

THOMSON REUTERS

EDITED TRANSCRIPT

Q3 2018 Pfizer Inc Earnings Call

EVENT DATE/TIME: OCTOBER 30, 2018 / 2:00PM GMT



CORPORATE PARTICIPANTS

Albert Bourla *Pfizer Inc. - COO*
Angela Hwang *Pfizer Inc. - Group President of Pfizer Essential Health*
Charles E. Triano *Pfizer Inc. - SVP of IR*
Frank A. D'Amelio *Pfizer Inc. - CFO & EVP of Global Supply and Business Operations*
Ian C. Read *Pfizer Inc. - Chairman & CEO*
John D. Young *Pfizer Inc. - Group President of Pfizer Innovative Health*
Mikael Dolsten *Pfizer Inc. - Global President of Worldwide Research & Development*

CONFERENCE CALL PARTICIPANTS

Alex Arfaei *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*
Andrew Simon Baum *Citigroup Inc, Research Division - Global Head of Healthcare Research and MD*
Christopher Thomas Schott *JP Morgan Chase & Co, Research Division - Senior Analyst*
David Reed Risinger *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*
Geoffrey Christopher Meacham *Barclays Bank PLC, Research Division - MD & Senior Research Analyst*
Jamilu E. Rubin *Goldman Sachs Group Inc., Research Division - Equity Analyst*
Jason Matthew Gerberry *BofA Merrill Lynch, Research Division - MD in US Equity Research*
John Thomas Boris *SunTrust Robinson Humphrey, Inc., Research Division - MD*
Louise Alesandra Chen *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*
Stephen Michael Scala *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*
Timothy Minton Anderson *Wolfe Research, LLC - MD of Equity Research*
Umer Raffat *Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research*
Vamil Kishore Divan *Crédit Suisse AG, Research Division - Senior Analyst*

PRESENTATION

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 *Pfizer Inc. - SVP of IR*

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.

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 *Pfizer Inc. - Chairman & CEO*

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 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 a CDK 4/6 inhibitor class in the U.S., holding at just under 90% share in terms of new prescription volume. Our current growth driver for Ibrance remains international markets, particularly across Europe and Japan, and we have -- 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 non-metastatic and metastatic castration-resistant prostate cancer, and the European Commission has very recently approved Xtandi for the treatment of adult men with higher risk, non-metastatic 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 owe it to warfarin to become the #1 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 onetime year-to-date true-up in the quarter for access payments with one customer.

Sales of Pevnar 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 in 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 in 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 NIVESTYM, 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 show that tafamidis significantly reduced the 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 patients have been diagnosed.

There are currently no approved treatments for ATTR-CM, making it a tremendously underserved market. Tafamidis holds both 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 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 2 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 hereditary breast cancer. Two other oncology candidates, lorlatinib and glasdegib are under priority review with the FDA. We expect to receive decisions of 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 appropriate path forward. We're also encouraged by other recent data reinforcing Inlyta as the TKI of choice in combination with checkpoint inhibitor for this condition.

In Inflammation & Immunology, 2 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 4 Phase 3 trials that are actively recruiting. The JAK3 candidate has been advanced to Phase 2b stroke 3 trial, which will start in the upcoming months for alopecia areata.

In Vaccines, we announced in September that our 20 valent 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 over 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 that these medicines will be launched in an environment where it can help the maximum number of people who need them. We continue to work with the President on his Blueprint for strengthening the healthcare system, providing more access and relieving the burden on patients at the point-of-sale.

For example, we recently responded to the administration 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 1 or 2 PBMs.

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 creating enhanced shareholder value. In fact, we've 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 *Pfizer Inc.* - COO

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 Lyrica LOE that will negatively impact our growth in the next 2 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 growth and to have already begun this evolution.

As you know back in December, we announced that we would be organizing the company into 3 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 would 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 5 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 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 it to operate as a true standalone 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 the 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 Pfizer Inc. - CFO & EVP of Global Supply and Business Operations

Thanks, Albert. Good day, everyone. As always, the charts I'm 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. in 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 the 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 the 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 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 our other income. I'd like to provide some additional commentary. First, the increase in guidance was mainly due to 2 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 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 analogy.

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 wanted 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 new and onetime factors such as mark-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, lorlatinib 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 is 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 *Pfizer Inc. - SVP of IR*

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from Alex Arfaei from BMO.

