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# EDITED TRANSCRIPT

PFE - Pfizer Inc at JPMorgan Global Healthcare Conference

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## CORPORATE PARTICIPANTS

**Albert Bourla** *Pfizer Inc. - CEO*

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

## CONFERENCE CALL PARTICIPANTS

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

## PRESENTATION

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

Good morning, everybody. I'm Chris Schott, pharmaceutical analyst at JPMorgan, and it's my pleasure today to be hosting a fireside chat with Pfizer. From the company, we have Albert Bourla in his first presentation since becoming the company's CEO as well as Mikael Dolsten who's the head of the company's R&D organization.

Before I kick off, I do want to mention this housekeeping item, we will not be having a breakout session after this. So we're just doing the fireside.

## QUESTIONS AND ANSWERS

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

And with that, maybe first question for Albert, given this is your first major presentation to investors as CEO, maybe share your vision of the growth potential for Pfizer and what we can expect under your leadership.

**Albert Bourla** - *Pfizer Inc. - CEO*

Thank you, Chris. Happy new year to all. I hate doing that, but before I start, I would like to remind you this presentation may contain forward-looking statements. Please see our SEC filings. They made me do it.

Before I go into what has changed with Pfizer, basically, let me remind that myself and Mikael, as others, we were pivotal members of Ian's leadership team. So everything that happened during Ian's period happened for a reason and happened with us setting a big part of it. Things are changing in Pfizer now but not because the leader is changing. In fact, things are changing because the previous leader was very successful. Things are changing because the situation is very different. When Ian took over in 2010, Pfizer was facing the largest, the biggest LOE challenge in the history of our industry. Our revenues in 2010 were \$62 billion. And 5 years later in 2015, we're down below \$50 billion. At the same time, the productivity of our structural organization, the first decade of the millennium, was not that strong. So as a result, what was coming in was not enough to offset what was going out, so thus, the big decline, the steep CAGR decline. I'm fortunate now that I'm taking over a very different situation. In fact, the exact opposite. We are about to face the last LOE challenge, that will be the Lyrica LOE, in 6 months at the end of June. And following that, we have a virtual LOE-free period until 2026. There is a very small one in the middle of that period but will not move the needle. So Lyrica will affect this year's growth because we will have half-year LOE compared to no LOE in '18 and will affect 2020 because we will have no LOE compared to half-year -- full year LOE, excuse me, compared to -- in '20 compared to half-year LOE in 2019. But at the same time, we had a very good productivity in the second decade of this millennium in terms of R&D. And right now, we feel that our pipeline is at the best state we ever had. So the combination of those 2, we think, will position Pfizer plus Lyrica LOE into a very strong top line growth company.

I don't underestimate the challenges, but there will be, of course, headwinds like the pricing pressures that the entire industry is facing. But bottom line, I believe that in this new environment with price pressures, companies that will be able to deliver breakthrough medicines that society needs still will thrive. Those that do not, likely will struggle.



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So with that in mind, the new name of the game for Pfizer in the years to come is top line growth, and I would like to remind everyone 2 things that are relevant with top line growth in our industry. The first is that in an industry with this ROIC and in an industry with this type of margins, top line growth can mean only one thing in bottom line growth: leverage. The second thing that I would like to remind is that in the new environment of health care and pharmaceutical market, the only way for a pharmaceutical company to grow top line is to do 2 things: bring breakthrough medicines to patients that significantly improve the current standards of care. Mediocre or incremental innovation is not going to be rewarded the way that it used to be rewarded in the past. The second thing that needs to be done is that we need to reinvent business models so that we can allow access to people that do not have enough. With all of that in mind, our strategy to achieve this top line growth can be simplified into 3 words: innovating for growth. And when I say innovating, I mean both scientific innovation and everything that we need to do to ensure that we bring to the market breakthrough medicines, more than our fair share of our research budget and capabilities. And the second, it is commercial innovation, what we need to do to make sure that we are addressing access, affordability and cost pressures coming from the overall health care system cost. Underneath, of course, will be a lot of subledger details. There are things that we need to do with capital allocation, and I believe, next year, we'll have a very drastic reallocation. We're budgeting to have a very drastic reallocation of our expense base into different areas. We need to organize ourselves in a very different way so that we can maximize the growth potential. We need to make sure that we change the way that we operate so that we can remove bureaucratic processes. Innovation and bureaucracy is like water and oil, they don't mix well together. And of course, we need to make sure that we evolve our culture as an organization from a culture that was managing decline to a culture that can optimize growth.

