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Conference Call Transcript

CRXL.F.PK - Crucell at Bank of America/Merrill Lynch Global Healthcare Conference

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PRESENTATION

LEON KRUIJMER - CFO

Good afternoon. I'd like to give a very quick -- so bird's eye overview, if you will, of Crucell. We're a Dutch company, incorporated in 1993. We basically were a -- very much a biotech company. One location doing engaging research and having an enormous burn rate, until 1990 -- 2005. 2006 we bought Berna Biotech in Switzerland, we bought SBL in Scandinavia, and we bought a North American marketing operation from [Arkansas] and since then we basically have grown into a fully integrated pharmaceutical company focused on producing and developing vaccines.

The key technology in Crucell is a technology called PER.C6. PER.C6 is a cell-based production platform that if you want to compete and price to replace CHO for a certain number of applications. The advantage of the technology, that it is a human cell, so the therapeutics that are being made on it, especially antibodies and proteins, have not only the human molecule that you make, but also the finishing of the cell -- the surface of the cell, the glycosylation, is human-like, which has a number of therapeutic advantages.

We have production facilities in Switzerland and Korea, Spain and Sweden and we have concentrated all our research in our headquarters in the Netherlands, where we also have a very modern recombinant vaccine plant, which plant basically is involved in the making of pipeline batches of product. We have many partners in our technology business. Our technology is basically licensed out to anybody that intends to make a commercial product with it, both in the area of vaccines, as well as in the area of proteins and antibodies.

If a license agreement is exclusive, then it will carry royalties -- then it will carry -- and milestones. In the case of antibodies and proteins, there are what we call portfolio licenses, which means that it's up to a company to develop a product on it. Once the product is there, we are -- stand to gain royalties.

We also have, in terms of our holdings, 6% of the company called Galapagos Genomics. Galapagos is a spin out of Crucell, in 1998. It's a company we set up together with Johnson and Johnson in Europe, and Galapagos has grown into a company with approximately 100 million in sales this year, listed on the Euronext as well, in Amsterdam and Brussels. And it has a unique system of generating new product leads and new drug leads.

In addition to that, we own 12% of a company called ADImmune. ADImmune is still a private company in Taiwan, located in Taipei. We are helping this company with the technology and with engineering advice to set up a plant to produce flu vaccine and we see that as a potential source, and that's what the agreement is all about; a potential source of antigen that we will buy to expand our flu business in a few years hence.

In terms of financial performance, in the top right-hand -- sorry, top left-hand graph, you see the sales development. The big jump between 2005 and 2006 is a result of acquisitions; the rest is organic growth. So far this year, we've grown 42% over the last year. In terms of profitability, we've reached profitability in 2008. And we've generated cash from operations and overall cash over the last two years, the amount of cash that we had by the end of last year was EUR171 million. Cash, as we stand [here] is approximately 150 million.

Just to compare the first half year of '09 versus the first half year of '08, you will see that these revenues have increased 42%. An operating loss of 12 million has been turned into an operating profit of 5.6 million. Profit or loss before taxes has been turned into a profit before tax, and the overall net result has increased 19%, reduces losses -- the losses have been reduced 19%.

Quickly, something about our profitability; the graph here -- the bar chart you see, depicts the sales per quarter. Traditionally, the second half of this year, the Company has always been prominent in the first half year because in the second half year we tend to sell flu vaccine, which is not included in the first half year. Therefore, also, the cash use is more expensive in the first half year, because that's when you build the inventories that will be sold in the second half year.

In terms of 2008, which will be more or less representative for 2009, PDX vaccines are about 50%, they will increase in importance somewhat and they're driven by the growth of one vaccine, called Quinvaxem, which is a 5-in-1 vaccine that we sell to UNICEF. Travel and endemic vaccines is 25% of the business, respiratory, about 15% and then other businesses, like distribution, also 12%.

The mission of the Company, very clearly, is to combat infectious diseases. And we have a number of diseases -- targets also in our pipeline, like tuberculosis and like malaria, which are predominantly diseases of the third world.

