

## Q4 2017 Earnings Call

### Company Participants

- Albert Bourla, Chief Operating Officer
- Charles E. Triano, Senior Vice President, Investor Relations
- Frank A. D'Amelio, Executive Vice President, Business Operations and 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 & Executive Vice President

### Other Participants

- Alex Arfaei, Analyst
- Andrew S. Baum, Analyst
- Charles Butler, Analyst
- Christopher Schott, Analyst
- David R. Risinger, Analyst
- Geoffrey Meacham, Analyst
- Gregg Gilbert, Analyst
- Jami Rubin, Analyst
- Jason M. Gerberry, Analyst
- Jeffrey Holford, Analyst
- John T. Boris, Analyst
- Jonathan Miller, Analyst
- Marc Goodman, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Timothy Minton Anderson, Analyst
- Vamil K. Divan, Analyst

## MANAGEMENT DISCUSSION SECTION

### Operator

Good day, everyone, and welcome to Pfizer's fourth quarter 2017 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 fourth quarter 2017 performance and 2018 financial guidance. 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; John Young, Group President of 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](http://pfizer.com/investors).

Before we start, I'd like to remind you that our discussions during this conference call will include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially. Additional information regarding these factors is discussed under the Disclosure Notice section in the earnings release we issued this morning as well as in Pfizer's 2016 annual report on Form 10-K, including in Part 1 Item 1A that is filed with the SEC and available at their website, [sec.gov](http://sec.gov), and on our website at [pfizer.com](http://pfizer.com). The forward-looking statements during this conference call speak only as of the original date of this call, and we undertake no obligation to update or revise any of these statements.

Discussions during the call 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 current report on Form 8-K dated today, January 30, 2018. You may obtain a copy of the Form 8-K on our website at [pfizer.com/investors](http://pfizer.com/investors). 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.

We will now make prepared remarks, and then we'll move to a question-and-answer session. With that, I'll now turn the call over to Ian Read. Ian?

**Ian C. Read** {BIO 3358997 <GO>}

Thank you, Chuck, and good morning, everyone.

During my remarks, I will speak about: our performance for the year; the continued advancement of our pipeline, which we believe is more robust and productive than it has been in more than a decade; and the expected impact of U.S. tax reform on Pfizer. Frank will provide details regarding the quarter and our 2018 financial guidance.

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Pfizer had another solid year in 2017. Despite having just over a \$3 billion negative revenue impact due to LOEs and the divestment of Hospira Infusion Systems, we were able to offset this impact and report flat operational revenue, as we saw growth in many of our anchor brands. We also saw continued growth in emerging markets, which was up 11% operationally compared with the previous year.

I'll begin with a few words regarding the performance of each of our businesses, starting with Pfizer Innovative Health. This business had another strong year, growing its top line 8% operationally thanks to the continued strength of several of our best-selling medicines. Ibrance revenues grew 47% operationally to \$3.1 billion for the year. To date, Ibrance has been prescribed to more than 100,000 patients around the world and received regulatory approval in more than 80 countries. However, revenues in certain developed European markets were negatively impacted by a one-time price adjustment of full-year 2017 revenues. This adjustment was the result of agreements to establish pricing levels comparable to historical European pricing analogs for oncology products, ensure patient access, and drive expected future growth in these markets. We see this as a positive for the future of the brand.

We remain confident in the profile of Ibrance based on a number of factors, including safety and efficacy. We are working to build on Ibrance's initial success with trials in the early breast cancer setting and in the HER2 positive metastatic setting and move our novel next-generation investigational CDK inhibitor, which may be effective for patients as they become resistant to Ibrance. We expect to have this asset in the clinic this year.

Eliquis alliance and direct sales revenue grew 47% operationally to \$2.5 billion, and it is the number one new-to-brand oral anticoagulant prescribed by cardiologists in 21 markets.

Xeljanz experienced 45% year-over-year operational growth and achieved its first year of blockbuster status. We expect our inflammation and immunology franchises to continue to strengthen with the recent U.S. approval of Xeljanz for psoriatic arthritis, and we are hopeful that we will receive U.S. approval for a third indication, ulcerative colitis, this year.

Chantix revenue grew 18% operationally to nearly \$1 billion for the year.

Lyrica revenues within Pfizer's Innovative Health grew 9% operationally to \$4.5 billion for the year. Lyrica continued to be a strong contributor to Innovative Health, and we anticipate that Lyrica will maintain its market exclusivity in the United States until the end of 2018 or through June 2019 if the FDA grants approval for the pediatric extension exclusivity.

Pfizer's share of Xtandi's U.S. net sales was \$590 million for the year. In the fourth quarter 2017, Pfizer's share of net sales was \$168 million, up 12% from the third quarter 2017 and 22% from the fourth quarter of 2016. The number of urologists actively prescribing Xtandi continues to grow and reached an all-time high of more than 1,700 in the fourth quarter of 2017 compared with approximately 500 for Zytiga.

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In terms of potentially expanding Xtandi's benefit to men with non-metastatic prostate cancer, in September we announced that the Phase 3 PROSPER trial in non-metastatic castration-resistant prostate cancer met its primary endpoint. And we look forward to presenting detailed results at the ASCO GU [American Society of Clinical Oncology Genitourinary] Congress on February 8. We are also pleased that in partnership with Astellas, we have submitted the PROSPER data to the FDA, seeking to expand the label to the non-metastatic CRPC setting. We are awaiting the FDA's acceptance of the application for review.

Finally, we continue to review strategic options for our Consumer Healthcare business. This could include anything from a full or partial separation of the business to ultimately deciding to retain the business, and we continue to expect to make a decision during 2018.

Turning now to Pfizer Essential Health, while revenues for the year declined, due in large part to expected product LOEs, we once again saw strong operational growth both in emerging markets and our biosimilars portfolio. Emerging markets revenue grew 7% operationally for the year to \$7 billion. China led the way, growing 16% operationally. Our biosimilars business grew 66% operationally in 2017 to \$531 million, and we remain the number one biosimilars company globally. We also advanced six biosimilar pipeline products during the year through various regulatory and data milestones.

PEH's growth in emerging markets and biosimilars were offset by product supply shortages in the sterile injectables business. Our sterile injectables shortages are primarily for products from the legacy Hospira portfolio and are largely driven by capacity constraints and technical issues. As we stated previously, we have a robust action plan in place and we believe will make substantial progress in 2018 towards reducing these shortages.

Turning to Inflectra, at the end of December its share had increased to 5.6% of overall U.S. infliximab volume, up from 4.9% at the end of September. This increase was primarily due to the product's continued strong performance in closed systems such as the VA, where the insurer and provider are the same entity. Despite J&J's exclusionary contracting with regard to Remicade, we continue to see increased coverage from Inflectra amongst commercial payers. And just last week, the appellate court ruled that a key patent that J&J has asserted to block access to Inflectra is invalid.

Last quarter I talked about the expected decline in the number and revenue impact of LOEs facing our business and the further strengthening of our R&D pipeline. We expect these trends to continue. In terms of LOEs, we expect the full-year year-over-year impact to be about \$2 billion in 2018, which remains significantly lower than our recent past. We expect the impact of LOEs will remain in the \$2 billion range through 2020 before improving to \$1 billion in 2021 and then \$500 million or less from 2022 to 2025.

At the same time, our pipeline continues to generate exciting new opportunities for our company and for the patients who benefit from our innovative therapies. In 2017 we

received 10 approvals from the FDA. This is significantly more than we achieved in any year in the past decade.

Let me touch on some of our most recent advances. In oncology, we recently presented positive results from the Phase 3 EMBRACA trial, which showed that our PARP inhibitor, talazoparib, significantly extended progression-free survival versus standard-of-care chemotherapy in patients with BRCA-positive metastatic breast cancer.

In partnership with Merck KGaA, we look forward to continued progress with Bavencio, our PD-L1 inhibitor. We have upcoming data readouts in second-line non-small-cell lung cancer and first-line renal cell carcinoma in combination with Inlyta. In addition, the triplet study exploring the combination of Bavencio, our 4-1BB agent, and our OX40 monoclonal antibody in solid tumors entered the clinic in the first half of 2017. We will continue to evaluate this combination throughout 2018.