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

Very helpful. You mentioned innovation. And I know you've highlighted a new kind of drug candidate -- pipeline, about 25 candidates pending, 15 of which could have blockbuster potential. Maybe just elaborate a little bit more, for both Albert and Mikael, just the state of the pipeline at Pfizer today. And within those 25 assets, what are you most excited about that this point?

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**Albert Bourla** - Pfizer Inc. - CEO

Maybe I start by saying what excites me the most, but then I will ask Mikael to add all these details since most of those pipeline is his baby or his babies. I think the fact that most of what makes me comfortable with this pipeline is the fact that it is very diverse and very large. I would feel more nervous if our growth trajectory was based on the success of 1 or 2 franchises. But right now, there are 5, 6 therapeutic areas, but each one of them has significant blockbuster assets underneath. When we put out a list, we say that we have up to 25 potential approvals by 2022. And we said 15 of them, they have blockbuster potential. And we -- speaking about blockbuster potential, we define it as both \$1 billion of annual revenues and they are spread with oncology, with rare diseases, with vaccines, with internal medicine, with immuno-inflammation, and we have also the effectives with the hospital business units that now we have created. So this is what excites me the most. And maybe, Mikael, you can give more specific details in each one of these areas.

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

Happy to do that. Thank you. We are very excited in the organization with Albert's vision and organizing for growth platform for the company and clearly, a huge opportunity with the pipeline and partnering, as we all hear, to add onto it. So for the 2019, we see 3 blockbuster-type approvals in near-term potential. I'll start with tafamidis for rare disease cardiomyopathy transformative drug where we have -- our filing is accepted by FDA under priority review breakthrough status with an action date of July. We have BAVENCIO-Inlyta, the first TKI immuno-oncology combination also in preparation for filing breakthrough designation. And finally, we have a biosimilar bundle with 4 high-value biosimilars that all have potential registration opportunities this year. Three more readouts that relate to the list of the up to 15 in 5 that Albert alluded to this year. Very soon, the next study readouts from tanezumab, our pain drug, followed by JAK1 from our JAK platform in atopic dermatitis. Rivipansel pivotal readout this year also for rare disease. And then next year, we have the big opportunities to expand in oncology, early, nonmetastatic disease readouts for lbrance; in prostate, for nonmetastatic cancer hormone sensitive with Xtandi; and finally, the C. diff vaccine, also big readout next year.



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

Great. So a lot going on. Maybe digging a little bit into very -- maybe for -- on tanezumab, just elaborate a little bit more about how you see that opportunity. It's obviously an unmet need. It's a very interesting profile, but maybe we'll start there and there's a few safety questions we can dig into after that.

**Albert Bourla** - Pfizer Inc. - CEO

Look. I mean, tafamidis -- or tanezumab, I think that the profile of tanezumab, it is a very good one. This is based on what we know so far. We need to wait and see, of course, the results of the remaining pivotal studies. But I think that there would never be a better time to bring to the market a nonaddictive and non-opioid therapeutic option than today. So with that in mind, I think that pending the results and the pending good labels, tafamidis could be a very significant product.

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

When I think about...

**Albert Bourla** - Pfizer Inc. - CEO

Tanezumab could be a very significant product.

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

They both could be significant. When I think about it, it seems like rapidly progressing osteoarthritis is kind of the key concern with this. Can you just give us some color of what you believe would be acceptable rates of that signal as we think about the remainder of the Phase 3 as being unblinded over the next few months?

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

Happy to add to how Albert describes tanezumab as a major opportunity for novel improve benefit to risk treatment of pain and specifically, rapidly progressive OA. And I just wanted to underline that, of course, we learn much more. We have a number of studies coming, but so far, we saw very robust efficacy across all endpoint that provide, I think, very compelling benefit versus alternatives. Every year, tens of thousands Americans are dying because of prescription opioid overdose and misuse, and we spend tens and tens of billions in society because of the impact of those drugs. The rapidly progressive OA was seen in 1.3% of the treated patient. These were treatment advanced patients that were not suitable or had declined from other pain medications and were in a very much urgent need of pain medications. And indeed more than half responded with 50% more reduction in pain by tanezumab. Of those 1.3% that had rapidly progressive OA, actually, the majority of them had mild to moderate radiological change with mainly narrowing of the joint space and the minority had structural changes. So we think that would be a compelling benefit to risk for patients that have few other medications. However, we need obviously to wait for the readout to fully understand the profile, which is coming over the next few months from a number of trials in OA and chronic lower back pain.

