PFE - Pfizer Inc at Barclays Capital Global Healthcare Conference

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Good morning and thank you very much for your attention for the last presentation of our Barclays Healthcare Conference. I have the distinct pleasure to introduce Dr. Mikael Dolsten. I want to tell a story about Dr. Dolsten in a moment, but I also want to acknowledge part of the Investor Relations team and Jim Davis. I want to publicly thank Jim for being incredibly responsive to all of our questions, because we have tons of them. Thank you for that. You’re very, very good.

The story I want to tell on Dr. Dolsten, because I think Pfizer is really undergoing a change, a cultural change, and the key is, how do you actually do that?

I had the opportunity to visit an old colleague, or a person I once knew in another life who actually now is at Pfizer on the West Coast. And, candidly, his name is Dr. David Cox. And I had known David because I follow some other companies as well. And I asked Dr. Cox, I said, you know, Mikael has just joined. What do you think about him?

And he said, you know what’s really, really intriguing is that on Friday night, this past Friday, it’s about 9 o’clock; I’m actually at home. And remember, he’s in San Francisco. And he said, I get an e-mail from Mikael. And he said, have you read the latest article in Nature? And he provides a title and et cetera and et cetera. And of course, it’s midnight back in New York.

And I said, that’s really remarkable. And he said, no, it’s tremendously remarkable because you have the Head of the R&D division who is a true scientist. And that’s very, very rare. And that may actually explain the rationale for some of the cultural change.

Mikael, thank you very much for coming. We’ll have Q&A in this room afterwards, and thank you all for being here.

Thank you for that nice introduction. And the clock of science and business never stops, and that’s the pleasure and the challenge, of course.

So I will share with you some of the aggressive changes we have been doing to really address R&D productivity in this industry and how we focus on what is the innovative core of our large Company and to position us with a pipeline of differentiated medicines and vaccines that matter most for patients and customers.

And first, I just wanted to remind us about forward-looking statements in this presentation, in this slide on cautionary language, which can be found together with the slides on our website.

So over the last couple of years, we have been on a really focused journey of building an R&D organization for the future. And we have turned the Company from traditionally a small-molecule pill-in-the-bottle company to really having, I think, some of the most leading and diverse capability in designing small molecules, large molecules and vaccines.

And we have moved into a structure where we were focused early on on understanding science, business and finance in a more holistic manner and where we are intrigued by internal and external capabilities and how they can, in a boundary-less fashion, be brought together to build a pipeline, and where we have put a lot of emphasis in building a talent base and culture of more
entrepreneurial, creative character and trying to incorporate the best of a company of Pfizer's size and deep competence with the agility and flexibility of small, nimble units.

And building on that foundation and having completed successfully the integration and acquisition of Wyeth, we have now put a turnaround strategy into what we call the three distinct dimensions. And they are approached by us in parallel, although each of them kind of focus on the short-, mid- and long-term competitiveness of our Company.

So in Horizon 1, where we delivered a portfolio, we have really emphasized in the organization how you create and design and develop medically differentiated products based on unique understanding of disease-causing mechanism and, at the same time, embrace early business and financial input into the portfolio design.

In the second Horizon, we focused more on pushing the boundaries of drug design for the future, making drugs that can be far more superior to what we have in technical aspect availability today. And we also embarked into a new way of looking at open and external innovation to create a different way of working with the most leading academic medical centers.

And in Horizon 3, we take the ambition of fully utilized precision medicine across many different disease segments. And you will see examples how it’s today playing out in oncology. But we really look upon it as transforming the entire therapeutic area space of this industry and medical practice. And Horizon 3 is also where we see the various external initiatives create more of a networked R&D across the Company with all our partners.

Early this year, we took the decision to accelerate this turnaround strategy, and it included taking a clear stand on what is the right input into R&D to get an output of sound return of investment. And we discussed in the introduction here that for some time, I think the R&D organization has viewed the more funding, the better. But our thesis has been that we really want to deploy the capital in a very diligent and thoughtful manner to rather focus on the return of the investment than the total size of the investment.

And to really address all levers of productivity, whether we look at the probability of success, the quality of the output, the speed and the cost per product, we focused on three different priorities.

The first one is really about the focus -- focus on those diseases and therapeutic modalities where we saw strong probability of high competitiveness and we believe we could reduce risk prior to large investments.