Alex Arfaei *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

Folks, you've now repeatedly mentioned steady growth prospects after 2020. I think you've characterized it as a mid-single-digits growth on the revenue side. What are the key growth drivers of that from your perspective? I'm specifically interested on 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 non-biopsy test for diagnosing patients. Given that reimbursement doesn't seem to be a



barrier, I'm just wondering what are your expectations about potentially improvement in the diagnosis rate. Do you see it as gradually improvement -- or improving, or could we actually see a step wide increase given that doctors have a very good reason to actually identify these patients now?

Ian C. Read Pfizer Inc. - Chairman & CEO

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.

Albert Bourla Pfizer Inc. - COO

Thank you, Alex. And as you know, beginning of the new financial year, we have reorganized our company into 3 distinct business units and each one of them has distinct growth drivers. So let me give you a summary of them. In our primary and fundamental Innovative Medicines business, it's 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 5 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 PROSPER and we are expecting to present results for ARCHES, and which is another metastatic setting. We're 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 4 new molecular entities by the end of the year in oncology. Although they are smaller in size collectively, they -- the 4 are 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 the thing 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 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 up straight to drive the growth in this part of the business. When it comes to the Established Medicines business, over there, also, we believe that we can have sustainable, modest though, growth, but the drivers are very different. Over there, it is urbanization. It is China. Right now, what you see, we have already 24% growth in China. This means \$700 million we have generated more or less in 9 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 exist with consumers.

Ian C. Read Pfizer Inc. - Chairman & CEO

John? Thank you, Albert.

John D. Young Pfizer Inc. - Group President of Pfizer Innovative Health

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 with 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 think of as red flag symptoms and the availability of the treatment itself will, obviously, play a big role in 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 a diagnosis. But now it's become much easier to diagnose patients using a noninvasive imaging technology called scintigraphy. They are running about 15,000 machines in 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 these medicines to patients and the physicians some time next year.

Operator

Your next question comes from Vamil Divan from Crédit Suisse.

Vamil Kishore Divan Crédit Suisse AG, Research Division - Senior Analyst

First one is, I guess, if for Ian and Albert. Congrats, Albert, by the way, on the new appointment. So last quarter, you had mentioned you believe the administration had the intention of removing safe harbor for rebate, and they were moving to a marketplace where we won't have rebates over time. Over the last year, weeks and months, it feels like more of the commentaries have 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 they were 3



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 a perspective on what's going to drive that product over the next couple of years before we get the additional data in the adjuvant setting.

Ian C. Read Pfizer Inc. - Chairman & CEO

Well, thank you, Vamil. I mean, I think we're still waiting the guidance to come out from Secretary 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 the administration can lower prices for patients at the point of purchase. I mean, discounted point-of-sale also effectively achieve the same thing. The mechanisms of achieving this lowering of prices for the patient are -- could be various. I still think the administration's focused on that, the new Part B rule or new Part suggested rule in Part B is -- I don't think it's in the best interest of patients to effectively import price controls from abroad and in 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. Will that, I'll pass it over to John to talk about Ibrance.

John D. Young Pfizer Inc. - Group President of Pfizer Innovative Health

Okay. Thanks for the question, Vamil. So in terms of the growth trajectory for Ibrance, we've always viewed it as having 3 main phases. Phase 1 was obviously the U.S. launch in maximizing the market opportunity there. And since launch in the U.S., we've entrenched Ibrance as the new standard of care. We've treated over 90,000 patients. So a 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 reimbursements in the EU 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 adjuvants or early breast cancer opportunity, and that gives -- address a population roughly double the size the current metastatic population. We're still a few years away from potentially entering this phase of growth should our clinical trials be successful. We're very excited and positive about the opportunity that, that potentially represents for Ibrance and its life cycle.

Operator

Your next question comes from Chris Schott from JPMorgan.

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

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, which is just on a higher level, could 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?

Ian C. Read Pfizer Inc. - Chairman & CEO

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

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

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 on margins. We've talked about, at that point, the revenue growth in the mid-single digits. And hopefully, 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. Now between now and then, clearly, with the Lyrica LOE, we'll have to work our way through this. We'll give guidance to 2019 on our next call relative to the specifics and by line item. But beyond, beyond the Lyrica LOE, clearly, we're optimistic about our ability to expand margins.

Ian C. Read Pfizer Inc. - Chairman & CEO

Angela, please?