In 2018, we expect to advance multiple oncology filings in the registration process, including: talazoparib in BRCA-positive metastatic breast cancer; Xtandi for non-metastatic castration-resistant prostate cancer, for which we have submitted an sNDA based on the Phase 3 PROSPER data; lorlatinib, which has shown activity in almost all known clinically acquired ALK mutations in ALK-positive non-small-cell lung cancer; dacomitinib in EGFR-mutated non-small-cell lung cancer based on the positive ARCHER-1050 findings published in September; and our SMO inhibitor, glasdegib, for acute myeloid leukemia based on Phase 2 results.

In Inflammation and Immunology, we have seven ongoing JAK clinical programs providing us with the strongest immuno-kinase franchise in the industry. The Phase 2 data for our oral once-daily JAK-1 in atopic dermatitis was presented in September, and this asset is the first and only JAK-1 to enter Phase 3 in 2017.

In vaccines, we began Phase 3 trials with our C. difficile vaccine. The studies have been enrolling well, and our recent competitive decision has positioned us as a potential first-in-class vaccine.

Leveraging the success of Prevnar, we also moved into Phase 2 of our next-generation pneumococcal vaccine candidate with the potential to cover 20 stereotypes. In addition, we're advancing a Phase 2 tetravalent staphylococcus aureus vaccine with Fast Track designation.

In 2017, we also continued to take important steps towards becoming an industry leader in gene therapy. We see gene therapy as a field that holds tremendous promise for patients in areas of devastating need, particularly in rare monogenic diseases with loss of function. We finished the year with two assets in the clinic that are potential therapies for hemophilia B and hemophilia A.

In 2018, we expect readouts from multiple pivotal studies in rare diseases, including rivipansel for sickle cell disease and Vyndaqel in cardiomyopathy. We also have begun screening patients for our potential gene therapy for Duchenne muscular dystrophy. We

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also broke ground on a \$100 million commercial gene therapy manufacturing facility in Sanford, North Carolina, and when complete, will have end-to-end capabilities from manufacturing to commercialization.

Before closing my remarks today, I would like to spend a few moments discussing the new U.S. tax code and its expected impact on our business. As you know, Pfizer has been advocating for many years for comprehensive tax reform. That's because the system that had been in place put U.S.-based multinational companies at a competitive disadvantage vis-à-vis foreign competitors with regard to the tax rate and international access to capital. The new tax code addresses these issues and helps level the playing field to make U.S. companies more competitive.

After evaluating the expected positive net impact the new tax code will have on Pfizer, we have decided to take several actions. Over the next five years, we plan to invest approximately \$5 billion in capital projects in the U.S., including the strengthening of our manufacturing presence in the U.S. We also expect these reforms to favorably influence future investments.

We plan to make a \$500 million contribution to our U.S. pension plan in 2018. In the fourth quarter 2017, we made a \$200 million charitable contribution to the Pfizer Foundation. This organization provides grants and investment funding to support organizations and social entrepreneurs in an effort to improve healthcare delivery. We have also earmarked approximately \$100 million for a special one-time bonus to be paid to all non-executive Pfizer colleagues.

Given the more favorable repatriation provision, we are currently reviewing our capital allocation opportunities under the new tax code. We will remain disciplined in our approach, with value creation for shareholders remaining our compass.

In summary, we continued to deliver our strategy in 2017. As a result, we saw: continued growth of newer brands; achieved a record number of product approvals; further advanced our pipeline, which we believe will be a significant competitive advantage and growth driver going forward; and we entered 2018 even better positioned to deliver new medicines for patients and increase value for our investors going forward.

All of these achievements have been made possible by the strength of our leadership team, which we further strengthened recently with Albert Bourla taking on the role of Chief Operating Officer, John Young leading Pfizer Innovative Health; and Angela Hwang becoming the head of Pfizer Essential Health. These appointments are a testament to the depth and breadth of our leadership talent, which has positioned us very well for continued success.

Now, I will turn it over to Frank to provide details on the quarter and our outlook for 2018.

**Frank A. D'Amelio**

Thanks, Ian. Good day, everyone. As always, the charts I'm reviewing today are included in our webcast.

Now, moving on to the financials. Fourth quarter 2017 revenues were approximately \$13.7 billion, which include the favorable impact of foreign exchange of \$114 million, partially offset by a slight operational decline of \$39 million. If you exclude both the prior-year quarter revenues for Hospira Infusion Systems, or HIS, and the positive impact of foreign exchange, fourth quarter 2017 revenues increased \$240 million, or 2%.

Our Innovative Health business recorded 5% operational revenue growth in the fourth quarter of 2017, driven primarily by: Eliquis globally; Xeljanz in the U.S.; Prevnar 13 in emerging markets; and Lyrica, Ibrance, and Chantix in the U.S.; all of which were partially offset by lower revenues for Viagra in the U.S. because of generic competition beginning in December of 2017 and Enbrel in most developed Europe markets due to continued biosimilar competition.

Revenues for our Essential Health business in the fourth quarter decreased 8% operationally, of which 5% was attributable to the divestiture of the HIS business in February of 2017. The remainder of the decrease was due to an 18% operational decrease from Peri-LOE products, including expected declines of Pristiq in the U.S. and Lyrica in developed Europe markets, as well as a 10% operational decline in the sterile injectables portfolio, primarily due to continued legacy Hospira product shortages in the U.S., all of which were partially offset by operational growth of 72% from biosimilars, mainly driven by Inflectra in the U.S. and developed Europe.

In emerging markets, Pfizer's overall Essential Health revenues grew 10% operationally in the fourth quarter, primarily due to 10% growth from the Legacy Established Products portfolio and 23% growth from the sterile injectables portfolio.

Fourth quarter reported diluted EPS was \$2.02 compared with \$0.13 in the year ago quarter, primarily due to a lower effective tax rate due to the enactment of the Tax Cuts and Jobs Act, or the TCJA, in late 2017. As a result, Pfizer's fourth quarter full year 2017 provision for taxes on reported income was favorably impacted by approximately \$10.7 billion, primarily reflecting the remeasurement of U.S. deferred tax liabilities, which includes the repatriation tax on deemed repatriated accumulated earnings of foreign subsidiaries.

Our fourth quarter reported diluted EPS was also favorably impacted by lower restructuring and implementation cost and unfavorably impacted by higher losses on debt retirement.

Adjusted diluted EPS for the fourth quarter was \$0.62 versus \$0.47 in the year ago quarter. The increase was primarily due to a lower effective tax rate, lower adjusted total cost and expenses, and fewer shares outstanding.

I want to point out that diluted weighted average shares outstanding declined by 80 million shares versus the year ago quarter due to our share repurchase program,

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reflecting the impact of our \$5 billion accelerated share repurchase agreement executed in February of 2017 and completed in May of 2017. In addition, the full year 2017 weighted average shares used to calculate EPS was 6.058 billion shares, a reduction of 100 million shares compared versus full year 2016.

As I previously mentioned, foreign exchange positively impacted fourth quarter 2017 revenues by approximately \$114 million and negatively impacted adjusted cost of sales, adjusted S&A expenses, and adjusted R&D expenses in the aggregate by \$127 million. As a result, foreign exchange favorably impacted fourth quarter 2017 adjusted diluted EPS by approximately \$0.01 versus the year ago quarter. As you can see on the chart, we've met or exceeded all components of our 2017 financial guidance.

Moving on to full year 2018 financial guidance, it's important to note that this guidance includes a full year contribution from Consumer Healthcare and assumes no generic competition for Lyrica in the U.S. during 2018. We currently expect generic competition in June of 2019, contingent upon a six-month patent term extension for pediatric exclusivity, which we are currently pursuing.

We expect 2018 revenues to be in the range of \$53.5 billion to \$55.5 billion. This range incorporates an anticipated \$900 million favorable impact of foreign exchange. I want to point out that beginning in the first quarter of 2018 forward, total Viagra worldwide revenues will be reported in Essential Health due to generic competition that began in the U.S. in December of 2017. Previously, revenues for Viagra in the U.S. and Canada had been recorded in our Innovative Health business through December of 2017.

We expect the effective tax rate on adjusted income to be approximately 17% in 2018 and sustainable for the foreseeable future, which is significantly lower than the approximately 23% that we previously anticipated for full year 2017 and reflects the enactment of the TCJA. Because of the significant changes and complexities to the tax law, this financial impact on 2018 guidance is provisional only and therefore is subject to further analysis, interpretation, and clarification of the tax reform legislation. I want to point out for modeling purposes that based on 2017 results, a 1% reduction in the effective tax rate on adjusted income results in an approximate \$0.03 increase to adjusted diluted EPS.