The second one links to strategic externalization, finding a way to work with external partners that actually strengthens the internal core of the Company. And it's two particular distinct ways.

One is in more of operations of R&D, where we have embarked now into transition into strategic partnership with a few major CRO companies and allow ourselves to really internally focus on what we think is for us value-adding and competitive edge inside the Company.

But also, on the innovative side, when it comes to access to new products, exploring a more clearer priority between what we do inside, what we license opportunistically from the outside, and some areas where we almost entirely depend on outside partnership to build our pipeline. And we feel this gives us much better flexibility in how we deploy our capital. And also, by adjusting the input into R&D, we think we can address the fundamental return of investment.

And the third category here, summarized on the differentiated innovation, is a number of approaches to maximize the ability to deliver drugs that have a distinct advantage versus current treatment. And that included, for us, looking at decision-making with a whole new set of tools, moving our contemporary biology in early clinical to the best biomedical hubs in the world to ensure that we really worked in an interactive manner with other key scientists as well as with the leading clinicians that have ideas on how we could run studies in the future different and be part of changing the future of R&D rather than responding to it.
And you saw some announcements how I think we are building up our presence in Cambridge, UK; Cambridge, MA; San Francisco; La Jolla; New York; and Shanghai. And we have really a kind of unprecedented footprint that parallels where some of the best innovations are occurring outside our walls.

From that introduction on our journey to build an R&D leader for the future, the turnaround strategy, the acceleration to create an engine for sustainable innovation, I share with you our more latest-stage pipeline in registration or soon to be in registration.

Prevenar 13 Adult is a very important medical product. Prevenar has given tremendous benefit for infants, and indirectly, by reducing the prevalence of pneumococcal strains, also helps people through all other ages. But it continues to be a significant health threat for adults, and older adults.

And we submitted filing in Europe and US end of last year. We have announced that we have completed a set of trials to demonstrate immunity in adults with Prevenar 13 compared to the current unconjugated pneumococcal vaccine on the market and in combination with other concomitant vaccines. And we have announced that all those studies have successfully reached endpoints.

We are, in near term, finding opportunity in a number of exciting areas. Crizotinib represents kind of a flagship of a next generation of precision medicine drugs that has delivered and we have reported at conferences from our Phase I study has delivered unprecedented response rates in a fraction of lung cancer patients, in the range of 65% response rates, and progression-free survival of more than 10 months in lung cancer that -- or haven't responded to, have failed standard of care. And you would expect to discuss response rate in the 10%-plus and progression-free survival in weeks rather than in almost a year. And that's based on genetic identification of a small subset of 5% to 7% of lung cancer patients that share a unique genetic change, the ALK fusion protein.

We are in a rolling submission of Crizotinib that will end in near term, and we look very much forward to the outcome of the regulatory dialogue on this drug that would provide unique opportunity for patients that suffer from this subtype of lung cancer.

Tofacitinib is our [per oral] inhibitor of JAK, a key enzyme in lymphocytes, and would represent the first per oral drug in decades for rheumatoid arthritis as a disease-modifying drug. We have seen and reported [AC oral] value in similarity to biologicals, a tolerability and safety profile very well compatible with what you see for rheumatoid arthritis drug.

And we have now, just recently, in a topline report shared that we have confirmed in 12-month study earlier response and efficacy parameters we saw in our six-month studies. And we are completing, over the next couple of months, the remaining part of the Phase III program to allow filing.

The second one, axitinib, I just wanted to very briefly touch upon. It builds on our franchise in renal cell cancer and the ability of Sutent to provide great benefit for patients. It's a next generation of more selective inhibitor around VEGF and related angiogenic pathways and has higher potency. And we also there reported end of last year that we beat second-line Nexavar, sorafenib, in renal cell cancer and allowing us to put together a plan for filing.

So, as you can see, a very exciting time with drugs that provide real benefit in very significant diseases that we now are dealing with in the registration phase. We do have a very rich Phase III portfolio, as you can see, on the large number of NMEs and line extension, whether of drugs in late stage or of drugs on the market.