Angela Hwang Pfizer Inc. - Group President of Pfizer Essential Health

Thanks for the question, Chris. I'm going to talk a little bit just about our prospects 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 plan. 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 prospects 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 biosimilars 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 5 next biosimilars that we have in our pipeline.

Operator

Your next question comes from Jami Rubin from Goldman Sachs.

Jamilu E. Rubin Goldman Sachs Group Inc., Research Division - Equity Analyst

First, I just want to say, Ian, it's been a real pleasure to work with you and learning from you over the years 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 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 multiples since early last summer, it would seem to me that you have a lot more options today than you did 6 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 Essential Health business.

Ian C. Read Pfizer Inc. - Chairman & CEO

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

Albert Bourla Pfizer Inc. - COO

Thank you, Jami. Look, at \$64 billion acquisition, it is a large M&A for any standards, but you're right. But for us, we have the ability and the balance to execute basically whatever we would like to execute, if we see value to customers. The way that we see right now of large M&As is not based on our ability to execute or not. It is based on how distracting 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 what 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 that 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 markets for both -- on opportunities that will not bring the distraction operational structure that a large M&A could bring, but could enhance our growth trajectory or our pipeline. Now on the second question on the options, basically, you're asking on the optionalities. Obviously, external separation in the form that we have 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 to 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 launch. In the Consumer health care business, we already said that we are examining options to separate or not this business and to come to a decision by year-end. In our newly Established Medicines business, the focus right now, it 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 the -- to China, where most of the growth is coming, and this is right now where we are.

Operator

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

John Thomas Boris *SunTrust Robinson Humphrey, Inc., Research Division - MD*

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 look at pricing going into next year. 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 discount since there's -- to approve the potentially 10 entrants and pricing possibly eroding there, what the impact might be on Xtandi going forward.

Ian C. Read *Pfizer Inc. - Chairman & CEO*

Okay. John, thank you for that 3-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 raised 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 our -- how we will take our price increases as we did last year. So with that, Frank, do you want to talk about price and volume right now?

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

Sure. So John, global basis price was minus 2%, volume was plus 4%. So operationally, plus 2%. We're 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 then 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.

Ian C. Read *Pfizer Inc. - Chairman & CEO*

John?

John D. Young *Pfizer Inc. - Group President of Pfizer Innovative Health*

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 3. 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 generics 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 therapeutic substitution. And Xtandi now has different indications than ZYTIGA, so 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 the ZYTIGA.

Operator

Your next question comes from Steve Scala from Cowen.



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

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 noncash 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?

Ian C. Read *Pfizer Inc. - Chairman & CEO*

Okay, thank you. We'll ask John to take 2 of the 3 questions, and then Frank will take the noncash question. John?

John D. Young *Pfizer Inc. - Group President of Pfizer Innovative Health*

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 adult 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 CDC is likely to happen some time in 2019. Our belief is that given the effectiveness shown by Prevnar 13 in preventing vaccine-type community-acquired pneumonia in adult 65 and over, we continue to support a broader recommendation, 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 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 immunotherapy space, we are really very encouraged. We've always said that we believe that the true value of IO is to be expected in effective combinations, and the results of our first Phase 3 IO combination study support that view. So the JAVELIN Renal 101 trial you're referring to that combine BAVENCIO and Inlyta in previously untreated advanced renal cell carcinoma, that 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 route or PD-L1 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.

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

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

Operator

Your next question comes from Umer Raffat from Evercore.

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

I 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 rebates. 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 you're expecting a 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 bookends around how big this could be from your perspective, given all the investor debate around that.

Ian C. Read *Pfizer Inc. - Chairman & CEO*

Thank you, Umer. Well, on pricing, what I'm trying to indicate is we did voluntarily agree to defer price increases until the Blueprint was implemented or the end of the year. We're working with the President on parts of the Blueprint. And I expect our approach to pricing at the end of year will be that 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 January. So thanks for the question on that, and then we'll turn to John for tafamidis.



John D. Young Pfizer Inc. - Group President of Pfizer Innovative Health

So thanks for the question, Umer. Obviously, as you know, we don't give forecast ranges for individual products. Let me just sort of underscore what I mentioned already, that we're incredibly excited about the opportunity. Anytime you have positive clinical data that demonstrates significant reduction, 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've said, it's highly under-diagnosed at the moment. So 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, we will make sure that our expectations are obviously going to be part of our 2019 guidance when we get that in the first quarter next year.