Finally, as a result of the enactment of the recent legislation, we expect to repatriate the majority of our cash held internationally in 2018. As a reminder, as of the third quarter of 2017, Pfizer had approximately \$24.2 billion of cash and investments.

Finally, we expect adjusted diluted EPS will be in the range of \$2.90 to \$3.00, which incorporates \$0.06 favorable impact from foreign exchange and \$5 billion of anticipated share repurchases in 2018, the impact of which we expect to be offset by about half from dilution related to share-based employee compensation programs.

Moving on to key takeaways, we delivered solid financial results in the fourth quarter of 2017. Excluding HIS revenues from the prior year quarter and the impact of foreign exchange, revenues increased 2% operationally year-over-year, driven by the strong growth from Eliquis and Xeljanz.



We issued 2018 financial guidance ranges reflecting 4% revenue growth and 11% adjusted diluted EPS growth at their respective midpoints compared with 2017 actual results. We accomplished several key product and pipeline milestones. And we returned \$12.7 billion to shareholders in 2017 through dividends and share repurchases, including a \$5 billion accelerated share repurchase agreement. 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>}

(24:56) for the prepared remarks. Operator, can we please poll for Q&A now?

## Q&A

### Operator

Your first question comes from Alex Arfaei from BMO Capital Markets.

**Q - Alex Arfaei** {BIO 15433937 <GO>}

Great, thank you. Good morning and thank you for taking the questions. I guess the first one for Ian. How should we think about the European pricing adjustment longer term? Are these established contracts or should we expect more step-downs, and could it have implications for U.S. pricing and pricing in general?

And then a follow-up for Frank. I appreciate that you're still reviewing your capital allocation opportunities, but your \$5 billion share buyback seems conservative given all the options available to you. If we think about the potential divestiture of the consumer business, more efficient access to ex-U.S. cash, how should we think about potential upside there?

And finally, Mikael, the tanezumab Phase 3 pivotal trials are coming up. How should we think about some of the previous safety issues that have delayed the seemingly promising asset? Thank you very much.

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

Thank you, Alex. So I'm going to let Albert answer your European price question. But I would like to point out ahead of time that these negotiations were not related to competitive pressure. And I see the establishment of pricing for Ibrance in Europe as a major positive for the business going forward, at prices that are consistent with European oncology analogs. Albert, do you want to add any more context?

**A - Albert Bourla** {BIO 18495385 <GO>}

Yeah. First of all, as you said, the mBC is something positive you said it now and you said it in your remarks and let me clarify. The demand in Europe continues to show very strong

growth. We had 20% this quarter compared to previous quarter, and we had 29,000 Ibrance patients in Europe this year. To put that in context, in the first year of the U.S. launch, we had 20,000.

Now, the negative on this quarter, as Ian said, it is due to one-time price adjustment with the full-year revenues, and these were part of finalizing broader reimbursement negotiations that will establish pricing levels to the historical, very comparable to historical European pricing analogs, and at the same time, ensure broad patient access to drive potential future volume and very important revenue growth in these places.

I'm very satisfied with these agreements. Overall, they recognize the value that Ibrance brings to patients. And at the same time, they offer an attractive cost benefit to the payers. So in conclusion, in 2018 we expect to see strong volume and revenues growth in Europe and other national markets as a result of these deals.

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

Thank you. Frank, do you want to talk about the capital allocation?

**A - Frank A. D'Amelio**

Sure. So, Alex, you mentioned the \$5 billion in buybacks. Let me just run the numbers, and then I'm going to bump this up to a capital allocation conversation. So we've announced \$5 billion in buybacks. We also announced we were increasing our dividend to \$0.34 a quarter. The combination of dividends and buybacks for 2018 will return more than \$13 billion directly to shareholders.

Now let me bump it up to more of a capital allocation conversation. The four priority areas that we've had in the past continue to be our four priority areas. Those are, obviously, investing in our business, dividends, buybacks, and M&A. So those were the areas; they remain the areas. And the nice thing about Pfizer is we have the ability to play in all four areas, as we've demonstrated in the past. Now, given tax reform and given that we're exploring strategic options for our Consumer business, we will continue to review what our options are. We'll continue to evaluate our options in these areas on a going-forward basis.

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

The answer to tanezumab please, Mikael.

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Thank you. Alex, thank you for shedding attention on tanezumab. We are very excited about the trial of six different studies, 7,000 patients that are starting to read out early fall this year, and then each of the trials further on into 2019.

We have a unique position in this space as we gathered tremendous experience and insight in how to manage our NGF antibody and deal with rare events recorded as rapidly progressing OA. We have been able to design the trial to minimize the risk for such to

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occur. That includes reducing concomitant chronic use of NSAIDs. It includes lowering the dose of tanezumab, particularly in OA, where some of these rare cases we're seeing in our trials, while keeping higher doses in chronic lower back pain, where this issue was not really reported. We've introduced risk management program and stopping criteria for individual patients. So overall, we think we have really learned uniquely and been able to design a study that should minimize the risk of such events.

I also want to take a step back and say that the macro environment for the need of new pain medications have really changed. The perspective a number of years ago was that unmet medical need was rather satisfied. Unfortunately, we have learned that the current pain medications, particularly opioids, have severe issues, not just when it comes to impact on GI, respiratory, but also the great addiction crisis that we are battling with. In contrast of course, monoclonal antibodies like this that can be given conveniently sub-cu every eight weeks we believe have a very attractive profile, and we look forward very much to the readout of the trials and report those. Thank you.

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

Thanks, Mikael, next question, please.

## 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 questions. So just I wanted to know. There's been a lot of discussion around these potential new entrants entering drug distribution. We heard the news today around Amazon, Berkshire, and JPMorgan. The quote in the commentary around, you're obviously talking about healthcare cost and the impact coming out of the economy. You guys generated \$26 billion of sales in the U.S. last year. Just if you can, comment on how you see this impacting things maybe near term and also longer term. And how is it not ultimately a bad thing for larger companies such as Pfizer that generate so much of their sales from the U.S.?

And then my second question, just quickly around guidance, a totally different topic, with Xtandi, you mentioned some of the positive news you had there. But just if you can, talk about how you're thinking about that product. Obviously, we may see Zytiga generics in the market later this year. I'm wondering how you think that might impact Zytiga's business. Thanks so much.

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

Vamil, thank you for the question. You know, vis-à-vis Amazon, I think we've discussed this before. We welcome any entrants to the distribution system that can improve efficiencies and ensure that patients get their medication at the appropriate cost and the appropriate time. So although I would say that the distribution system, not necessarily the way that the rebates and price were handled, the distribution system is already highly efficient.

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Now with regard to the announcement today, I really am surprised at your comments. I don't really know how to react to it. There's very little detail in the announcements. Nevertheless, I would see it as totally positive for our industry. Any attempt to lower healthcare costs are going to have to involve, my belief, in using medicines to ensure adherence, to ensure management, the appropriate management of diseases.

We represent 2 points - or we represent 10% to 14% of healthcare costs, so I would hope that private actors that come into this space would initially see more opportunity throughout the whole distribution chain of costs and would look at us as a positive way of controlling costs. So I think it's encouraging that private actors enter in this, and it's encouraging for the use of modern pharmaceuticals.

And Xtandi, would you deal with that, please, Albert?

**A - Albert Bourla** {BIO 18495385 <GO>}

Of course, Ian. First, let me start by saying how pleased we are to see total demand for Xtandi growing 26% compared to the fourth quarter of 2016. Particularly, the number of urologists actively prescribing Xtandi continues to grow and reached an all-time high of 1,700 in this quarter, which is more than three times the number of urologists that are prescribing Zytiga, for example.

Urologists right now represent 41% growth in 2017 compared to 2016, and of course, not to mention that we had - not to miss mentioning that we had another quarter of sequential sales growth. Sales this quarter were 12% higher than the sales of the previous quarter.

And as regards to Patient Assistance Program, as a percentage of total demand, it was generally stable compared to the third quarter of this year, which is what we were expecting knowing that the people that are enrolling ourselves in this program, they are enrolled for the full calendar year. We believe that the demand for Patient Assistance Programs as a percentage of total demand will decrease in 2018 as compared with what we saw in 2017.

