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PFE - Pfizer Inc at Cowen Health Care Conference

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## CORPORATE PARTICIPANTS

**John Young** *Pfizer Inc. - Group President of Pfizer Essential Health*

## CONFERENCE CALL PARTICIPANTS

**Steve Scala** *Cowen and Company - Analyst*

## PRESENTATION

**Steve Scala** - *Cowen and Company - Analyst*

Representing the Company is John Young, who is Group President of Pfizer Essential Health. John has been with Pfizer more than 25 years, and has held a number of senior global positions across the organization. He's a scientist by training. He began his Pfizer career in the UK as a trainee sales representative, and held various positions in sales and marketing before taking the role of Australia Country Manager and later the UK Country Manager.

Following these experiences, he assumed the role of regional president of Europe, Canada, Australia, and New Zealand for the Primary Care business unit. He was later appointed president and general manager of the Primary Care business, where he led both the commercial organization and clinical development of medicines in key disease areas, including cardiovascular disease, diabetes, and pain.

John is a member of the boards of European Federation of the Pharmaceutical Industry Associations, the National Committee for US China Relations, and has been a member of the UK Government Bioscience Working Group, and also the Ministerial Industry Strategy Group since 2008.

John holds a BS degree in biological science from Glasgow University and an MBA from Strathclyde Graduate School of Business, and he is married with three daughters.

So with that, I will turn it to John.

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**John Young** - *Pfizer Inc. - Group President of Pfizer Essential Health*

Good morning, everyone. Let me start with our legal disclaimers. So our discussions during this session may include forward-looking statements that are subject to substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements.

Additional information regarding these factors can be found in Pfizer's 2016 annual report on Form 10-K filed with the US Securities and Exchange Commission, and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com). The forward-looking statements in this session speak only as of the original date of this session, and we undertake no obligation to update or revise any of these statements.

If your family is not in good health, nothing else really matters. Good health is essential. And today, I would like to tell you about Pfizer Essential Health.

Our business really complements Pfizer Innovative Health. Our goal is to positively impact global health by making Pfizer quality medicines accessible to patients all around the world, and in doing so, to enable Pfizer Essential Health to create sustainable, profitable growth for our shareholders.

Since we formed this business in 2014, it's developed significantly. I am really proud of the leadership position that we have built in core product categories. We have a portfolio of over 600 medicines across the globe, and help to treat more than 300 million patients globally each year. However, we are extremely focused, we are very innovative, and we provide essential solutions to growing health problems.



I'm very proud to lead this business and to tell you today why I believe that we are uniquely positioned to deliver sustainable value to our patients, to our customers, and to our shareholders.

So today I'm going to share how we have actively evolved the portfolio of this business, our strategy to help us to achieve sustainable growth, and the key drivers behind that growth. Pfizer Essential Health's competitive advantage is our unique combination of our reputation, scientific and TA expertise, and our size and global reach. Many of our medicines are on the WHO's Essential Medicines list, and Pfizer Essential Health is a valued partner to many governments and NGOs around the world.

Importantly, we provide a steady cash flow to Pfizer. And for Pfizer shareholders, we also offer the potential for growth with attractive margins at a significant scale. And as the impact of product LOEs on our core portfolio lessens, we're poised to deliver a low to mid-single digit growth over the medium to long term, driven by our core portfolios.

So let me walk you through how we have evolved this business and set it on a path for sustainable growth. We began as the Established Products business back in 2008. Our goal back then was simply to maximize the cash flow from Pfizer's LOE products and developed markets. And we achieved this goal of managing the tail incredibly well, compared to market analogs proving that value really can be delivered through focused management of brands at the tail end of their life cycle.

In 2014, we expanded our footprint into emerging markets where an increasing number of customers and patients in growing markets were looking for high quality treatments for important conditions such as cardiovascular disease, pain, and serious infections.

A pivotal milestone for us was in 2015 with the acquisition of Hospira. And this really achieved two major goals for our business. It complemented our biosimilars pipeline with in-market assets, and it gave us leadership in our Sterile Injectable business.

Another milestone late last year was the acquisition of Astra Zeneca's anti-infective portfolio. And I'll talk in more depth about these portfolios in a minute.

So we are consistently exploring areas that fit with our strategic priorities. And this also means looking at potentially divesting portfolios or businesses that we would define as being non-core, if we believe that that would maximize shareholder value. For example, earlier on this year, we completed the divestment of the legacy Hospira Infusion Systems business to ICU Medical.

It's our goal for this business to return to sustainable growth, focus on our core portfolios of essential medicines, and to increase patient access to quality medicines globally. That gave rise to the new name for our business, Pfizer Essential Health.