I also wanted to have the opportunity to just share with you some of the new science coming into our portfolio in Phase I and Phase II. Starting with immunology and inflammation, an area where we clearly are pioneers with Enbrel and tofacitinib, but the story doesn't end there, it just starts -- IL21 receptor, we have been the leader in understanding that cytokine and have developed a biological that blocks its receptor function. It’s now in Phase I studies.
Anti-MAdCAM antibody may offer a unique, much more selective way to interfere with inflammatory bowel diseases. We are soon initiating Phase II studies. And the anti-TNF antibody that we pursue together with Ablynx are just in the very late-stage readout of our Phase II proof-of-concept study in RA.

Oncology, a couple of exciting assets in this part of the clinical pipeline. With Torisel and Rapamune, we have been the leader in understanding the powerful mTOR enzyme and its role in cell proliferation and protein synthesis. We have designed synthetic inhibitor of mTOR that have a much broader reach than the original natural products and inhibit both mTOR 1, 2 and PI3K and preclinically showed dramatic efficacy versus the other available mTOR inhibitors. And we are now dosing patients with solid tumors.

As the Company that brought Sutent and axitinib forward within the VEGF angiogenesis area, we now are moving biologicals into the pipeline and building on the need for more efficacy versus fewer VEGF-blocking antibodies. You can see our dual inhibitor of VEGF/Ang-2 that is now on its way to patients, and the ALK1 mAb that inhibits another pathway of angiogenesis in early clinical studies, show encouraging signs.

And finally, a small molecule against CDK4 and 6 enzymes involved in cell division, where we have designed a drug that seems to have higher specificity than other drugs that have been pursued, we believe we can dose more optimally. And here we will again use precision medicine to identify high-responder patient groups.

And vaccines, moving from the Prevenar company, we are expanding with both additional vaccines for bacterial diseases and, beyond that, also vaccines for therapeutic purposes, not only prevention. Meningococcal group B, we are right now in ramp-up for Phase III that will come in a couple of months at full scale.

And staph aureus represents an area of tremendous medical opportunity. We have seen the difficulties with staph aureus and infections, where they’re community related or, particularly, in hospitalized environments with multiresistant strains. And we have developed Phase I data of our staph aureus vaccine that gave very high immunity, good tolerability. And we are now planning for a proof-of-concept study, and our additional very exciting vaccines that within a year or so will enter clinical studies.

I spoke about Horizon 2 as innovate new capabilities. And one example here of an area where we are putting together various pieces of distinct chemistries -- on one hand, highly selective monoclonal antibodies, sophisticated linkers and active-payload small molecules to better create a therapeutic window in inhibition of cancer cells. In this case, we used calicheamicin as payload and an antibody to lymphoma cells. And we have recently reported very high response rate in refractory lymphomas that have been through multiple treatments with chemo and rituximab. We’re now just in enrollment for Phase III.

I wanted to give that as an example of next-generation therapeutics and underline that right now we have more than 10 projects in preclinical phase using a variety of antibodies and new chemistries that can, in a completely unique way, address cell activity and the need to deliver high amounts of drugs into the tumor area. And within one year, we aim to have a novel, exciting drug that builds on these principles and targets cancer stem cells.

In the Horizon 2, we also spoke about taking a lead in open and external innovation and allowing to share some of these great capabilities that we have in antibody and peptide engineering with the best investigators in academia. Rather than working kind of in a serial relationship, we really wanted to create team over these boundaries.

So we have signed agreement with UCSF and the seven world-class New York City universities here in which we will deploy unique groups within close proximity to this academical center that will work, dedicate with them and together select the most exciting proposals, allow principal investigating academia to test antibodies that we will generate for them in their experimental models and also to do the first proof-of-mechanism studies in patients in the hospitals.

And we think this will offer a complementary approach to our internal pipeline, and we will, in this agreement, have an option to license the drug and do the proof-of-concept study with preparation for [prebuttal] registration strategies. We have got, so
far, a very strong response from these universities and a number of others that are expressing strong interest to join in this new way of translating science.

Precision medicine I mentioned as a key driver for really change the game in the R&D ecosystem that we are embarking on for the future. And referring to the kind introduction here, David Cox, he heads one of our genetics groups based in San Francisco that works in many key academic centers to identify genetic drivers of human disease and genetic markers for high-responder patient populations, and also to understand how do you best combine drugs using scientific rationale and not just empirical findings.

