

Crucell at UBS Global Specialty Pharmaceuticals Conference

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Unidentified Participant: Good afternoon and welcome to the UBS Global Specialty Pharmaceuticals Conference. I'm pleased to introduce Leon Kruimer, CFO, Crucell NV. There will be a Q&A session in Room 26 after this presentation.

Leon Kruimer: Thank you very much. Good afternoon. And I would like to thank the host UBS for giving us the opportunity to present our company here. I am the CFO of the Company, I have been for the last 12 years, and it's my pleasure to present the state of the Company right now and the outlook for it.

Crucell is a company that works to fight infectious diseases. We have a powerful portfolio of products that are marketed, vaccines that are marketed worldwide. We also at the core are still the development company that we started as. That is developing product in the same field. And I will get in each of them in the next couple of slides.

Worldwide, Crucell, we consider ourselves as the largest independent vaccine producer with very strong partnerships with the same companies that we also compete with. The companies that are shown here, Glaxo, Merck, Novartis, Pfizer, and Sanofi are each companies we are either developing products with, we have technology licensing deals with, we actually produce a number of products for Pfizer, for Wyeth before, but at the same time, we also compete in the same field with very similar type of products worldwide such as hepatitis A, hepatitis B and pediatric vaccines.

Just a quick overview of Crucell, we are based in the Netherlands, very close to Amsterdam, actually in the old university town of Leiden and are a spin out of the University of Leiden in 1993. We have bought a number of companies in 2006, companies with longstanding vaccine experience such as the old Swiss Vaccine Institute that was called Berna Biotech at the time. We have eight products in the market, six products in our pipeline, and that is excluding another five products which are the realm of a corporation with Johnson & Johnson that I will talk about.

We have a very strong technology base. Probably the key technology that we have is manufacturing cell based manufacturing technology which is particularly adapted to produce viral material to make vaccines or to make antibodies and proteins.

We are profitable. We have a strong cash position. And 2009 was a particularly good year for us with record sales and record profits.

The development of our sales is shown in this picture where you can see that in 2005 sales were \$38 million. That actually represented the revenues that are generated by our technology front size in terms of milestones, in terms of some royalties, and other technology related income. In 2006 we made a number of acquisitions, so the jump there is through acquisitions, and since then we have had about a 35%, 36% average annual growth rate which is purely organic. It's driven by the growth in pediatric vaccines and one particular vaccine that is sold to UNICEF I'll tell you a little bit more about, but also in our franchise of travel vaccines which are sold throughout Europe and more and more in Asia and China.

The performance of 2009 versus 2008, 2008 was the first year we ever achieved sustainable profitability. And in 2009, if you compare that to 2008 was both in sales and operating income and grew more than a quarter. But also operating profit, profit before tax, and the net bottom line each showed significant increases from year to year.

Two words about corporate development and I mentioned something about it two slides ago. The company tripled in size both in people and in sales, etc., after a number of acquisitions we made in 2006. We took two years to integrate all these acquisitions. By 2008 they were successfully integrated. 2009 was a year where we changed the global branding for the company so that our products and the appearance of our facilities is now uniform worldwide. The organization is very much product focused and the sales that we generate with our vaccine portfolio which are about last year about EUR300 million, are going towards investing in our R&D expenses, i.e., the increase of our funding for our pipeline.

We achieved a 30 million cost savings program, it's actually improvement of EBIT from year to year on an annual basis and that was done through a number of actions, actually hundreds of actions, to improve the operations in every aspect from sales and marketing to production to customer service and even in R&D.

Our margins improved over these years from 31% in 2006 to 42% last year. In 2006 we made a loss of 85 million and last year before tax we turned out a profit of 40 million, so it's been a very successful turnaround.

Last but not least we did in the fourth quarter of last year a very important deal, a transforming deal with Johnson & Johnson which was actually based on our development expertise and our know how. We think that this corporation will accelerate the development going forward.

What we do, and I've said this, we use the profits from our growing vaccine business to fund our development pipeline. We have been very successful over the last decade in order to make demands on the capital markets in order to raise money for our development pipeline. As a matter of fact, in different transactions we managed to raise approximately EUR1 billion in all kinds of different transactions going back as far as 1997.

We realized at one point that if the capital markets would dry up in tough times for development companies like ours, you would need to have an in-house source of finance, and that was part of the reason, part of the strategic reason of why we made the acquisitions. I think it was a very fortunate move because if I look at today's environment, it would be extremely difficult to raise significant amounts of money for a company that is not making a profit.

Our marketed vaccines are in three areas. Pediatrics for children's vaccines, travel and endemic vaccines, and respiratory vaccines or influenza vaccines. And we are one of the smaller players in influenza and we see this as a significant opportunity going forward also to increase sales.

Also we are a distributor for some products such as Prolastin mentioned here and Gardasil in Europe and our sales forces in different countries such as the Nordics distribute these products.

In pediatric the most important product is Quinvaxem. It's a product we introduced in

2006, we got approved, and it is sold to UNICEF for the majority. It's sold to PAHO, Pan American Health Organization in Latin America, and it's sold more and more also to independent governments for vaccination of newborns mostly in developing countries.