As regards to Zytiga generics, there are differences between Xtandi and Zytiga. There are differences in terms of dosing frequency. There are differences in terms of requirements for steroid co-administration, and there also very different monitoring requirements. And as you know, in the future we hope to have different indications also based on potential approval of the PROSPER study in non-metastatic castrate-resistant prostate cancer and more studies that are coming in the earlier setting. So of course, we will continue monitoring the market, but we are not right now concerned about Zytiga generics.

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

Thanks, Albert. Can we move to our next question, please?

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Your next question comes from David Risinger from Morgan Stanley.

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

Thanks very much and congrats, Ian and Frank, on all of your efforts to educate Washington having finally paid off.

With respect to my questions, I wanted to ask for a little bit more color and perspective on Ibrance in Europe. I think it would just be helpful if you explain which countries agreed, how it all came together so quickly to result in a price reset in a given quarter, since obviously many countries negotiate pricing independently. So that's my first question.

Second, with respect to Inflectra, has J&J's contract language changed such that Inflectra will have greater commercial access and commercial uptake in 2018?

And then my third question is for Frank. How should we think about the tax rate beyond 2018? Should we expect it to decline below 17%? Thanks very much.

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

So, David, thank you for the congratulations. I do believe that Pfizer has played a major role in putting a spotlight on the disadvantageous corporate tax situation for U.S. multinationals, so I appreciate the comments.

Now on Ibrance, I would like to - number one, we're not going to get into a discussion of which countries. This is all proprietary information that is important for us that we don't discuss in public. Two, it was not quick. It was a result of ongoing negotiations over a substantial part of 2017.

And I think what you need to be focused on, if you don't mind me saying so, is what does this set up for the future of Ibrance? And we have managed to establish wide reimbursement and pricing at what we believe for the European market is comparable analogs. We don't see there's any spillover to other markets internationally or within the European context. So we see this agreement as setting a strong baseline for patient access in Europe and continued growth of the franchise. So I think this is extremely positive for Ibrance. It comes in an unusual way as the negotiations reflected the full impact in one quarter rather than spread over the whole year or spread over a period of years. So in my point of view, it's very, very positive going forward for Ibrance and for our patients in Europe.

Would you like to deal with Inflectra, please, John?

**A - John D. Young** {BIO 16960082 <GO>}

Thanks for the question, David. I'm obviously not aware of any changes that J&J have made to their contracting status. I think we've commented on that previously, and Ian mentioned this in this call. Let me just say that we obviously continue to work towards

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minimizing the impact in 2018 of their exclusionary contracting practices by growing in closed systems and continuing to seek increased coverage amongst commercial players.

As Ian mentioned in his prepared remarks, in quarter four approximately half of Inflectra's volume comes from closed systems such as the VA, where the insurer and provider are the same entity. And in those closed systems which prioritize healthcare savings over short-term rebating, as of quarter four we've now reached a 58% share of infliximab.

But we obviously are very conscious that those closed systems represent only a small proportion of the market, around about 5%. But we really believe that our performance in those closed systems demonstrates that where payers, providers, and patients have access to Inflectra that it can offer significant value to the healthcare system, and we'll continue progressing that aggressively.

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

And then on the tax rate question?

**A - Frank A. D'Amelio**

Dave, we said for this year approximately 17%. And then in terms of going forward, I would continue to use approximately 17%. We believe that rate is sustainable. If anything were to change, obviously I would let you and everyone else know.

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

Thank you, next question please, operator?

**Operator**

Your next question comes from Geoff Meacham from Barclays.

**Q - Geoffrey Meacham** {BIO 21252662 <GO>}

Good morning, guys, and thanks for the question. Ian or Frank, just on the topic of repatriation, in the past you guys have talked about tapping into uninvested foreign earnings, not just OUS cash. So should we view the \$24 billion you mentioned, Frank, as a ceiling for repatriation, or are you still evaluating?

And then more on the pipeline, when you think about Pfizer's I-O strategy, you're moving beyond avelumab and 4-1BB. What's the capacity - or should I say the priority to expand the number of I-O combinations? I know you guys are looking at OX-40, but obviously you have room for many more combos. And maybe what's the rate-limiting step for that to happen? Thanks.

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

Geoff, the \$24 billion is the ceiling on the repatriation. Of course, it does mean that all future cash flows can come back to the U.S. without restriction, which I think is the really

important point rather than the \$24 billion we're bringing back. It's the unfreeing [sic] [freeing] (42:17) permanently of our access to our global capital cash flows.

## A - Frank A. D'Amelio

And it's up to \$24 billion.

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

And it's up to \$24 billion. I-O strategy, Mikael, please?

## A - Mikael Dolsten {BIO 16368411 <GO>}

Yes, thank you. We look at I-O field development into three buckets as part of your question: initial monotherapy with PD-1, PD-L1s, including our Bavencio; combinations of those agents with chemo targeted or I-O agents; and three, longer-term aiming to turn cold tumors hot.

In the first bucket, we are present mainly as a minor player with Bavencio approvals in Merkel cell, bladder cancer, and planned readout in lung cancer. We didn't really plan to be a leader in this space. However, we really aim to grow impactful leadership with Bavencio in segments or of combinations, which are near and mid-term a promising opportunity.

We have now five pivotal studies over the next 18 to 24 months with various Bavencio combinations that we think will be really interesting to watch: ovarian second-line and third-line with chemo; renal first-line with Inlyta and Bavencio; gastric first-line maintenance with Bavencio off the chemo, bladder first-line maintenance of Bavencio off the chemo variant; Bavencio combined with various chemo combinations.

In addition to those pivotal readouts in the more near term, we mid-term see more than 20 Bavencio combinations, whether radioimmunotherapy pivotal studies in head and neck or with our vast number of targeted agents, which is really a unique aspect of Pfizer compared to many other players in this space. That includes for lung lorlatinib and Xalkori, for breast with Ibrance/fulvestrant, for leukemias or myeloid corrected (44:24) with glasdegib. And of course, we are conducting additional I-O studies with 4-1BB combined with OX-40, where we have encouragement that this may from an immune point of view be a really interesting combination.

And finally, I want to say that we are really one of the few that have both an I-O agent, Bavencio, and a PARP inhibitor, talazoparib. And we do think that will be a very powerful combination, and we're running broad basket studies over many solid tumors and expect opportunities to pick from those data sets into pivotal studies in the near term.

The longer-term bucket was aiming to turn cold tumors hot, and we have invested in numerous platforms there, which combine with PD-1 for avelumab such as cancer vaccines, oncolytic viruses, antibody drug conjugates where we have Phase 1/2 studies

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with PCSK7, or nano-particles loaded with various immuno-targeted agents, and finally by functional antibodies.

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

Thank you, Mikael. That's a comprehensive review. And of course, immuno-oncology is one stool of our oncology platform, because we're both in - we're in breast, we're in targeted agents, we're in prostate cancer. And so I think we have a very robust overall strategy.

I would like to point out that while we are behind in lung, our expectations are we have two important readouts, one this year and one later on, which is in - we have a very creative design. Let's see what the results are in lung and how positive it can be. We haven't in any way given up in our attempt to participate in that large market. Thank you very much.

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

Thank you, Ian and Mikael, next question please, operator.

**Operator**

Your next question comes from Jeff Holford from Jefferies.

**Q - Jeffrey Holford** {BIO 4872636 <GO>}

Thanks very much. My first question is just on the second-generation Ibrance product that you have. There are very specific resistance mechanisms that you're identifying within Ibrance patients, and I wonder if you can just talk a little bit about those and how this circumvents them.

And then the second big-picture question, obviously you guys have looked at a potential separation of the Essential Health business. In the past, you did talk about a number of factors that influenced that decision, not that you didn't (46:50) before. I'm just wondering if now that we have the tax reform in place, whether that potentially influences that decision going forward and when you might next look at that again. Thank you very much.

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

Thank you, Jeff. I'll ask Albert - sorry, Mikael, to discuss the second generation, as you've named it, for Ibrance agents.