Crucell, in terms of sales, is the sixth largest flu -- the sixth largest vaccine manufacturer on earth. Last year, we sold over 100 million doses in many countries. With the addition of Berna Biotech and SBL, we have a tremendous and rich history of vaccine experience and we do some contract manufacturing for large manufacturers in the area of conjugation.

We have a seat on the GAVI Board, which is important because it's the policy setting party for WHO and UNICEF. And again, we've shown very strong sales growth over the last couple of years. This is a picture of the products we make. Again, in three categories; pediatric, travel and respiratory. And then we also do some third-party distribution for companies like MSD and Novartis, in certain parts of Europe.

We make two vaccines that are non-injectable. It's Vivotif for typhoid, which is our capsules and it is Dukoral, which made by the SBL, a Swedish subsidiary, which is a vaccine for cholera and for traveler's diarrhea, which is in drink. So, it's very easy to administer and are two of the approximately seven vaccines that we make.

Let me spend two minutes on our Quinvaxem, which again, is a very important product. Quinvaxem is a fully liquid, five ingredients in one vaccine, which is sold to UNICEF, to the Pan American Health Organization for Latin America, and also to a smaller extent in private markets around the world.

Our partner in this vaccine is Novartis, from which we buy four of the five ingredients, and which we share the profits of this product. This product was introduced in 2006, where we sold about 6 million vaccines. The next year we grew to almost 22, and last year, we sold about 40 million vaccines. Up until now, Glaxo was the only competitor in this market.

We have, in the tender period, the three-year tenders are written out by UNICEF. In tender period 2007 to -- up until including this year, we are delivering a total of \$0.5 billion worth of this product, in excess of 200 million alone this year. For the new period, 2010 to 2012, we have been awarded, so far, \$300 million worth of product and new Indian competitors, like Shantha and Panacea, have also been awarded contracts in this tender period.

The market for this product last year was probably approximately 75 million doses. And according to UNICEF, this market will increase to about 200 million doses per year, and that includes India, which accounts for about 50 million doses itself.

Very briefly, the pipeline highlights. We have four products in the pipeline so far; it's an antibody for rabies, which we built together with Sanofi Pasteur. We get significant milestones and other R&D support for this program. We are waiting to do a -- about to do a second and third Phase II study in India. Phase II studies in the United States and the Philippines have already been conducted.

Tuberculosis is a product where the Aeras Foundation, which is sponsored by the Gates Foundation, is trying to boost the existing BCG vaccine with different competitive products. So far, the booster, that consists of auto recombinant vaccine, has reached the highest level of immunogenicity.

Malaria vaccine is in Phase I trials in the United States. It's a study sponsored by the NIH and we'd like to take that and accelerate it also. And Ebola, Marburg, and Lassa vaccines is something that is specifically made for the US government in the vein of bioterrorism and homeland security. For this particular product, we are the only company that still works on this and we have been awarded a financing of \$70 million for the -- earlier in the year.

Right now, there are over ten clinical studies going on between these products in South Africa, the Philippines, Kenya, India and the United States. In addition to that, we have discovered antibodies against the flu, which is something we're very excited about. We've found a specific antibody that neutralizes a very broad range of flu vaccines -- of flu viruses, both the seasonal vaccines, as well as swine flu, as well as H1N1 and other types of pandemic vaccines.

We recently acquired a complete tetanus state on hepatitis C antibodies. We see antibodies for these type of infectious diseases as a clear growth area, also and are where we can forge product partnerships and strategic collaborations around them, in order to further our growth.

PER.C6, our cell-based production system -- we have over 80 licensees and have been thousands of people injected or treated with products that are made on PER.C6, which says something about the safety. The whole product is underpinned by what is called the biologics mater file, a complete safety file that is deposited at the FDA. So licensees of ours can refer to that file when they file their product application, which saves you a lot of regulatory hassle in the process of doing clinical trials.