Quinvaxem is a product which is sold for a large majority in tender, so-called tender to UNICEF. So every three years you've basically got to bid for the business and then you get assigned to different times values of product you can sell to UNICEF. The actual selling, the actual ordering goes on by purchase orders which come throughout the year.

You can see in the left-hand curve that in 2006 when we introduced this product late in the year, we sold about 6 million doses. And over the next three years at quite steep growth rate, we have managed to sell in excess of 130 million doses. We are at this moment the largest and the most reliable producer of this product. We have sold over the last three years, from 2007 to 2009, approximately half a billion dollars worth of this product. And so far for the tender period 2010 to 2012 we have received another 410 million in orders.

Prior to this year, we competed only with GSK which has a similar product but not five in one, but four in one. And GSK is actually looks like its retreating a little bit from this particular market. The new companies that we are competing with are Indian companies, companies like Shanta now owned by Sanofi Pasteur and companies like Panacea. They do have some quality issues and I think we are the company that is tapping into that void and it's actually benefiting our sales this year and hopefully next year and allowing us to take an extra chunk of the business.

Some update on Quinvaxem. We were recently awarded another US\$110 million contract by UNICEF. That award adds seven new countries to our list of customers. The total award that we now have over the last four years is US\$910 million, so it's a very significant product and we have a very good service record for this product and very good pharma track record.

The other opportunity is that Quinvaxem supply is now extended beyond the GAVI countries. In other words, there are a number of countries which are not necessarily supplied by UNICEF. They are now also taking this product onboard and again, that would be another opportunity on top of the existing opportunity with the NGOs, the non-governmental organizations that we service.

In the first quarter of this year, our shipments were relatively low and accordingly our sales were relatively low compared to last year, lower than the same quarter last year. It is important to understand that for this particular product, the shipments, the individual shipments are quite large. The smallest shipment that we make would be multiple million dollars and some shipments might be as much as from \$5 million to \$8 million. So depending on the timing of the shipments and of the sales that we report from certainly month to month but also even quarter to quarter, can be quite choppy.

Just to put everybody to rest, in April we sold more than we had in the entire first quarter. So it really -- we've taken up the slack again and are back on track in terms of units sold.

In terms of our development portfolio, Crucell has a wide array of technologies. Again with PER.C6 being the production technology that we use to manufacture vaccines and antibodies and proteins. And a number of other classical vaccine technologies. The jest of the -- the message here is that Crucell, in order to make a whole wide range of vaccines, classical vaccines plus new vaccines that we are developing, recombinant vaccines, doesn't have to go outside and get licenses from other companies, but we

basically have all of these technologies in-house.

Over the last couple of years, our scientists discovered an antibody which is called 6261 by a lab code name and it's an antibody that binds and discovers a very constant region on an ever changing series of flu virus families or slates. The significance of it is that we can make this antibody, and we are, then we can neutralize a whole range of flu viruses which is a completely different approach than the classical approach of giving everybody a new flu shot every year, because every year there is a new flu virus that infects the world. This could also be the key to making a universal flu vaccine, one that doesn't necessarily vaccinate you against every single flu virus, but certainly one that might protect people over a number of years from different type of families of flu virus that go around.

Anyway, this is a very important discovery and it led to a lot of interest of the industry. And it led eventually to one deal that we closed with Johnson & Johnson late last year which was an innovation, a development, and also a commercialization agreement specifically targeted towards five defined new product targets.

The first out of that was that flu monoclonal from the previous slide. The second of it is an effort to make a universal flu vaccine. Many people have worked on that, nobody has ever succeeded, this might just do it. But it will be tough. And three, four, and five are still targets that are not disclosed but that we will hopefully disclose in the next couple of months. It will be vaccines, it will be antibodies. They might not necessarily all be in the field of infectious diseases.

The focus of it, the five products still to be disclosed, the existing Crucell pipeline is out of scope. So in other words, our malaria program, our tuberculosis program, don't fall under this corporation. We maintain our independence and entrepreneurial spirit. We thought it was very important. We think that we have in-house, not to be cocky, but we think that we have in-house the speed and the entrepreneurs that can develop products relatively fast with high risk. But we in that sense are attractive, an attractive partner to pharma companies. The idea is that we would develop until Phase IIa and Johnson & Johnson would take it from Phase IIb all the way to approval. And that really is sort of the best of both worlds. It combines the speed and innovation of a biotech company compared with the tremendous development expertise and the regulatory expertise of a large company which biotech companies like us simply don't have.

We maintain the bulk manufacturing rights for products and we also get the marketing rights for Europe and for national non-governmental organizations like UNICEF, World Health Organization, and the relationships that we have. And JNJ gets North America and the rest of the world.

The economics of this, of this deal which combines the strengths of both companies, the potential deal value is over EUR1 billion. And the way we get this, they made an upfront cash investment of about EUR300 million at a 30% premium. So in effect we issued shares at close to EUR21. For that they get 18% new shares in the company and JNJ is now an 18% shareholder. But they have no control and no board seat. And that was important for us to maintain our independence and pursue our own development track for all the other companies.

