additional value creation. Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Well, thank you for your comment, David. I appreciate them. On the discussions with payers, I would say there has been, outside of our walls, limited discussion with payers. Obviously, there are different positions between the PBMs and insurers and ourselves as through – regarding the effectiveness of the passing on of rebates to the point-of-sale or to the patient.

We've done a lot of internal work looking at it and understanding how we'd operationalize it. But really, there's not a lot of discussions we can have outside of our four walls until we see what the rule looks like when it's published.

That being said, I continue to think it's a very effective way of taking pricing pressures away from the patient, especially not exposing to list price. I'll pass it over to Albert for his further comments.

A - Albert Bourla {BIO 18495385 <GO>}

David, the reason why we organized this Pfizer into all these businesses is because we believe that they have different growth drivers. And we believe that the main value contributor for a corporation like Pfizer, it is topline growth.

So with this reorganization, we tried to maximize the opportunities and upgrade the talent that each one of them has, for example, by focusing our efforts on innovative business in this pipeline, focusing our efforts on innovative business into creating new markets, because a lot of our products and future portfolio are coming to new market, because they are addressing unmet medical needs. This is crucial.

When it comes to the Established Medicines, the way that we describe this business, it is off-patent iconic brands like the Lipitors, like the Viagras, like the Celebrex of the world. So we are not transferring over there everything that it is off patent.

But those brands that they have significant growth potential, presence and potential in particularly parts of the world. These are not brands that we expect to grow in developed Europe or the U.S. But these are brands that we are growing, And we are expected to continue growing in China.

In fact, to be able to enhance this opportunity, we are relocating a senior management team in China to be able to manage this opportunity, including a new member of the executive team. So this is the growth strategy over there, plan to explore China as a whole in terms of the contribution to pharmaceutical innovation.

And in terms of our Consumer business was always operating as an autonomous business. We are enhancing its autonomy, particularly around manufacturing issues this year. And we continue examining options.

My reference to Jami's question before around, we never – we always examine options for our business, and particularly your interest on the established business. As I said, right now, the important thing it is to stand up this business. It is – before examining options for a business, you need to make sure that operationally is – it's doing very well. And this is the focus.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you, Albert.

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

Thank you, Albert. Next question, please.

Operator

Your next question comes from Geoff Meacham from Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Great. Good morning, guys. Thanks for the question. Albert, you mentioned simplifying the organizational structure and not having an appetite for bigger deals. But – and I know you still have to finalize the strategy. But are you comfortable with the number of therapeutic areas in Innovative? Is the creation of Cerevel a strategy that you think could be a blueprint for other categories that are less of a priority?

And the second question, just on the recent drug pricing proposal. And I recognize that most of the drivers for Pfizer today are more Part D than B. I know you don't want to give specifics, but how do you guys view the delta between the U.S. and O-U.S. net pricing? Are there methodologies that you think make more sense to make comparisons easier? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

Well, Geoff, I'll answer the pricing one. I don't think it makes sense to make the comparison to start with, because what you're doing is you're importing one country's industrial policy in pre-writing into a country that's based on innovation.

So number one, I don't think – but to regards how the government may or may not create baskets and reference pricing, however it starts out, it always continues to get worse as the only intention of that type of reference pricing is to drive down the cost to the government. And it's not interested in ensuring the best treatments get to patients. So overall, I think we – hopefully the rule will be revised and reconsidered. With that, pass it over to Albert.

A - Albert Bourla {BIO 18495385 <GO>}

Thank you, Ian, and thank you for your question. I mean it's a very, very good question, like all the questions that have been asked today.

I think the fact that we narrow our area of focus is a very big part of our efforts last year and contributor to the higher R&D productivity. It is not only relevant to us in general. It is just that this consumer industry, companies that they are focusing on smaller number of therapeutic areas. They have in general much higher returns to shareholders.

As we said, obviously Pfizer is a very big name and can apply with one machine from one end, it meets multiple. So and this is the question, what is the right balance?

I think right now we do have the right balance. We are focusing on six therapeutic areas that they are enough to pump our growth in the years to come. And also they are a small number relatively so that we can build something with expertise in each one of them.