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So looking internal in the Company, because we have put together four parts of the Company in 2006 and forged one company out of it. We have a corporate excellence program called Healthy Ambition. Part of that -- an important part of that program, is to forge companies -- costs out of the Company. The target was 15% of the 2007 cost base, which is approximately EUR30 million, and we are well on our way to achieve that by the end of this year.

The outlook for 2009 is one of accelerating growth, strong vaccine sales. We forecasted a 20% revenue growth for the year overall, in constant dollars, a significant improvement of operating profit, pretax profit and solid cash flows, despite the fact that we are, again, investing in inventory, plus we are on an approximately 50 million capital expenditure program for new plant agree -- a brand new plant to make Quinvaxem and hepatitis B. That plant will have the first test runs next year. It is ahead of schedule, it is within budget, and it is important because the money we invest in Korea allows us another seven-year tax holiday once that plant becomes operational.

We also look to key partnerships, as I said, again, around products, around technologies, et cetera. There is focus on the progress on clinical development, where you've seen we have a number of programs in Phase II, and we will continue to broadly out-license our technologies.

And with that, I'd like to finish. I thank you very much for your attention. If there are any questions, I would be pleased to answer them.

QUESTION AND ANSWER

Unidentified Speaker

I have a very quick one to start with. Have you -- can you provide a revenue breakdown? I mean, given that you target a lot of infectious diseases it seems in stagnating emerging markets, can you just give us a feel for how much your revenues comes from the US, Europe versus emerging markets?

LEON KRUIER - CFO

I would say that about this moment of the product sales, about 50% is from emerging markets in the sense that it UNICEF and those type of organizations that we sell to. And a certain number of our products are sold in tenders to specific countries such as measles, rubella vaccine, which we sell to certain North African countries. And most of the travel vaccines are sold in western markets, specifically designed for travelers that go to endemic areas.

Respiratory vaccines are sold in southern Europe, Spain, Italy, Switzerland and parts of Germany. So it's about -- to your question, it's about 50%.

Unidentified Speaker

So 30% emerging markets and 50% is Europe and the US combined pretty much?

LEON KRUIER - CFO

Yes. Yes.

Unidentified Speaker

Does anyone have a question? I'm curious about the PER.C6 cell. There was a lot of controversy last year when you achieved very high yields. And I think some of your competitors were arguing that the main challenge is not to produce very high yields, but more the downstream prices (inaudible) whatever you have in those deals --.

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LEON KRUIER - CFO

Right.

Unidentified Speaker

-- if you can comment on what you view that as. And what they're getting wrong --?

LEON KRUIER - CFO

Well, I think -- not actually wrong; I think that downstream processing is a challenge where you go from 100% what you produce to significantly lower amounts that you have of pure product, pure protein or antibody after you do the downstream processing.

The question is, what was the curve from downstream processing? As long as the percentage that you will have left at the end of the day is the same - right, when your yield is very high, your production, 100% so to speak, will be higher than otherwise. And as accordingly, when you do the same amount of effectiveness in downstream processing, you will have more product in the end. So, we think that the yield on your primary production of the protein is extremely important because it will determine the amount of product that you have left after downstream processing.

Unidentified Speaker

Has any product produced in the PER.C6 cell line already been approved?

LEON KRUIER - CFO

No. No.

Unidentified Speaker

If not, what's the --?

LEON KRUIER - CFO

It's all in clinical trials.

Unidentified Speaker

Are there any specific safety concerns with the cell line in terms of being carcinogenic or --?

LEON KRUIER - CFO

No. None. And I think in previous years, starting in 19 -- starting in 2000, we worked intensively with Merck, North America Merck, in order to come up with a biologics master file and address any safety concerns that the FDA would have, which allowed Merck to use PER.C6 as a production system in their HIV trials. And those trials were suddenly aborted because the product -- there were product issues, but not with the way that the vaccine was actually produced.

So I think safety concerns have never been an issue, although we have to prove that it was very safe, but they are certainly not an issue today in the use and use (inaudible).

There was a question over there.