And as you can see, we talk about precision medicine and not personalized medicine, aiming towards treating somewhere between 5% to 20% or 30% of patient clusters that share common genetic, biochemical or clinical phenotypes.

And we see this as a concept that nicely will allow you to have a much earlier clinical readout because of a stronger sign of efficacy, like I shared with you an example of crizotinib going from weeks to a year. It would also allow you to run smaller, focused trials. And we think the real upside for patients and payers is that you treat those that really benefit, and you provide them with meaningful treatment duration, as we have seen in our attempts and others. And we think this is something that really aligns the interest of payers with science and pharmaceutical companies.

And on this slide, I have shared with you that we are taking a very broad approach and trying, really, to change R&D. It’s not just oncology. Obviously, some great opportunities in oncology because the science has moved fast. Like I mentioned on crizotinib in the upper left side here, you can see the CDK4/6, where we are moving into solid tumors that are RB-positive and seem to be more sensitive; the targeted approach with inotuzumab for lymphoma.

But you can also see cardiovascular medicine, next-generation cholesterol-lowering. We have targeted a genetic marker for patients that seem to be protected from cholesterol and cardiovascular disease, PCSK9, and have now demonstrated very strong cholesterol-lowering with a monoclonal antibody and use this understanding to select patients that would benefit maximally and patients that are not fully treated by statins.

And you can see that in some cases, it’s profound genetic understanding. In other cases, like the liver glucokinase, we see an early entry to focus on patients that don’t tolerate very well metformin or have contraindications and how with a new drug that also will have liver selectivity can provide a clear therapeutic benefit. And that may allow us later to expand also beyond these first target populations.

And that’s true also for our breakthrough science IL21 receptor. We really are focusing on inflammatory diseases where we see signs of strong activity of the IL21 cytokine biology.

So I hope I managed to bring together to you how we have embarked on a new way of navigating R&D, bringing together science, business and financial consideration, looking at crisp focus on differentiated product in our pipeline, pushing the boundaries for drug discovery internally and in very much network with key external partners and taking a lead to pursue precision medicine, I think the biggest opportunity to increase the advantage of innovative drugs versus today’s generic drugs.

Thank you for your attention.
QUESTIONS AND ANSWERS

Unidentified Audience Member

Mikael, thank you very much. The question revolves around -- there's a clear change going on, and I'm very respectful of that. But in the average lab at Pfizer, what's the mood? What's the mood of the R&D people? What's the mood of the research people, the benchtop folks? What is the mood of the development folks?

Mikael Dolsten - Pfizer Inc. - President, Worldwide R&D

So I think like all of us when you go through a change, we have a significant excitement about making this happen, to be able to implement and show the metrics of success. And we have defined very clearly what those metrics are. And we're also defining a kind of a new culture together, where we bring together what we think the best from the kind of biotech and pharma and where we try to incentivize colleagues to take action, take decisions. And we are also looking at ways to actually make them feel that their reward is not just how well the big company is doing, but how their own asset is progressing in the pipeline.

And we're also building a culture of more empowerment for our Chief Scientific Officers to take a broader business responsibility and move the projects. I'm sure there will be some areas where we have people now feeling sad about the exits we are making from some sites. But what I have been impressed with, whether it has been impacted colleagues or colleagues that are part of going forward, it seems like everyone has felt that this is the right move for Pfizer and for this industry to do.

Unidentified Audience Member

There are some recent talks and articles written about the potential for Pfizer to spin off some of its businesses and to sort of downsize. And we've heard from journalists, but not from the Company. And so can you give us a little more color as to what you guys are thinking about and what the options might be?

Mikael Dolsten - Pfizer Inc. - President, Worldwide R&D

Yes. So in the same way as I spoke for R&D, that the more is not better, but you really need to have a focus, how you maximize return of investment and how you offer shareholder value for their investment or commitment to your company, the same type of approach we have done for the entire -- and are doing -- groups of businesses that we have.

And our CEO, Ian Read, has stated that we have an innovative core of our Company with adjacent businesses, that each of them are doing really well, but we need also to understand what is the maximum value for those businesses, which of them actually have a higher value by being inside Pfizer and can benefit from the capabilities and our financial strengths, our reach in the market, and which would do better as businesses and create more value for shareholders to be outside the Company.