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Yes, thank you. We have two current approaches to deal with resistance to CDK and breast cancer. We are starting this quarter, as our plans are, with a second-generation CDK drug, and that's based on unique proprietary science that we have performed to identify resistance mechanisms that can occur related to the cell cycle. And we look



forward very much to start that in breast, and it has also application outside of breast as a resistance mechanist.

And the second resistance we have noted is related to targeted polyps with PS3K (47:55). And we have a Phase 1b study with a unique inhibitor, gedatolisib, and have seen so far encouraging data and are expanding those studies.

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

Thank you. Why don't we go to Frank for the discussion of the separation?

**A - Frank A. D'Amelio**

Yeah. So, Jeff, on optionality, if you'll recall, we have laid out four questions. So was the business performing well inside the company? Will it continue to perform well? On a standalone basis, was there trapped value, and can we unlock that trapped value in a tax-efficient way? So let's focus on questions three and four.

With tax reform, question four is yes. To the extent that there's trapped value, we believe we would be able to unlock that trapped value in a tax-efficient way. But let's really zoom in on question three, which is, is there trapped value. When we announced we're looking at optionality, specialty pharma valuations had price/earnings multiples that were 20-ish. If you look today, they've been cut roughly in half. So we really don't see any trapped value. So our current view is for the foreseeable future, the key for our Essential Health business is execution, to really get that business humming, to deal with our sterile injectables, continue to grow biosimilars, to continue to grow in emerging markets, and continue to manage our Peri-LOE products as effectively as possible. So that's our view for the foreseeable future.

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

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

**Operator**

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

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

Hi, good morning and thanks for taking my questions. First, just wanted to get your guys' perspective on 2018 M&A valuations that are getting paid. I think investors and even company management teams have been vocal that the valuations have been pretty lofty. So just curious to get your perspective on the valuation. It certainly seems like a seller's market.

And then secondly on Xtandi, can you comment a little bit year to-date 2018 the dynamic between the PAP and the co-pay foundations? I realize you have no line of sight into the co-pay foundation, but potentially you have a line of sight into the PAP. So just wondering

if the patients are being funneled in a way that will improve revenue recognition or revenue generation with Xtandi patients in 2018. Thanks.

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

Well, vis-à-vis the valuations, every deal is a deal-by-deal. So it's very difficult for us to assess the value transactions on deals because it's not clear what the opportunities with the specific assets and researching capabilities companies have when they pay for these assets. They would appear to be in terms of P/E and multiples lofty prices, but once again, everybody does their own deals and every deal is specific. So we will continue to look for value in the BD space. And when we find it, we have the capability and the capacity to operate on it.

With that, I will ask Albert to discuss the issues around the dynamics.

**A - Albert Bourla** {BIO 18495385 <GO>}

Dynamics, yes. Jason, look, I have no visibility on what is going on in terms of co-pay foundations. I know because we have made it publicly available that we are contributing. But I'm not aware of the amounts that we are giving by quarter or by month because we have established very strong, let me call it, Chinese wall between our commercial operations and the groups that they are contributing to these foundations.

What I know, it is only how many people are enrolled in the commercial free goods, which is the Patient Assistance Program, and this is what I've said before. In the fourth quarter, it was the same more or less amount percentage-wise as we had in the third quarter. And from the first indications that I can see how many are enrolling in 2018, I expect this number to be lower in 2018 than in 2017.

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

Great. Thanks, Albert. Next question, please.

**Operator**

Your next question comes from John Boris from SunTrust.

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

Thanks for taking the questions and congratulations on the solid results. So, Ian, just going back to the question on M&A going forward, I think you previously mentioned that you essentially wanted to take a pause on large-scale type of M&A until tax reform was in the rearview mirror and how things shook out on repatriation. I think you've also provided some commentary that there were some significant binary events that would have to occur going forward also for consideration on larger-scale M&A. Just wondering how the tax outlook shapes that view going forward.

The second question on tax, tax rate goes down by 500 basis points. Can you just walk us through the pushes and pulls of what's going on with the international subsidiaries that

caused that 500 basis point contraction, and then why the tax rate wouldn't continue to go down as you do, and certainly how does that influence your tax planning going forward?

And then last question just on tafamidis, cardiomyopathy and the trial potential read-out, what do you potentially expect out of that? Is there a potentially mortality outcome out of that? And can you contrast the drug with Alnylam and Ionis's drugs that are being studied in that area? Thanks.

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

Okay. So on M&A, I think we've been reasonably consistent over the years when we discuss M&A to say that we had the capacity before tax reform to do M&A. In fact, we attempted to do two large ones, which were thwarted by government interventions. So the tax reform was really more important from the point of view of M&A, from the point of view of how you would finance a deal or what the relative values of companies would be. And I expect to see some changes in that as some premiums for previously established tax advantages for certain companies disappear. But it doesn't really change our underlying focus of how we look at M&A and how we look at the disposition of our capital that Frank talked about earlier.

So we'll continue to look at M&A from the point of view of value for our shareholders, and we'll be directed by the science and the opportunities. And we'll also look at opportunities across the other spectrums, which is the dividends and the buybacks and investment in the business. So I think it's really the continuation of a very thoughtful, I believe from the point of view of Pfizer of deployment of capital. Frank, do you want to answer the tax rate, please?

#### **A - Frank A. D'Amelio**

Sure. Yeah, and John, let me run the numbers just to ground everybody. So we had guided this year to approximately 23%. Now obviously, we're giving guidance for next year of 17%, so approximately a 600 basis point decrease in the tax rate year over year.

Now in terms of the going-forward rate, I had answered earlier that for modeling purposes we should assume that that 17% - approximately 17% was sustainable. And you asked me about the international impact with our subsidiaries. At a macro level, the way to think about this is, we do business in over 150 countries. Every country obviously has their own tax structure, their own tax rates. A slug of our business is outside the U.S. A major part of our business is inside the U.S. The new corporate tax rate going forward is 21%. On overseas earnings, we have now a territorial system, but with a minimum tax of 10.5%.

When you do all the work and all the tax planning and we work through everything, the blended rate gets us to that approximately 17% that I alluded to. So going forward, you all should expect us to sustain give or take a 17% tax rate.

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

Mikael, do you want to take on the tafamidis question, please?

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Sure. We have a tafamidis study for cardiomyopathy. As you know, the drug is registered in Europe to deal with what's called TTR Amyloid Polyneuropathy. This study in cardiac condition is 400 subjects and the first and largest study in this important segment, including both patients with mutation and a large population with excess of amyloid but no mutation. We expect readout first half of this year. And pending the data, we will then consider further potential regulatory action.

It's of course the first of its kind in this rare disease, so there is high risk but also very high upside given that this is a much larger population than neuropathy and there are very few treatments. This is (57:06) drug and differed from injectables such as oligonucleotides that you referred to. We look really forward to the readout and to review it.

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

Thanks, Mikael. Next question, please?

**Operator**

Your next question comes from Gregg Gilbert from Deutsche Bank.

**Q - Gregg Gilbert** {BIO 3565226 <GO>}

Thank you. First on the Innovative side, for your new JAK, can you talk in some more detail about how you'll develop it and differentiate it versus Xeljanz over the longer term and versus other JAKs in the space?

And then shifting over to the Essential side, just questioning whether your manufacturing and supply chain network is where it needs to be there. It sounds like you've described that as more a fixing legacy problems versus investing new capital. Can you shed some more light on the strategy there? Is it a set of extensive band-aids, or is it a fundamentally new approach to have success on the Essential side?

And lastly, what do you plan to do with your own biosimilar version of Remicade, which would presumably be more profitable than the Celltrion version? Thanks.

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

Gregg, thank you for the questions. It's good to see lots of questions on our pipeline as it comes into focus. Mikael, would you like to talk about the JAK-1 and the JAKs?

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Yes, thank you. So we have six next-generation immuno-kinases, including five oral. And they have been uniquely designed to go into areas where we think the first generation of JAKs such as Xeljanz is less optimal. And while we're very excited about Xeljanz's strong

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performance in RA and its possible further expansion into ulcerative colitis, we have a JAK-1, as you noted, went into Phase 3 for atopic dermatitis and have a unique profile for that. We have two JAK-1 that is targeted to the mechanism of psoriasis and Crohn's, which is colitis. We're JAK-3 selective into RA. And in derm, we look at interesting conditions such as alopecia, where two of these JAKs, again, are uniquely targeted.