Operator

Your next question comes from Louise Chen from Cantor Fitzgerald.

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

I had a few on the pipeline. So first question here is on tanezumab. Would you expect to see 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's 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?

Ian C. Read Pfizer Inc. - Chairman & CEO

I think we'll ask Mikael to answer the first and last question. The one in the middle, we'll refer it 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 the -- what we expect from tafamidis. Clearly, it's a substantial opportunity, but one that we're not ready to talk about until we give our guidance next year.

Mikael Dolsten Pfizer Inc. - Global President of Worldwide Research & Development

Thank you for your interest in tanezumab. And let me just punctuate that we are really excited about the data from our first study that showed that more than 50% of the patients got 50% or greater reduction in OA pain and about 35% reported a 70% or greater improvement in pain. So these are real great benefit for patients. Now concerning chronic lower back pain, those patients are, in general, younger. Most of them do not have as advanced the way as a typical OA pain population. And we, in general, have excluded patients that have severe way in the chronic lower back pain because we're using a higher dose for that study. Hence, we do not anticipate that there will be a major impact or rapidly progressing away in that patient population. Concerning DMD, we have a very, I think, strong DMD gene asset that we're using with a unique gene expression asset, and also, our capsid has certain unique features that we think will optimize its delivery to muscles. And we've started treating patients and a part of a dose escalation. But this far, we are pleased to see the tolerability of the gene therapy product, and initial observations are encouraging. And we look forward to continuing this study.

Operator

Your next question comes from David Risinger from Morgan Stanley.

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

And Ian, let me add my congratulations and best wishes to you after a very successful career and value-creation at Pfizer. My 2 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.

Ian C. Read Pfizer Inc. - Chairman & CEO

Thank you for your comments, 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 the insurers and ourselves as to --



regarding the effectiveness of the passing on of rebates to the -- at the point-of-sale or to the patients. 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 4 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 exposed into list price. I'll pass it over to Albert for his further comments.

Albert Bourla Pfizer Inc. - COO

David, the reason why we organized this Pfizer into these businesses is because we believe that they have different growth drivers, and we believe that the main value contributor, for corporation like Pfizer, it is top line growth. So with this organization, we try to maximize the opportunities and address the challenge that each one of them has. For example, by focusing our efforts of Innovative business in its pipeline, focusing our efforts of Innovative business into creating new markets because a lot of our products and future portfolio are coming to new markets because they're addressing unmet medical needs, it is crucial. When it comes to the Established Medicine, the way that we describe this business, it is off-patent iconic brands, like the Lipitors, like the Viagra, like Celebrex of the world. So we are not transferring over there everything that it is with pipeline. Of 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 expecting 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 a growth strategy over there, plus explore China as a whole, in terms of their contribution to pharmaceutical innovation. And in terms of our Consumer business, it was always operating as an autonomous business. We are enhancing its autonomy, particularly around manufacturing issues this year, and we continue examining options. The -- my reference to Jami's question before around we never -- we're always examining options for our business and, particularly, during the -- 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 business, we need to make sure that operationally is doing very well, and this is the focus.

Operator

Your next question comes from Geoff Meacham from Barclays.

Geoffrey Christopher Meacham Barclays Bank PLC, Research Division - MD & Senior Research Analyst

Albert, you mentioned simplifying the organizational structure and not having appetite for bigger deals, but -- and I know you're still to finalize the strategy. But are you comfortable with the number of therapeutic areas in Innovative? Is the creation of Cerevel 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 give specifics. But how do you guys view the delta between the U.S. and OUS net pricing? Are there methodologies that you think make more sense to make comparisons easier?

Ian C. Read Pfizer Inc. - Chairman & CEO

Well, Jeff, I'll answer the pricing one. I don't think it makes sense to make the comparison start with because what you're doing is you're importing one country's industrial policy and free riding 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 in 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 -- hopefully, the rule will be revised and reconsidered. With that, I pass it over to Albert.