So while Pfizer doesn't give guidance by business segment, I'd like to give you a sense of the financial trajectory for this business by portfolio. Pfizer Essential Health is a \$22.5 billion business globally. And broadly, we think about our core portfolios like this. And I'll start from the bottom of this slide and work up.

Our peri-LOE portfolio comprises legacy Pfizer products that have recently lost, or are anticipated to lose, patent protection. It contributed around 19% or \$4.2 billion of revenue in 2016. Now we obviously expect that this portfolio will continue to decline as the products in it are subject to generic competition, particularly in emerging markets. However, the absolute impact of LOEs will obviously get smaller as the size of this portfolio declines.

Legacy established products is our largest portfolio, generating revenues of \$11.2 billion in 2016, and that portfolio was split between the developed and the emerging markets. It contains off patent brands, and contributed half of our 2016 revenues, excluding the Hospira Infusion Systems business. Our revenue trajectory in legacy established products in developed markets has been fairly stable over the past several years. It declined around 1% operationally last year, and we expect a comparable performance this year.

Legacy established products in emerging markets has also been fairly stable. We've had volume growth from this portfolio, and revenues up 3% operationally last year.



We've seen dramatic growth in our sterile injectables, driven by the addition of the legacy Hospira portfolio, which now offers our customers the breadth that they would expect, and it comprises more than 250 products. We're the global leader in sterile injectables with 2016 revenues of around \$6 billion. And we expect to continue to be able to grow our sterile injectable business through both new product launches and through continued geographic expansion of our portfolio.

Our biosimilars portfolio also performed strongly in 2016 with revenues of \$319 million and operational growth of 74% last year, and we expect to continue growing that portfolio in 2017 and beyond. Our biosimilars pipeline is among the deepest in the industry with 14 assets; 8 late stage development and 6 at earlier stages of development. And we've recently launched Inflectra in the US, only the second biosimilar to come to market in the US and the first monoclonal antibody biosimilar.

And our final portfolio is CentreOne, our contract manufacturing organization, which we incorporated into PEH following the Hospira acquisition.

So why do we believe that we have an opportunity to grow our current portfolio? Well, in part because of the cadence of LOEs. As you can see from this slide, from next year onwards, the impact of LOEs dramatically lessens. This year we expect around about a \$1.6 billion negative impact on our revenues due to new generic competitors, primarily due to Pristiq, which lost exclusivity in the US earlier this month, and a few other products in the US and Europe.

But by 2019, we expect an annual LOE impact of only around \$200 million. The 2022 to 2025 time period has almost no LOEs in our core portfolio at this time. And the average annual impact is projected to be only approximately \$200 million; significantly less than the historical impact that the Essential Health business has borne.

So as I mentioned before, this business was originally created to help maximize the cash flow from Pfizer's LOE products. Now we believe that we're still well-positioned to be able to maximize the value of these products in the marketplace. And even if additional products, LOE products from Pfizer's innovative health business, such as Viagra or Lyrica, were to transfer to the Essential Health business, it would initially create a short-term increase in cash flow prior to LOE, and then result in a higher revenue headwind following the LOE.

However, the impact of LOEs in the US and developed markets will be relatively discreet and relatively short lived. And importantly, it won't distract us from the significant opportunity to drive sustainable growth in our core portfolios.

And we are extremely focused on growth. So now I'd like to talk about our strategy to return Pfizer Essential Health to sustainable growth. Our goal is to accelerate growth by actively managing our portfolio by growing or strengthening core portfolios, and divesting non-core or declining products or portfolios where we believe that that would maximize shareholder value.

Our R&D organization will continue to advance our pipeline of biosimilars, sterile injectables, and late stage anti-infective assets, while seeking new opportunities to enhance delivery of our portfolio of legacy brands.

Now we are building new capabilities and evolving how we interact with our customers using new digital, as well as traditional channels, to ensure that they are getting, our customers are getting the information and the support that they need from us.

We will also continue to ensure that our cost base is both lean and efficient. In fact, we reduced standalone SI&A expenses by nearly \$900 million annually from 2014 and 2016. And we'll continue to look for opportunities to maximize our efficiency across our expense base.

And finally, our success is only possible because of our people, our colleagues all around the world. We have a highly engaged workforce in PEH with a strong commitment to acting ethically and compliantly in all we do, which we term winning the right way.