So we are going through a comprehensive review that we aim to complete during this year. And you could see that we started it already some time ago, since we have announced that we are looking for strategic alternatives for a business unit called Capsugel.

Unidentified Audience Member

Dr. Dolsten, I'd love to hear your thoughts about -- maybe this is a two-pronged question. How much time are you actually spending I guess internally at Pfizer, and how much time are you actually out recruiting? And are you recruiting new people or considering to recruit new people to help maybe strengthen that fundamental core that you put up as a first proxy?
Mikael Dolsten - Pfizer Inc. - President, Worldwide R&D

Yes, that's a really good question. So, although we go through some change and we have stated that we are focusing on those therapeutic areas that really we think we can win in this industry and where we will have strong alignment between science and business, where we see good probability of technical and commercial success, and we are moving out of some areas that we feel we would better pursue more opportunistically together with biotech companies.

At the same time, when we move our research groups, like to Cambridge, Massachusetts, to Cambridge, UK, and as we maintain and strengthen the existing ones in La Jolla, San Francisco, New York and so on, we do that with a mix of building on our internal talents and recruiting new staff.

And we feel that creates the right, vibrant mix of colleagues that bring in different skills in this new culture that we are putting together. And you may have seen that some of this is also very targeted recruitment. And I could exemplify in our development operation, where we are now moving to a model that the majority, the great majority, probably 90% of our development operations, will be run outside the Company.

And in order to manage that in the absolute best way, we are combining some really skilled internal colleagues with recruiting one of the most experienced heads of a CRO company, John Hubbard, who led ICON. So that was one example of trying to move to a strategic model, take use of a flexible organization and benefit from those companies that do nothing else than execute clinical studies, but keeping the design and monitoring, to some extent, of the partners internally and bringing in someone that has a unique complementary skill that you may not always seen in pharmaceutical companies.

And we have done similarly in some of these initiatives. The Centers for Therapeutic Innovation, we brought also in someone that comes more from the biotech sector with a very strong scientific profile. And I think we will continue to blend very experienced Pfizer colleagues with this targeted recruitment, and I see that as a very exciting new culture that we are building.

And I can tell you, we don't see problems to extract even the most, the best people in biotech or academia. They seem to be really excited over taking part in the next chapter of R&D productivity.

Unidentified Audience Member

I want to ask you a question about Prevenar in Adult. And I think the Street -- and I might be a little rusty on this -- has somewhere between $800 million and $1 billion, I think, of additional sales from Prevenar in Adult. And that number seems odd to me because it's either going to be zero or it's going to be many, many billions.

And so how should I be thinking about it? How am I thinking about it wrong? If this gets approved in the adult population, why would it not be used widespread? So help me think about that, please.

Mikael Dolsten - Pfizer Inc. - President, Worldwide R&D

Yes, you could say the current unconjugated polysaccharide vaccine is used based on immunogenicity data. But there is not a lot of convincing efficacy data, and it's a tough challenge to put that together. That's kind of the smaller market. We think by providing efficacy data there will be much more wide use of an adult pneumococcal vaccine.

Although our registration is based on immunogenicity, we also have launched an 85,000-patient study in The Netherlands where we are looking at the ability to prevent pneumococcal infections in the population. And we think that could certainly grow the use of pneumococcal vaccines.
Another aspect is that the current vaccine, unfortunately, upon repeated injections, you lose the response to it. So if you immunize as an adult, usually it seems like a response. It depends on what age you immunize, but it deteriorates over a couple of years. So you need to reimmunize. But the current vaccine, you get poorer and poorer response.

And what we have seen with Prevenar 13 is that you can really maintain and induce repeated response and which could offer a very attractive protection and allow you to, at a much earlier time and age as an adult, to take the first immunization and see an opportunity to maintain it.

So I could certainly see that Prevenar Adult could have a business potential, pending the readout of this efficacy, and we have earlier talked about estimates around $2 billion, trying to balance between conservative and upside scenarios. And I think there is room for a lot of ranges here, pending how we will be able to show in the efficacy studies, and as the population above 50 years of age that will benefit from a vaccine that has great tolerability and could save from the number of adults that die in pneumonia sounds like an attractive commercial scenario to build on for the future as we learn more, completing registration and hopefully soon as a marketed product.