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

And so the last question is do you feel you have visibility with FDA when you see the data to understand if you kind of hit the right targets? Or is this going to be some sort of negotiation with the agency depending what we see on that rapidly progressing OA?



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

I think, as always, an agency wants to see the totality of the data. We think the drug, if the profile continues to be as compelling, would be a very important new medical entity in pain treatment, and we think that the way to monitor the things are pretty standard in health care system like standard X-ray.

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

Maybe pivoting to another one of your big growth opportunities, tafamidis. Just talk -- it's great news on the accepted filing. As we think about the launch of this product, help us just set some expectations. This is a product that you feel we should think about launching quickly, or is there going to be an education process and one that kind of a maybe more of a gradual ramp? Obviously, huge end market and longer-term growth opportunity, but just how do we think about the rollout of a product like that?

**Albert Bourla** - Pfizer Inc. - CEO

It's a fair question. The first thing that comes to mind for the rollout of a product like that is addressing a disease that is fatal. People that are diagnosed with this disease, they have life expectancy that it is in few years and is not in 10. I mean, it's 4, 5 years. And the efficacy of the product both in reducing mortality and hospitalization rates was significant and meaningful, not only statistically significant but also meaningful. So that's one. The second that we need to understand, it is that we study more and more of this disease, and the disease, it is a rare disease. It's very clear. Now it is a rare disease that is severely underdiagnosed at the same time, and one of the reasons why it was significantly underdiagnosed was that until now, there was no treatment. I think what brings to mind, it is the example with the ALK mutation and the ALK treatments. The ALK mutation, when the first treatment came into the market, which was Xalkori, was virtually no diagnosis, right? It was maybe 1% to 3%. And it took a lot of time until we bring the diagnosis rate to what it is today, which is in very high level. Virtually 80% of the people, 90% now I think we are approaching, will make a test if they have lung cancer for ALK and the reason was because there is a medication. The good news is that us, as a company, have a very good track record on educating markets and creating markets through the educational efforts. We have done it from Lipitor ages to the ALK coming now. But also, we know that takes time to come straight to your question. So it's not going to be that immediately that the medical habits will change, but I have high certainty that it will change within, let's say, a reasonable period of time.

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

And can you comment on pricing yet for tafamidis? Or is it too early?

**Albert Bourla** - Pfizer Inc. - CEO

I think it is too early. We are looking, in fact, of course, already now, and we are discussing, trying to understand the disease and the value that the medicine will bring. As always, the method that we're using to price our products, it is we price them compared to the value that they bring to the health care system so it's early to go into more specifics.

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

Okay. And one more on rare disease, beyond tafamidis, what should we be watching for next as we think about Pfizer's pipeline in rare disease and gene therapy?

**Albert Bourla** - Pfizer Inc. - CEO

I will ask Mikael to comment and take a bet he will speak about gene therapy? Mikael?

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

Yes, you're right on there. And it's been a privilege working with Albert together to build up Pfizer gene therapy platform that I think is industry-leading from research expert to pharmaceutical sciences and manufacturing that allow us to have an end-to-end capability and be a partner of choice for many companies. We have currently 10 new therapy programs, of which, 3 are in the clinic. Factor IX with Spark is now in pivotal study, and we're generating in '19 early data from the higher dose cohort of Duchenne muscular dystrophy gene therapy and also for factor VIII gene therapy together with Sangamo. And I'm encouraged of what I've seen so far from both of those trials. These are potentially very transformative therapies with a single-infusion approach.

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

So Albert, I know you talked about incremental R&D spend supporting this pipeline. As we think about the near-term P&L, do you see offsets elsewhere within the expense base to help absorb some of this -- the step-up in spend that you've been highlighting?