So now let me talk about our core portfolios in more detail, and I'll start with biosimilars. In 2016, we achieved \$319 million of biosimilar revenues with operational growth of 74%. Pfizer is the global leader by revenue in biosimilars, and this is driven by Inflectra, our biosimilar to Remicade. It's marketed under other brand names in some countries, and has already achieved over 111,000 patient years of experience, and has already been



approved in more than 70 countries around the globe. In the US, Inflectra launched at the end of last year. And while still early, we are seeing a positive reception from physicians, from pharmacists, as well as from payer customers.

Pfizer also has three biosimilars on the market in Europe. Inflectra, as well as Retacrit and Nivestim are biosimilars to epoetin and filgrastim.

Importantly, Pfizer Essential Health has the industry's leading biosimilar pipeline across multiple therapeutic areas. Our pipeline consists of 14 distinct assets at various stages of development in oncology, inflammation, as well as supportive care. 8 of our assets are at mid late-stage development and 6 assets at early-stage development.

We believe the opportunity for biosimilars is significant, with more than \$100 billion of biologic medicines expected to lose patent protection over the next 5 to 10 years. On the global biosimilars markets in which we will compete, is projected to grow from approximately \$1.9 billion today to around \$15 billion by 2024. As the leading company in biosimilars, we have the capabilities to build on our success and leadership, and to capitalize on the opportunity that this emerging category represents.

Finally, biosimilars are actually a great example of leveraging the strengths and capabilities across the whole Pfizer organization in cell line development, in biologic manufacturing, to create more affordable patient access and to create what we believe will be a significant commercial opportunity.

Turning now to sterile injectables, Pfizer Essential Health is a global leader in sterile injectables. These are lifesaving drugs that are typically delivered through an IV in a hospital setting. And our 2016 portfolio revenue was around \$6 billion and increased over 50% operationally, driven by the inclusion of the legacy Hospira business.

We are proud to have one of the broadest and most diverse portfolios of sterile injectable products; more than 250 products across 14 therapeutic areas. Last year, Pfizer completed 72 new regulatory submissions, gained 107 new approvals, achieved 24 new product launches globally, and more than 140 additional new product launches are planned globally between now and the end of 2019. And this marketplace is expected to continue to grow. It's around an \$80 billion a year market today, and that is projected to continue to grow at around 5% annually.

So drawing on our knowledge and experience in sterile injectables, our strategy will be to focus on the growth in key markets outside of the US, as well as to maximize the potential of our differentiated drug delivery systems and pre-filled syringe technologies. And increasingly to move our R&D towards complex and difficult-to-make molecules.

Moving now to the third growth portfolio, anti-infectives. Not only are we the leading anti-infective company globally today by a factor of 2, with revenues of around \$3.3 billion in 2016, but we believe we have an opportunity to meet a compelling global healthcare need in this space, both now and into the future.

The WHO characterizes antimicrobial resistance as one of the biggest threats to global health, which can affect anyone at any age in any country. But older or immunocompromised patients are especially vulnerable, and an aging population globally will only increase this level of risk.

Gram negative pathogens are a cause of many serious types of infection and have become increasingly resistant to many available antibiotic treatments. Currently, around 700,000 deaths each year are attributed to antimicrobial resistance globally, and that could potentially increase to around 10 million deaths annually by 2050.

We believe that Pfizer Essential Health is really well positioned to help to meet that need. We have more than 80 anti-infective medicines in our portfolio, and we expect the acquisition of Astra Zeneca's small molecule anti-infective portfolio to accelerate our growth.

And last week, in fact, Germany became the first EU market to launch Zavicefta, one of the assets that we acquired. Zavicefta is a new combination antibiotic for treatment of patients with certain serious gram negative infections, requiring hospitalization, and it also addresses one of the most important areas of unmet need in hospitals around the world.



So we've talked about a number of portfolios that make up our business globally. And now I want to focus on our strength across portfolios in the emerging markets. Over the past two years, Pfizer Essential Health has recorded consistent mid-single digit operational growth in emerging markets. Last year we grew around 6% with revenues of \$6.6 billion.

With an increasing population, and a continued growth in the middle class, we are well positioned to leverage our portfolio of quality branded medicines to meet that opportunity. Key markets for us include the BRIC-MT markets -- Brazil, Russia, India, China, Mexico, and Turkey -- where we grew 8% operationally in 2016 to \$3.9 billion. Overall, we believe mid-single digit operational growth is a sustainable goal for the Pfizer Essential Health business in emerging markets.

So we are very proud of the progress that we have made in Pfizer Essential Health. We have actively evolved this portfolio and this business. We are now a market leader in key growing portfolios, including biosimilars, sterile injectables, anti-infectives, and in emerging markets.