So the whole story is to go into other areas where Xeljanz may not be fully optimized, while we think we can grow Xeljanz in rheumatology and select segments of GI, but now we target broader diseases within derm, GI, then beyond Xeljanz. So we hope to expand the opportunity for JAK and obviously also plan for life cycle management on Xeljanz.

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

Thank you, Mikael. So in reality, we believe from the science of the JAKs we've been investing in for over 10 years, we can bring significant relief to specific patient segments with the specificity of the JAKs that we've developed. And this will be the backbone of our strategy and our competitive advantage, so that's very good. Now I'll go to - I'm going to ask for the biosimilars and also...

**A - John D. Young** {BIO 16960082 <GO>}

The manufacturing.

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

Okay, please go ahead, John.

**A - John D. Young** {BIO 16960082 <GO>}

So thanks for the questions, Gregg. So look, as Ian mentioned in his comments, in the Essential Health portfolio, we've obviously been experiencing some supply shortages with some products. The shortages are primarily for products from the legacy Hospira portfolio. And as Ian said, they are largely driven by capacity constraints and technical issues.

Let me just make a comment and say that obviously, as we've said before, during the Hospira acquisition, we were aware that there are manufacturing issues that were confirmed during the due diligence process. But we have a robust action plan in place, and we believe it will only progress during 2018 towards reducing sterile injectable shortages, and that will include investing capital in those specific plants.

Turning now to our own infliximab biosimilar, IXIFI, as you know, Inflectra's existing marketed infliximab biosimilar is currently available in the U.S., and it will continue to be available to patients and physicians. Although we're very pleased with the U.S. FDA approval of IXIFI as the first Pfizer developed biosimilar in the U.S., Pfizer doesn't currently plan on launching IXIFI in the U.S., and we're evaluating our strategic options for this product.

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

Thank you, John, next question, please.

## Operator

Your next question comes from Jami Rubin from Goldman Sachs.

### Q - Jami Rubin {BIO 1527982 <GO>}

Thank you. Ian, I think in the past you, as an industry leader, have spoken about the inevitability about industry consolidation. Today's news about the Amazon partnership, consistent pricing pressure, the Hillary tweet, I think that's when you started talking about it, but we really haven't seen it. And the last wave of large-scale deals was back in 2009. And today on the call, you're saying that there's less reason to do a tax deal obviously because of tax reform, and the spin is probably off the table now because you don't see trapped value.

I'm just wondering if you still see value and industry consolidation from synergies and scale. That is something you really haven't touched upon. And if you do, do you see Pfizer as a consolidator as you've been in the past, or do you think you will continue down the path of smaller-scale BD activity? Thanks very much.

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

Thanks, Jami. I do believe that given the pressures that are being applied by the consolidation in the payer network and the pressure there that exists on governments to find ways of curtailing overall healthcare cost, although I'm optimistic that actually drugs will play a bigger part in that as being very cost effective, I do believe there will be a need for further consolidation to deal with the size of our customers and the size of the opportunities.

I think these things come in waves. I think everybody is looking at potential combinations and consolidations. I can't tell you when it will start, but I believe there will be moments when there's a key detonator to initiation of further consolidation. I would say we have a core competency in consolidation of large companies into Pfizer. If there is an opportunity for shareholder additional value consolidation, I expect that Pfizer would be at the forefront of it. At the same time, we would also be looking at deals of different size. We never say never to big deals, but we also say we think we have the capacity to do both the small deals and the big deal when the moment arises.

And we also - by the way, I'm just getting some flags here from Frank. I think that we don't feel any pressure to immediately do any type of deal in the sense that we've just had a very good year in 2017. We're going to have a good year in 2018. We have very good franchises. We're focused on developing our own pipeline. That being said, we are opportunistic in looking for intellectual property that we can buy and do better than the present owners. We continue to look at that. And so I'm very optimistic about our hand and all the arrows that we have to fire in our arsenal. Thank you.

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

Thank you, Jami, next question, please.

## Operator

Your next question comes from Andrew Baum from Citi.

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

Thank you, a couple of questions, please. First for Ian and Albert, despite the rhetoric that the U.S. administration (1:05:10) to the industry given your last (1:05:15) on 340B hospitals, the proposal for PBMs to part from rebates, and you made the right action on drug pricing, (1:05:24) together with the new head of HHS administrator's comment, I'm just interested how you quantified the risk or whether you think it's more noise. Does it impact how you look at M&A valuations and such that you believe there is risk, are you more concerned of drugs under pharmacy versus medical benefits? That's my first question.

The second question is whether you could comment on the market pricing dynamic for pneumococcal oncology given the density in those areas for PARPs and PDK-4/6s, when you think that pricing is going to come under much more pressure than maybe we should be thinking about?

And then finally for Mikael, could you talk to Pfizer's biomarker adoption beyond PD-L1, particularly human mutational burden and how you're implementing that within your oncology programs? And you might like to comment on your foundation's recent relationship. Thank you.

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

Andrew, thank you for those three questions, all very powerful and all very extensive. I think on the question of the pricing risk, this industry has for decades had a pricing risk present in its commercial business. And in fact, we've highlighted that in our 10-Qs and things like that.

So I don't see that the pricing risk has dramatically changed from where it was 10 years ago or 5 years ago. I believe that we need to be in a constant dialogue with society and with payers and the government over the value of pharmaceuticals. I think that dialogue is ongoing with both the administration and Congress, and I think the dialogue is being informed by facts. And we are looking for ways, as you mentioned, to lower the cost, out-of-pocket cost for patients. The fundamental problem is not, I believe, the pricing of products because to be able to fund and run a modern innovative pharmaceutical company at a certain level of resources is necessary. Unless we see a breakthrough in innovation and a breakthrough in the process, this is the cost of bringing products to market.

The question is does society want to continue to support that innovation? I think the answer is absolutely yes. The next question is how will society ensure access to those products, so this is really about how you ensure people. Do rebates get to the point of sale where we think they ought to be? How do you make drugs affordable? Right now, the

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system is set up perversely to transfer the costs of lowering premiums for healthy people onto sick people. I don't think that's a good policy, and we're in discussions with the government to change that. So I think this pricing risk is reversed. I think it remains reversed, and it's a constant issue that the industry needs to deal with given the nature of the marketplace.

On your question about the density of small molecules, to a certain extent I would apply that to the density of PD-L1s. I don't think it's specific to small molecules. I think the pricing always rests on the value the products bring to the society. And we will continue to develop innovative products that have differences to competitors, and we will expect to earn a reasonable return on those products.

So there was one other question on the PD-L1. Mikael, do you want to talk to that?

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Yes, I'll be brief. We started with PD-L1, which was the initial most frequent used and for some tumors like lung useful biomarker. We are now assessing tumor mutational burden. Clearly, you have good insight into this field, and our innovation that we will see in the future status to start maybe even a combination of PD-L1 and TMB exploratory markers include immune cell subset, T-cell repertory sequencing, and then combination drug specific choices.

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

Thanks, Mikael, next question, please?

**Operator**

Your next question comes from Tony Butler from Guggenheim Partners.

**Q - Charles Butler** {BIO 1504193 <GO>}

Yes, thanks very much, two questions, please. One, Mikael, first on renal cell carcinoma, you've got a very interesting trial with Inlyta. Obviously, there will be an IO/IO combination I suspect in the market by the time your trial reads out. But I'm most interested in whether or not you think that Inlyta or a tyrosine kinase inhibitor actually improves the synergy with Bavencio.

And then second, still within oncology, if I might ask, clearly a little bit of euphoria around the CAR-T space, and I recognize you all have an interest in an off-the-shelf version with Cellectis, I'm just curious if you might comment yet again on whether you're ramping up some efforts there.

And then finally, Frank, once again on taxes, if I may, LOEs are diminishing. You've clearly stated that your U.S. business is doing extremely well, disproportionately, I might add. So the U.S. percentage of your total business increases, and again, I have to ask. Given those,

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unless there's something which we totally miss, why doesn't again tax change certainly out in the future beyond 2017? Sorry for that, but thanks.

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

Okay, I'll ask Mikael to address your first question.

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Yes, we do think that combining Inlyta with Bavencio is a really unique combination for renal cell carcinoma, and the data as reported were really impressive. And at least to me, I believe it stands out among the absolutely best seen thus far.