**Albert Bourla** - Pfizer Inc. - CEO

Yes. And as -- I'm sorry, you've noticed that I made the comment before, but in our operating plan for '19, we will give guidance in a month or so, right, for this year, but we have drastic reallocation of capital. So it's not only what looks on the surface but also what is underneath. So let me be a little bit more specific. We already said R&D will go up, and it will go up because our current pivotal programs are maturing so they are coming to more expensive phases, and many new pivotal programs have started. But although R&D is going up, within R&D, we have a significant control to decline of the overhead expenses. Mikael did a lot of rationalization. We consolidated some resource centers. We focused our efforts in areas that were more productive. So all the increase and even more will come from projects, not from overhead but within R&D. Now to offset the cost of R&D, we try to hold the SI&A. And I say try to hold because normally, SI&A, when you are 1 or 2 years before major launches and before growth period, needs to go up. The way that we try to do it, it is, again -- it's not what is on the surface, but it is underneath. We will have significant increase in direct SI&A expenses and by direct, I mean field forces, DTC, consumer advertising or promotions, all of these efforts that will go up. And we will have significant decrease to at least the same level, if not more, in indirect SI&A expenses. And with that, I mean general, administrative, management, marketing management, sales management, we did significant exercise this year, we restructured significantly the company. We called it organizing for growth. And we called it organizing for growth because I think the fundamental thing in organizing for growth, it is where you're placing your resources if you want to grow. And we significantly increased spans of control within the mid-level of management with all, the entire organization by 2, 3, 4 sometimes increased span of control, how many people are reporting to a manager, which means that we have much more empowered managers because they have much better, bigger role. And it's not only that this creates significant savings but even more importantly I would say, this creates better simplification because when you have a lot of fragmentation and many people need to sit at the table to make a decision, it's of course much slower and more difficult and bureaucratic than if the managers they have much more concentrated roles and there's broader also in the responsibilities. We expect that in '19, this reallocation will be in excess of \$500 million as a result of the reductions that we are doing better. But that all will come in our guidance because, as I said, we are increasing R&D and we are increasing direct SI&A.

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

Just share your views on capital allocation. It seems like M&A has been a big theme so far early this year, but how are you thinking, just given where the pipeline is and where your LOEs are residing right now, how are you thinking about capital allocation and cash deployment priorities from here?

**Albert Bourla** - Pfizer Inc. - CEO

Yes. I feel that we are lucky because we have a very strong balance sheet. And also, we have a very disciplined -- a culture of disciplined capital allocation, and I plan to maintain both to start with, right? When it comes to more details in capital allocation, we know that a growing dividend, it is very big part of our investment thesis right now. It is something that shareholders like and prefer and we are going to maintain this policy. We



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also -- we announced that in 2018, we significantly increased our buybacks, and this is because we -- for 2 reasons. One, we truly feel very confident about our pipeline. From our perspective, increasing buybacks, it is, one, investing in ourselves. And also, even if you see it from the financial engineering perspective, by buying back, we are able to increase R&D expenses without having the whole impact on EPS growth, right, because we are reducing the earnings per share. So that also will continue. And the third one, of course, it is to develop in business development, to invest in business development opportunities. And we will continue aggressively to invest in business development. It is that the need for Pfizer in the next years is different than the need of business development, of type of business development activities in the years before. In the years before, we had an issue with tax. That has been resolved. In the years before, we had an issue with growth so we were looking to buy revenues now or soon because this is what was lacking. Right now, we are not in the situation. Right now, we are in a situation that our R&D is very productive, and I feel that mostly R&D type of deals is what we need to enhance a bit further our pipeline, given that we have higher confidence in our capabilities to do it, given that now we have very good focus on R&D. We have focus on the 6 therapeutic areas. And so the general theme, it is that we are going to invest in bringing Phase 2, Phase 3 and other assets into the pipeline in those therapeutic areas that we know and we master. These are the therapeutic areas because we know will allow us to make fewer mistakes in selecting and will allow us to have better capabilities to develop because we know how to develop those. That being said, we never say never. We do have the ability because of our balance sheet to do virtually any deal that one can think in this industry, but this ability will remain in the next 2, 3, 4, 5. This, we'll never lose it right now in the foreseeable future. But right now, I feel we have a unique window of opportunity to get it right with our pipeline and the new launches, and that's why I don't want a disruptive deal.

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

Excellent. Well, we're about out of time. Thank you so much for the comments, and thanks very much, everyone.

**Albert Bourla** - Pfizer Inc. - CEO

Thank you very much.

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