Unidentified Audience Member

And when will be the data be available from the 85,000-patient study?

Mikael Dolsten - Pfizer Inc. - President, Worldwide R&D

That’s an event-driven, so we have to follow the number of patients that get pneumonias, et cetera. We don’t know the date, but it’s not going to be this year. We will release a number of immunogenicity data from our Phase III at American and European conferences from spring to fall.

Unidentified Audience Member

Can you describe the return on investment calculations that you are giving to your Chief Scientific Officers and their teams as you allocate capital across the research function? And then how are they reporting to you on their -- how are they reporting to the business units, then, on their progress on proof of concept, please?

Mikael Dolsten - Pfizer Inc. - President, Worldwide R&D

Yes, that’s a good question. So we are putting a number of tools in place, on one hand, to really look at -- the way to accomplish what you say on a shorter time period is obviously to try to put a value on, let’s say, a proof-of-concept drug, because otherwise you need to wait to see true value until the drug has reached the market and you see sales. So we kind of have analyzed what is the cost for Pfizer to buy a drug at proof of concept on the market and then look at the internal efforts and how we could beat that cost and offer also an opportunity, then, for us to have a greater knowledge about the drug versus buying it and just seeing some data.

But you’re also looking at the true internal rate of return, using such a model and putting a value of the output. And of course, we need to make sure that investing in internal R&D is a far better investment than any other investment that the market would offer -- and certainly, you know, better than a diversified stock portfolio.

Unidentified Audience Member

Two additional questions, one similar to Harlan’s. What is today’s probabilities of success in Phase II and III, by your estimation?
And the second question is, you mentioned innovative core, and we have heard that from Ian as well. Currently today, or what percent of dollar spend in R&D is for innovative core at Pfizer?

**Mikael Dolsten** - Pfizer Inc. - President, Worldwide R&D

So there are a number of benchmark numbers out there. And it depends to some extent whether you look at vaccines, biologicals and small molecules, and different companies have different mixes. You often see for Phase III somewhere 65% to 75% success rates. And clearly, where you need to be is in the upper range. And I think the use of much more targeted studies, not only genetic, but also looking at your clinical population with other ways to make it much more confined.

One example is Alzheimer’s disease, where many companies have made very broad studies, disease modification of Alzheimer’s [broadened] and trying to narrow in on a segment of that disease and using more sensitive psychometric scales. I think those type of approaches will allow you to push the range towards the upper end of success rates.

For Phase II, I think you have a number of attritions there. First is to reach efficacy with tolerability, and the second is strategic attrition that has been also trouble in this industry. And we have approached both with a number of rules and guidelines where we look at the confidence in the rationale very early on. We have a very thorough assessment of technical quality of a small molecule, a large molecule or vaccine.

We spend a lot of time in understanding what is true clinical differentiation versus standard of care and how could you, at Phase II, already get the sense of whether it’s meaningful and not just incremental. And we incorporate into that how regulators would translate that into a label and also how payers would look upon that value proposition.

And I think that, together, hopefully will drive -- Phase II success rates have been maybe around 30%, and I think we should be able to push them towards the 40% range. And to get rid of strategic attrition should be really within our hands using some of the approaches that I outlined. And I think we make a lot of, also, advances on the technical attrition.

In almost all our trials now, we get the proof of mechanism before we do a proof-of-concept study in patients related to the disease. And I think that also will allow us to push these metrics in a much more favorable situation.

**Unidentified Audience Member**

(inaudible -- microphone inaccessible)

**Mikael Dolsten** - Pfizer Inc. - President, Worldwide R&D

Yes, yes. We have said that we will spend, this year, between $8.5 billion and 2012 $6.5 billion to $7 billion. We don’t really want to commit towards what’s in discovery, what’s in Phase I, Phase II, Phase III, Phase IV. Part of our strategy is to have a flexible ability to move our funding. And obviously, we have certain fixed in each of the phases.

But rather than looking ourselves and having internal and external expectation, we want to maintain some flexibility to really, as a management team, be able to move funds where we see the best opportunities from year to year. So, unfortunately, we don't provide those numbers, and they may vary somewhat from year to year.

**Unidentified Participant**

(Inaudible -- microphone inaccessible)
Thank you very much.