Inlyta targets the micro environment as a VDF inhibitor, so I think it has unique position. And we view it currently as really promising and a preference for us than adding more immuno-oncology agents, as we see a very high response rate. And we look really forward to the readout that will come within the next 12 months or so from this study.

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

Thank you. On the question of CAR-T, we have seen the explosion of interest. We do have an off-the-shelf version, as you say it, which we're developing with Cellectis. We are currently looking at our strategy of how to ensure that that product can get to patients in the most rapid and effective way, and we'll be looking at our strategy around CAR-Ts. And the last question...

**A - Frank A. D'Amelio**

Yes, on the tax rate. So, Tony, in terms of the overall business, if you look last year, 2016, roughly 50% of our revenues were in the U.S., 50% of our revenues were outside of the U.S. If you look at 2017, about 49% of our revenues were in the U.S., about 51% were outside the U.S., so not a lot of change, but with a little bit more pointed towards the international part of the business.

When we put all of that together and we look at where the mix of our business is, when we look at the countries we do business in, where we manufacture our products, where we ship from, I'm currently comfortable with the 17% and my statement about sustaining that 17% beyond 2018.

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

Thank you, Frank, for covering that, next question, please.

**Operator**

Your next question comes from Chris Schott from JPMorgan.

**Q - Christopher Schott** {BIO 6299911 <GO>}

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Great, thanks very much, just two questions here. Maybe to come back to business development, I know the return seems to be there. You've highlighted you're agnostic to size. But given where the business and the pipeline stand today, I guess ideally, what are you trying to achieve as you're thinking about BD? Is it focused on enhancing near-term growth? Is it more about long-term growth? Do you want to stay in your existing verticals? Do you want to add verticals? I'm just trying to get a little bit more of what the strategic priorities are as you consider deals before we think about the financial terms associated with them.

And my second question was just on the Prevnar outlook for 2018. Are we still expecting the U.S. adult business to be under pressure? And can growth elsewhere in the franchise start to offset that erosion as we think about the 2018 outlook? Thanks very much.

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

Thank you, Chris. On BD, we look across the spectrum of BD from near-term to long-term. Clearly, if assets were available at appropriate valuations, we would have a preference for short-term acceleration in our revenue growth and our EPS growth. On the other hand, if there's availability of a different deal which also produces value although it might take longer; i.e., from consolidation and things like that, we would also be interested in that and continue to look across that spectrum.

I think we are well positioned. We can be considerate in the options we look at, and we do have a certain sense of urgency to find deals that would accelerate our revenue and EPS growth. With that, we'll go to Prevnar. Albert?

**A - Albert Bourla** {BIO 18495385 <GO>}

Chris, you're right. We do expect that there will be pressure in the adult sales in the U.S., which would be less as the product is coming more to a stable state. This will be offset by higher pediatric sales globally. And we do not provide guidance for specific products because this is already incorporated in the guidance that Frank gave. But I can tell you in general terms that Prevnar will be roughly flat in 2018 compared to 2017.

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

Thanks, Albert, next question, please, operator.

**Operator**

Your next question comes from Tim Anderson from Bernstein.

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

Thank you, a couple questions. Can you talk about how you see your international sales of Enbrel evolving from here as we move into 2018 relative to what we saw in 2017, further levels of price erosion, volume loss, and that sort of thing? In 2017, sales were down about 15% versus the prior year. Is that the sort of contraction that you expect we'll see in 2018 as

well as future years beyond that, so maybe 15% per year? I'm trying to understand what your long-term modeling shows in the setting of biosimilar.

And then second question, there's continued - or I should maybe say renewed interest recently on the topic of whether PD-1s and PD-L1s are the same, with the argument being that PD-1s might offer better efficacy because of mechanistic differences, I'm wondering what Pfizer's current view of this debate is.

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

Okay, Tim, on Enbrel, thank you for the question. As you know, we don't give product-specific forecasts, but I think the range as you described in your opening commentary is aligned with our internal thinking about the way that franchise will be managed over the future. PD-1/PD-L1, Mikael?

**A - Mikael Dolsten** {BIO 16368411 <GO>}

I would start to say that we have a unique situation that we actually have one PD-L1, Bavencio, and one PD-1. And the PD-1 is right now in studies with our cancer vaccine, very well behaving that has potential for sub-cu monthly administration.

On the other hand, we're very pleased with our PD-L1 that is more advanced. And we monitor carefully what you said, whether there are any new data that would indicate under certain specialized settings that one would be better than the other. But in the big picture, I think they look pretty similar overall within these two classes.

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

Thanks, Mikael, next question, please.

**Operator**

Your next question comes from Marc Goodman from UBS.

**Q - Marc Goodman** {BIO 1853567 <GO>}

Yes, good morning. I have a couple questions. First, Albert, in the past, we've talked about as the new competition have come in with CDKs, whether you had to take any price. And I was curious whether you've had to take any price now that there are three in order to maintain the dominant share that you have.

The second question is Consumer. If you could, just refer to the U.S. business, and it seemed a little weak in the quarter.

And then third question, tanezumab, you talked about six Phase 3 studies. Can you tell us how many you're expecting to actually report out this year? Thanks.

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

Okay, Albert, if you want to take the Ibrance and the Consumer?

**A - Albert Bourla** {BIO 18495385 <GO>}

Yes, Marc, so far despite the pressures any incumbent product faces when multiple competitors enter the market, we have not seen any material impact on Ibrance's performance. We believe the positive results from the other CDK inhibitors demonstrate the significance of CDK inhibition and will benefit the class overall. It's important to remember that almost 60% of newly diagnosed patients are receiving a CDK, but only 50% of the total population, so that demonstrates the potential to grow the class. Within this class, we remain very confident in Ibrance leadership based on the strength of the data, efficacy, safety profile, and that can go on and on.

Importantly, you know that there is no clinical relevant QT prolongation with Ibrance that was observed across the PALOMA trials. There is no requirement for ATG or hepatotoxicity monitoring in the current prescribing information. There is no requirement for monitoring the signs and symptoms of thrombotic events or precautions. So we feel that three years in the market with this, as we said, very large markets there, 11,000 prescribers, more than 100,000 patients, we feel we are very strong with that.

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

And I believe on the value we're receiving, it remains consistent with our previous years' experience and have not seen any undue pressure due to the competition on our pricing given the profile that Albert just described for Ibrance. Consumer's performance?

**A - Albert Bourla** {BIO 18495385 <GO>}

Yeah. Consumer, Frank spoke about it. We had 2% growth, and this was affected mainly by the U.S. The U.S. was declining 2%. And in the - excuse me, in the fourth quarter we were declining 2%. And in the U.S., what drove this decline was minus 8%. And the reasons are, first, the negative impact of Hurricane Maria in Puerto Rico, but also the U.S. were impacted by Nexium OTC LOE that happened in this quarter. As Frank emphasized, this business is performing at 5% every year in the last three years, and we are hoping to see it coming back to this level of performance this year.

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

Okay. Mikael?

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Yes. So we'll have the first, the short, the 16-week efficacy trial reading out this fall, followed by the slightly longer 24-week, 56-week, and safety trials in OA and chronic lower back pain for the U.S. and EU markets reading out the first few months of 2019. And that will really constitute the data package for potential filing consideration pending data for the major markets. And then we have other smaller studies for Japan and cancer pain later on.

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

Great, thank you. Next question, please?

## Operator

Your next question comes from Steve Scala from Cowen.

### Q - Steve Scala {BIO 1505201 <GO>}

Thank you. I have a few questions. On Ibrance's EU price, could you give us examples of the pricing analogs to which you're referring?

Secondly, Pfizer had been saying that Essential Health would return to growth in a couple years. Now that Viagra U.S. is in Essential Health and presumably Lyrica U.S. will be moving over in the future, how does this affect Essential Health's return to growth timing?

And then lastly, Inflectra U.S. increased \$10 million quarter-over-quarter, or a bit less than 1% of market share increase. Is that the trajectory we should be expecting going forward, or should we anticipate some sort of inflection? Thank you.

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

Thank you, Steve. I don't really - for proprietary reasons on pricing, I don't want to get into analogs. I would say that we are satisfied in the European context of the reimbursement price we got. It was very hard negotiations, but in the end, patient access was important as was the reimbursement price. We think we arrived at a fair compromise on that, and we think we have a basis for vibrant growth at an appropriate price for Ibrance in Europe, and I think that's the most important thing to look at there. John, would you take the other questions?