To your question, if we will employ this new, innovative type of partnerships, the answer is yes. And actually, the difference in the last two exits from, if I can call it like that, from us, it was related with (1:05:27) and neuroscience was different than the way that we did it in the past by just exiting or selling the asset. We do participate in the space, but we do participate in partnership with people that they have the focus and the expertise to drive much higher results there. And we will continue doing so if we have this opportunity.

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

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

Operator

Your next question is from Tim Anderson from Wolfe Research.

Q - Timothy Minton Anderson {BIO 3271630 <GO>}

Thank you. A couple of questions. On Ibrance, PALOMA-3 was published. It did not show an overall survival benefit. And I'm wondering if you think that potentially creates any hurdles, reimbursement or access, in ex-U.S. markets specifically?

And related to that, I wonder if that raises a question about the two adjuvant trials that are running. I know it's a different but related endpoint of DFS, so I'm curious to get your thoughts. Wondering if that could show, for example, a nonstatistically significant trend only.

And then a second question is on biosimilars. And really looking for any guidance you can give on operating margins. So directionally, if you look out at your long-term forecast, what are you expecting versus today? As volumes grow, you would get a scale benefit, and that should help. But an offset on the negative side could be more price erosion over time as there are more entrants per molecule. So how do those future margins in your forecast compare to today's margins? And how can you describe today's margins relative to, let's say, the branded business or the rest of the Pfizer business? Thank you.

A - Ian C. Read {BIO 3358997 <GO>}

So, Tim, on the biosimilars, we still continue to model that along the lines of a sterile injectable market, high barriers to entry, high cost to produce a biosimilar. I think we've seen some players repricing (1:07:37) and the European prices have been much as we see the sterile injectables in Europe, that have a lower price there. Initially, I think that regulatory body isn't as focused on the need for quality or focused on ensuring there is money to produce the next wave of innovative biosimilars.

I think the U.S. market will continue to be similar to sterile injectables. And if society wants a vibrant biosimilar market going forward, given the upfront cost to produce biosimilars, I do think the market has to react very similar to sterile injectable margins and the stickiness of hard-to-make products in that marketplace.

With that, I'll pass it over to John to answer the Ibrance question.

A - John D. Young {BIO 17639257 <GO>}

Okay. So thanks for the question, Tim. So let me just say in relation to the PALOMA overall survival data that we presented recently, although the difference didn't reach prespecified threshold for a statistical significance, there was a highly clinically relevant numerical improvement in overall survival of nearly seven months with Ibrance plus fulvestrant

compared to placebo plus fulvestrant. So overall survival was 34.9 months, compared to 28 months.

I think we were actually very encouraged that that analysis was very consistent with the improvement previously demonstrated in the primary endpoint for DFS in PALOMA-3. And we will obviously be engaging with payers across Europe and elsewhere in relation to sharing these data. But we remain very confident in the clinical profile and the effectiveness of Ibrance for patients who we've now demonstrated in a variety of settings for metastatic breast cancer.

In terms of your question about whether we see risk in our early breast cancer trials, we really don't see any read-across from these data, other than the fact that we obviously have seen very positive response clinically in patients with metastatic breast cancer. And we see no reason to change our perspective that this is not only a very significant and important opportunity for patients and for Pfizer, but actually about the potential profile for Ibrance in that indication.

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

Thank you, John. Next question, please.

Operator

Your next question comes from Andrew Baum from Citi.

Q - Andrew S. Baum {BIO 1540495 <GO>}

Thank you. Three, please. In reference to Xtandi, is there an argument to be made for launching an authorized generic for government plans in order to increase patient affordability, particularly for the nonlist patients? Number one.

Number two, just focusing on the anticipated move to net pricing for Medicare, I'd be very interested in Albert and Ian's view how long they think the commercial book of business will cling to rebates given economic incentives before migrating to net pricing, if indeed that does take place in government plans.

And then finally, for Angela, just given the pivot towards China on the Established Medicines business, could you give us some granularity about what is driving the growth in China over the last nine months? Many thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Okay. Andrew, on your innovative idea of launching an authorized generic, it's an unusual suggestion given that we have a product with an extended patent period and we're dealing with the access challenges through mechanisms such as contributing to foundations that allow patients who cannot afford the medicine to access it. And we also have our own not-paid-for prescription program as well. So I think the complexities of

running an authorized generic alongside a branded when both are patent protected are too substantial.