Albert Bourla Pfizer Inc. - COO

Thank you, Ian, and thank you for your questions. These are very, very good questions like all the questions that have been asked today. I think the fact that we narrow our therapeutic 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 the statistics of the industry. Companies that they're focusing on smaller number of therapeutic areas, they have, in general, much higher returns to shareholders. That being said, obviously, Pfizer is a very big plane, and it cannot fly with one machine on one end. It needs multiple. So -- and this is the question, what is the right balance? And I think right now, we do have the right balance. We are focusing on 6 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 scientific expertise in each one of them. To your question, if we

will employ these new innovative type of partnerships, the answer is yes. And actually, the difference in the last 2 exits from -- if I can call it like that, from us, which was related to the Car T, and neuroscience was different than the way that we did it in the past by just exiting or selling the assets. 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 in the end. And we will continue doing so if we have this opportunity.

Operator

Your next question is from Tim Anderson from Wolfe Research.

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

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 2 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 non-statistically significant trend only. And then second question is on biosimilars and really looking for any guidance you can give on operating margins. So directionally, if you look out 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. Is there more entrants per molecule? So how 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?

Ian C. Read Pfizer Inc. - Chairman & CEO

So Tim, on the biosimilars, we still continue to model that along the lines of the sterile injectable market, high barriers to entry, high cost to produce biosimilar. I think we've seen some therapy pricing in the European pricing system much as we see sterile injectables in Europe. They have a lower price there. Initially, I think that regulatory body isn't as focused on the need for quality or focused on ensuring to raise 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 viable biosimilar market going forward, given the upfront cost to produce biosimilars, I do think the market has to actually, very similar to sterile injectable margins and the stickiness of how to make products in that marketplace. With that, I'll pass it over to John to answer the Ibrance question.

John D. Young Pfizer Inc. - Group President of Pfizer Innovative Health

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 their difference doesn't reach prespecified threshold for a statistical significance, there was a highly clinically relevant numerical improvement in overall survival of nearly 7 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 this data. But we remain very confident in the clinical profile and the effectiveness of Ibrance for patients who have 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.

Operator

Your next question comes from Andrew Baum from Citi.

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

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's affordability, particularly for the non-list patients, number one. Number two, just focusing on the anticipated move to net pricing to Medicare. I'd be very interested in -- Albert's and Ian's view how long they think the commercial book of business will



cling to rebates, given the economic consensus before migrating to net pricing if, indeed, that does take place in government plans? And then finally, for Angela. Just the 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 9 months?

Ian C. Read Pfizer Inc. - Chairman & CEO

Okay. Andrew, on your innovative idea of launching an authorized generic, it's an unusual suggestion, given that we have a product with a 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 patients, 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 talk to -- I'll pass to Angela for the -- on why is China doing so well over the new leadership.

Angela Hwang Pfizer Inc. - Group President of Pfizer Essential Health

Thank you. Thank you, Ian. So we have had tremendous success in China this year, and I would narrow that down to our 2 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 or Norvasc and Sulperazon, 3 of those key products, each one of those have grown tremendously through this year and 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.

Ian C. Read Pfizer Inc. - Chairman & CEO

Thank you. 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. So I would expect to see a robust volume response to any ongoing pricing pressures.

Operator

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

Jason Matthew Gerberry BofA Merrill Lynch, Research Division - MD in US Equity Research

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 the road map to monitor and prevent these bone disorders from leading to joint replacement. 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.

Ian C. Read Pfizer Inc. - Chairman & CEO

Mikael, could you answer that?

Mikael Dolsten Pfizer Inc. - Global President of Worldwide Research & Development

Yes. We're excited about tanezumab, and we obviously look forward to the significant study readouts we have coming in next year. I think we've got a good first feel for, again, confirming the encouraged efficacy that was seen in this first study in a patient group that was in urgent need of new medications and had failed to get the benefit or were intolerable to current available medications. When it comes to management or the rapidly progressing OA, I want to just 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 -- or deterioration of the joint. I think you saw structural changes that occur also in the natural scope of osteoarthritis with a growing and 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 this new treatment options that offer alternatives 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 CLBP, we will work with reviewing data, dialogues with regulators. And assuming that the drive will continue to show this promising benefit risk, we will obviously, as always, when Pfizer provide new medicines, have proper educational and implementation program to make sure physicians and patients can use the drug in the most effective way.

Ian C. Read *Pfizer Inc. - Chairman & CEO*

Thank you, 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 analyst 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.

DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Briefs are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT BRIEFS REFLECTS THOMSON REUTERS'S SUBJECTIVE CONDENSED PARAPHRASE OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT BRIEF. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2018 Thomson Reuters. All Rights Reserved.