### A - John D. Young {BIO 16960082 <GO>}

Yes. So thanks for the questions, Steve. So we have consistently said over the last two to three years that we expect the Essential Health business to return to growth in the medium term. And actually, that remains our view that actually, as the headwinds from major LOEs and the portfolio that currently sits within PEH begin to lessen, and we're seeing, for example, in 2017 the impact of LOEs were something like \$1.4 billion in this business, expect that that will shrink to around about \$900 million in 2018 given the portfolio, combined with the continued growth of emerging markets, combined with the continued growth of biosimilars. So when you put all those things together, we continue to expect that actually in the near term that actually Essential Health is poised to deliver modest single-digit growth. And we still feel that that is a sustainable pattern of growth for this business.

In relation to Inflectra in the U.S., let me just say, first of all, Inflectra globally had revenues of \$135 million in the quarter. That was a 110% increase or \$70 million or \$68 million growth, and actually a \$41 million increase in the U.S. So whilst we've commented in answers to some other questions about some of the challenges in terms of access due to J&J's exclusionary contracting, we expect to continue to make progress in the U.S. with Inflectra in the course of 2018.

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

Great. Thank you, John. Next question, please?

## Operator

Your next question comes from Umer Raffat from Evercore.

**Q - Jonathan Miller** {BIO 19999837 <GO>}

Hi, guys. This is Jon Miller on for Umer. A couple of questions. At JPMorgan, you showed an interesting slide titled the Step Change in Pfizer R&D Productivity. The number one thing on that was IO/IO combinations. So how do you think your internal IO/IO portfolio measures up against external? And have your thoughts changed based on the early results from JAVELIN Medley?

Secondly, Frank, the 17% tax rate going forward, is your expectation that the non-GAAP tax rate is going to be consistent with the cash tax rate?

And last, I noticed you guys have an oral GLP-1 in Phase 1. Are you looking at that more in diabetes or in NASH?

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

Okay. I'll ask Mikael to answer the question on research, and then Frank will answer the tax question.

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Thank you for noting our (01:26:08) subject to attrition that's typical in development, blockbuster projections for the next five years. As you noted, it contained actually five opportunities in oncology. And the first one included BAVENCIO mono and combos for IO/IO. And we clearly continue to be positive about BAVENCIO's quality PD-1, and Ian alluded to certain trials coming up soon. And we follow with significant interest the triple combo with OX-40 and 4-1BB. We also, as I spoke earlier to have numerous pivotal study readouts with combinations of chemo and targeted agents and actually more than 20 of such combinations overall in the portfolio. So I think there is ample opportunity for us to make very valuable contribution in this field through IO/IO targeted and chemo combinations, and that's a very important part of our strategy.

**A - Frank A. D'Amelio**

On the GAAP tax rate versus the 17%, the 17% obviously is an adjusted results tax rate. The GAAP rate versus the adjusted, we'll see fluctuations quarter to quarter based on the accounting that we're doing for various items. Every quarter we typically have significant items, some positive, some negative. For example, this quarter we had a hugely positive significant item, which was the reversal of \$10.7 billion in primarily U.S. deferred tax liabilities, which caused an incredibly negative tax rate. So there will be volatility, there will be fluctuations from quarter to quarter with differences between GAAP and adjusted results, as there has been in the past.

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

And, Mikael, just on the GLP-1?

**A - Mikael Dolsten** {BIO 16368411 <GO>}

Yes. Thank you for noting that. We are really excited about this (01:27:57) GLP-1 small molecule we think may be the first, a real small molecule nature to be in human studies. And we look upon initial opportunity in NASH and (01:28:08) risk factors such as obesity. But certainly, we look at this profile also for treating diabetes, where this drug class has been so successful as injectable. And of course, an (01:28:25) drug with a unique profile seems very attractive across the entire metabolic spectrum.

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

Thank you, Mikael. And we'll take our last question now, please.

**Operator**

Your final question comes from Seamus Fernandez from Leerink.

**Q - Seamus Fernandez** {BIO 7525186 <GO>}

Thanks very much for squeezing me in here, so just a couple quick ones. Ian, can you just give us your big picture thoughts on Eliquis and its overall opportunity? Growth continues to be pretty spectacular given where this product is in its life cycle. Just wondering if you think given where we are in the developed world in terms of global markets overall, if this could possibly exceed Lipitor sales at peak

The second question, as we think about your pricing analogs and the discussion around international pricing of Ibrance, is it wrong to think that this may in fact anticipate success in the adjuvant setting so that there wouldn't be another step down in pricing as that patient population grows substantially?

And then the last question is on the PARPs. As we think about the opportunity for talazoparib, what is Pfizer doing in prostate cancer given some early data there for a combination of with talazoparib with Xtandi? Thanks so much for the questions.

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

Thank you. I'm going to let Albert in his capacity as Chief Operating Officer answer the Eliquis questions and the pricing on Ibrance, and then Mikael can answer tala questions. Thank you.

**A - Albert Bourla** {BIO 18495385 <GO>}

Let's start with Eliquis. Yes, we are very optimistic for Eliquis. We expect that growth will continue. The next leg of growth will be driven by increased NOAC penetration of the OAC market and increase Eliquis share gain of the class, or non-class.

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And this sort of gain is expected to be achieved by increasing focus on the following strategic initiatives. We are going to accelerate markets that are gaining with the market, and those markets will have achieved a leadership position in the risk reduction already. For stroke systemic embolus, we are going to generate and utilize local real-world data to seek preferential access for Eliquis, and we have a very good demonstration of this value so far with the first studies that we have performed, that they are getting the attention of payers. And of course, we are going to increase diagnosis of the NVAf patients in those markets who have achieved already a leadership position in risk reduction of stroke. So the news are very, very positive.

#### **A - Mikael Dolsten** {BIO 16368411 <GO>}

Concerning, talazoparib, we are very excited about that drug profile. You noted our report of the EMBRACA trial in breast cancer, where we had a nice superiority to chemotherapy and a very favorable profile. So we are looking forward to additional readouts for talazoparib and investment in the drug. And we have two prostate cancer studies, one that was recently initiated in combination with enzalutamide or Xtandi in a select subset of prostate cancer. And we also have a more advanced prostate cancer, an open single-arm trial that could be of potential pivotal character. And then we have invested significantly in combination with Bavencio for what we think will be a number of different tumor types. So I look forward to continue the dialogue as we advance what I think is a potential best-in-class PARP inhibitor.

#### **A - Frank A. D'Amelio**

Thanks, Mikael. We'll just go back to Albert for another comment.

#### **A - Albert Bourla** {BIO 18495385 <GO>}

Yes, because I forgot to mention - to answer your question about Ibrance. First of all, I cannot say it will be bigger than Eliquis, but what I want to say is that this is an extremely appealing opportunity for us. And a big part of the opportunity, as you alluded, comes from advancement of Ibrance into the early settings of treatments.

We have three studies that are related with or linked to our Phase 3 studies. And it is PENELOPE that is in high-risk early breast cancer, and that will become available towards the end of 2020. And the other one, it is the PALLAS that it is with intermediate-risk early breast cancer, and that will come a little bit earlier, in the third quarter of 2020. Of course, also we have PALLET.

In its totality, the early breast cancer represents a very big opportunity because virtually the number of patients is more than double. And also, the economic, the financial opportunity is larger because we have much longer duration of treatments. I don't think that - it's early to speak about pricing, as you alluded, because those are coming in the 2021 timeframe for negotiation with payers.

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

Thank you, Albert. So the pricing analog of your question of whether the overall survival data that come matures in Ibrance will influence the pricing in Europe is a good question,



but one that really is relatively remote. It's going to take three years to get that data. And assuming the data is positive, I would expect us to relook at the value of Ibrance. And if it was negative, which is very difficult in this type of long, long, long, long disease progression to get any really accurate information, I would expect that the use of Ibrance will be very well entrenched in the pattern of treatment by physicians by that time. Thank you.

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

All right, thanks and thanks, everybody, for your attention.

**A - Frank A. D'Amelio**

Thanks everybody. Thanks for your time.

## Operator

Ladies and gentlemen, this does conclude Pfizer's fourth quarter 2017 earnings conference call. Thank you for your participation. You may now disconnect.

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