There is no blocking stake in the takeover. There are significant milestones. There are milestones of more than 100 million per for each of the five development products. And approximately 80% of the R&D will be funded by our partner. And eventually after development there will be royalties on net sales. So this is typically an agreement which

will accelerate our development which makes it possible from a financial point of view and also makes it possible to increase our R&D spending while maintaining our profitability which is sort of a benchmark for success that we have set for ourselves.

Another antibody we have in development is an antibody for rabies. That is a product that we are developing together with Sanofi Pasteur. It is actually -- rabies is a horrible disease that kills about 55,000 individuals per year, mostly children in countries like Philippines, like India, like China. Half of the children, half of the affected 55,000, the casualties, are children younger than 15 years. And we've seen this and it's really an unmet medical need.

The product that we are trying to replace currently is a human immunoglobulin. It's a product that's derived from human blood that is very, very expensive. It costs about \$800 per treatment to make. And therefore this product is almost exclusively provided to patients in the United States and very few in Europe. Rabies is not very prevalent in western Europe to begin with. In the United States there are about 45,000 treatments and incidences per year, suspected incidents. The real market potential and the real need is the 30 million treatments that are needed in countries like China, like the Philippines, Indonesia, and India. We estimated our part of this deal has peak sales of about \$300 million a year.

The status of it, it's a program which is fast-tracked with the FDA which means that basically at irregular times you can go back to the FDA and discuss the development of the clinical trial which has tremendous advantages in terms of speeding up the process. We've completed two Phase II trials in the United States and in the Philippines and are about to start a trial second half of this year in India. We received development milestones, R&D funding, and eventually we will get marketing rights in Europe and co-marketing rights in China.

The other two vaccines, not antibodies, vaccines we have in our portfolio are so called T cell vaccines. They are vaccines that stimulate not only an antibody response but also the other side of the protection in our body which is to generate white blood cells in order to attract and attack the pathogen. It's a program in tuberculosis which is done together with AERAS. AERAS is actually the one that executed. It's a Gates Foundation based group that compares a number of different vaccine regimens together with the existing BCG, 80 year old vaccines against each other. So far the cells vaccine has received a higher, well the most effectiveness against these vaccines.

The second one is a malaria program. We had a Phase I malaria trial running in the United States funded by the NIH that took a very long time. We have that back right now and we just closed a deal with Glaxo and we will -- the idea is to jointly put our ingredients together and make a prime boost to our both vaccine regimen for this disease.

So to quickly recap, in tuberculosis there is also over time a one billion opportunity. There is the endemic -- there is also a demand for this product in the western world. Because tuberculosis is a disease where the existing vaccine is losing its power and it's a [disease] that slowly but surely is creeping back into developed world. It's partnered with AERAS Global TB Foundation. We have gone through four Phase I studies. A Phase I study in infants was started in South Africa just last year. A Phase I study was also started in January this year for more detailed analysis of immunology responses and that's a study that is carried out in Portland, Oregon in the United States.

The first Phase II study started in South Africa in the fourth quarter of 2008 and that's ongoing. It's fully recruited. And the second Phase II in adults infected with HIV,

because those are the people that most likely are prone to have tuberculosis in Africa, was started in April of this year. So to date, all data show acceptable safety level and show very promising immunogenicity which is exactly what we want.

Malaria. Malaria right now is we have two programs. One with the NIH, but the most important one is the one with GSK. The idea is to develop an effective recombinant prophylactic preventive malaria vaccine without any of the side effects that some of the possible pills have that you use to prevent malaria today. It's a very large market. The customers in the developed world are the US Army most of all which is very keen on having this product, but also a travelers market. A Phase I in the United States is completed and the unblinded safety data revealed, again, safety profiles that were acceptable which is not surprising because so far with PER.C6 and all these programs of PER.C6 are recombinant based, many of these things have been carried out.

We started a new Phase I study in semi-immune adults in Africa, Burkina Faso just in April. That is also funded. But the most important, again, is to put GSK's vaccine, the protein based vaccine, the GPS vaccine and our vaccine together in order to make a prime boost vaccine that will really work. That is shown in this picture actually although it's a bit complicated. But the idea is that it shows that the antibody response that each of the individual vaccines, both GSK's and ours shows it's acceptable but that the white blood cell count really goes up dramatically if you combine both vaccines. And without it, we believe an effective vaccine cannot be made.

So that wraps it up. Let me share with you our outlook for the year. We will continue our strong operating cash flow which is close to 75 million per year to accelerate our product development, to invest in R&D. Last year we spent 70 million on R&D, EUR70 million. We intend to increase that by as much as a third and that's already visible in the first quarter. We do want to maintain profitability. And that in spite of the fact that revenues and other operating income we expect broadly in line with 2009. But this is despite the fact that we received an additional award from UNICEF for our Quinvaxem vaccine. But it's early in the year and we want to be careful that we make, or that we keep our guidance in place.

With that I'd like to end it. Thank you very much for your attention and I'd be pleased to answer any questions in the breakout room.