So good health is essential. At Pfizer Essential Health, we combine our history of industry leadership, a comprehensive knowledge of global healthcare markets, and a broad portfolio of really trusted, quality medicines to benefit patients around the world at virtually every stage of life. We have actively shaped this business and our portfolio, and we're using Pfizer's competitive advantages -- our experience, our size, and our global reach -- to achieve our goal of returning Pfizer Essential Health to sustainable growth by making a meaningful difference to global health.

So I'd like to thank you for your attention, and now I'd like to open it up to a question or two from the audience. And I'll welcome additional questions in a separate Q&A session, which I believe is in Salon K just next door in around about 10 minutes. So let me open up for any questions from the floor. Steve.

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## QUESTIONS AND ANSWERS

**Steve Scala** - Cowen and Company - Analyst

John, what has surprised you the most about the biosimilars market, what has gone better than expected, what has been more challenging? What has surprised you the most?

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**John Young** - Pfizer Inc. - Group President of Pfizer Essential Health

So, we expected that there were going to be many uncertainties in this marketplace and many unknowns when Pfizer made a decision to begin development of a portfolio of biosimilars 5 or 6 years ago. And so at that stage, when we looked at the regulatory landscape, neither the EU nor the FDA had a clear pathway to bring biosimilars to market.

And plainly, there was a lot of conjecture around what the value proposition for biosimilars was going to be. Was it purely going to be a price play? Were they going to be commoditized? How would we be able to, and what information would be important for physicians and for patients for them to be comfortable that actually adopting a biosimilar in their clinical practice was going to be something that would add value. So we knew that there were many factors that were going to be uncertain.

But honestly, I think as we've seen regulators both in the EU and the FDA begin to give clarity around what a development program looks like, around the importance which we anticipated of the preclinical data really being the foundation of an application for a biosimilar product, with clinical data being confirmatory.

In terms of the pricing and adoption environment, we always expected that patient share adoption would probably be relatively slow initially. And I think I draw on our experiences in Europe, Steve, I think what we would say is the first 6 months or so is really doing some basic blocking and tackling to be able to introduce your product to formularies, to be able to provide some education to physicians about the nature of what your product is, about what value it can potentially add. And importantly, I think, to give them confidence that it actually comes from a company that knows what they're doing and that has a heritage in biologics. And I think we've really seen that play out.

So I think we would probably say in Europe, we have probably seen more aggressive pricing, traded off with higher rates of patient uptake in some markets. But I think the other lesson that we've had is that not every marketplace is the same. And whilst we're in the very early stages of introducing Inflectra in the US marketplace, I think we will see something very similar play out. We'll probably see different rates of adoption across different channels of the hospital system in the US, and we'll probably see different rates of discounting and reimbursement to really provide value to those customers in those different channels.

So I think whilst there is much that was uncertain 5, 6 years ago, I think broadly speaking, our assessment as to what the key variables are has pretty much played out as we expected back then. And I think we certainly have a much clearer sense as to what this market opportunity is today, and how it's likely to continue to evolve in the future.

Any other questions? I think we've still got two, three minutes left to take questions from the floor if that would be helpful. Yes, Steve.

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**Steve Scala** - Cowen and Company - Analyst

What are your thoughts on the FDA guidance on biosimilar interchangeability?

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**John Young** - Pfizer Inc. - Group President of Pfizer Essential Health

So I think it's obviously very -- the FDA's guidelines on interchangeability were obviously very important. So I think what it has done is to lay out the expectations that the FDA has in terms of data sets for products to be deemed interchangeable. And importantly, Steve, this is interchangeable by pharmacist, the pharmacy customer. So I think the FDA have been very clear on what they expect in this space.

I think we feel that that's actually important guidance. Because frankly, I think as a company that has a strong heritage as a biologic manufacturer where our commitment is that we will always bring to market high quality products, supported by a data package that can give physicians, payers, patients confidence that actually the clinical outcomes that they will get for their patients will be similar to what they would get on the originator brand.

And so I think the guidance, where for example the FDA have said that they would look for a comparator in the clinical study to prove interchangeability by a pharmacist to use the US originator product, is important guidance. I think it sets the bar fairly high, but candidly we would say that that's probably appropriate for the development of interchangeability by a pharmacist.

But importantly, I think at the moment, an individual healthcare professional already has the opportunity if they, along with the patient, believe that actually there is a real value to be offered by moving a patient to a biosimilar to be able to do so. So we will continue to engage with the FDA, both in terms of understanding that guidance and to make decisions about whether we will amend or do new studies for our clinical programs going forward.

All right. So thank you, everyone. Appreciate your attention.



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