And then on a net pricing, if we get to net pricing, which – or the removal of rebates or rebates going to the patient, I would expect that the commercial book of business would move reasonably quickly to the same system. I can't see us maintaining a dual system there.

And then I'll pass it to Angela for the – on why is China doing so well within your leadership?

A - Angela Hwang {BIO 20415694 <GO>}

Thank you. Thank you, Ian. So we have had tremendous success in China this year. And I would narrow that down to two portfolios. First, our cardiovascular portfolio and second, our anti-infective portfolio. I think in both of those what we're seeing are some favorable, I think, epidemiology that stems from low diagnosis, low treatment, and the ability for our products to have a prominent market share in the treatment of those diseases.

So if I think about Lipitor, and Norvasc, sulperazone (1:12:46) as three of those key products, each one of those have grown tremendously through this year through expansion.

And not only is this expansion I think from a sort of getting more patients treated, but we also have had a very focused effort on geographical expansion. So moving beyond the large cities into smaller cities, into county hospitals. So I think it's a combination of the continued high patient demand, coupled with our geographical expansion that is leading us to continued success and rapid growth that we're seeing in our portfolio.

A - Ian C. Read {BIO 3358997 <GO>}

Thank you. And just to punctuate that, I think that the untapped volume in China, given its size and given the narrow segment of society we sell to, is colossal and a good hedge against any pricing pressures. I would expect to see a robust volume response to any ongoing pricing pressures.

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

Thank you. And, operator, can we take our final question, please.

Operator

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

Q - Jason M. Gerberry {BIO 17237298 <GO>}

Oh, hey, thanks for squeezing me in. Just a couple on tanezumab. So just kind of curious as we think about these upcoming Phase 3 readouts next year, just your thoughts on the importance of providing doctors with a roadmap to monitor and prevent these bone

disorders from leading to joint replacement. And so my first part of that question is on the recent Phase 3 data, are you confident that if physicians diagnose type 1 RPOA, they could diagnose, stop treatment, and potentially stop symptom progression there?

And then my second part of that question is just that, there were no cases of osteonecrosis. I know that going back to 2010, 2012, during the period of the clinical hold, you guys and FDA had a little bit of a difference regarding diagnosis of osteonecrosis versus RPOA. So just wondering if you're confident you're on the same page with the FDA there. Thanks.

A - Ian C. Read {BIO 3358997 <GO>}

Mikael, could you answer that?

A - Mikael Dolsten {BIO 16368411 <GO>}

Yeah, we're excited about tanezumab. And we obviously look forward to the significant study readout we have coming next year.

I think we've got a good first feel for again confirming the encouraged efficacy that we're seeing in this first study in a patient group that was in urgent need of new medication and had failed to get the benefit or were intolerable to current available medication.

When it comes to management of rapidly progressing OA, I wanted just to say that we had 1.3% of that, the majority of it was actually of Type 1, which is more of a mild change in the joint space narrowing. And we had a smaller fraction that was of Type 2 with that much more deterioration of the joint.

I think, yeah, these are structural changes that occur also in the natural scope of osteoarthritis with a growing aging patient population and can be easily managed by physicians according to medical practice. And we look upon the overall benefit risk as very encouraging for these new treatment options that opportunities in a difficult situation where opioids have caused an unfortunate situation for many patient groups.

Of course, as we get the entire readout of the tanezumab OA and CBT, we will work with reviewing data, dialogues with regulators, and assuming that the drug will continue to show this promising benefit, we will obviously as always when Pfizer provide new medicines, have proper educational and implementation programs to make sure physicians and patients can use the drug in the most effective way.

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

Thanks, Mikael.

A - Ian C. Read {BIO 3358997 <GO>}

Thanks, Mikael. Before we close, I'd just like to say to the analyst community, I expect this to be my last call for Pfizer on the analysts call. I'd like to thank you all over the years for

great questions and keeping management focused on shareholder value. Thank you very much.

Operator

Ladies and gentlemen, this concludes Pfizer's Third Quarter 2018 Earnings Conference Call. Thank you for your participation. You may now disconnect.