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Unidentified Audience Member

The FDA, so far, has been pretty reluctant on improving new adjuvant (inaudible) before it can happen. Does the model (inaudible) PER.C6, both (inaudible-microphone inaccessible).

LEON KRUIER - CFO

The -- just to repeat it for the microphone. The question was that the FDA has been reluctant to approve new adjuvants, so how likely is it that PER.C6 would produce something, which needs an adjuvant? Or --?

Unidentified Audience Member

No, no, no, no. No which needs an adjuvant -- there is (inaudible-microphone inaccessible)

LEON KRUIER - CFO

Right.

Unidentified Audience Member

And does that prevent its approval of the (inaudible)? I'm wondering, will it be -- (inaudible-microphone inaccessible)?

LEON KRUIER - CFO

Well, the -- what we do in terms of making a vaccine is basically growing the virus on a cell-based production system. Right? That is somewhat apart from the fact whether that vaccine -- that raw material for the vaccine [CAP] needs to be adjuvated. So far a number of the recombinant vaccines, because they're live vaccines, are powerful enough not to be adjuvated. Virtually the products we have in our pipeline are not adjuvated.

Maybe I understand it wrong, but --.

Unidentified Audience Member

Yes. I'm not talking about the latent or potential (inaudible-microphone inaccessible) adjuvant.

LEON KRUIER - CFO

Right.

Unidentified Audience Member

I'm just talking about --.

LEON KRUIER - CFO

Adjuvants period?

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Unidentified Audience Member

How likely is it that we will see (inaudible) to approval with (inaudible-microphone inaccessible) in PER.C6 as a whole?

LEON KRUIER - CFO

Well, I -- all I can say is that for the studies that we do, and as far as they're with the FDA, we agree to clinical endpoints and once that is agreed, the study -- maybe we need to talk about (inaudible) with the adjuvant. Adjuvant is something that's particularly controversial at certain times. But --

Unidentified Speaker

I don't think you're referring to (inaudible) at all -- I think it's more of a question -- yes?

LEON KRUIER - CFO

Right.

Unidentified Audience Member

Okay. Fine.

Unidentified Audience Member

What do you think will be the first product to go in front of the FDA using PER.C6 (inaudible-microphone inaccessible)?

LEON KRUIER - CFO

It could be a product from - actually and English company that conducts the trial in America. The company's called Ark Therapeutics. And the product is called Trinam. It is for, basically, vascular repair after surgery. The product is Phase III and your guess is as good as mine when it comes out of Phase III.

Yes?

LEON KRUIER - CFO

Peak margins?

Unidentified Audience Member

Yes.

LEON KRUIER - CFO

Our margins have increased from 2006, where they were about 31% to about 45% last year. The increase in margins is driven by increased volume, increased efficiency, driving cost of sales down and about 3% to 3.5% margin of foreign exchange impact last year; that was the fact.

That is working against us this year. We're faced with a relatively high Swiss franc, vis-a-vis the euro, and a high Korean won vis-a-vis the euro. Korean won and Swiss franc are -- happen to be our manufacturing cost basis, so it does affect our cost of sales.

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In addition to that, I think that our margins can increase still quite a bit from the 45% current level, but that will depend on product mix and it will depend on how much milestones and royalties and this type of license-based income are part of our top line because that has a very big impact on our margin.

Unidentified Speaker

I've got a question on just trying to understand really how the tenders was on Quinvaxem. I mean, how much visibility do you have in advance as to what share you could get in each specific tender.

LEON KRUIER - CFO

I don't.

Unidentified Speaker

You don't have any idea?

LEON KRUIER - CFO

We don't. No.

Unidentified Speaker

Do you have any competitive edge over some of the other companies that compete --?

LEON KRUIER - CFO

Well, I think the -- Quinvaxem is a product, which is quite early in its product life cycle. We have, at this moment, approximately 50% overall capacity in a new plant in Korea. So, I think we're an important party in supplying UNICEF with this product, which again is important for UNICEF because it addresses one of the United Nations' millennium goals -- right -- to half child mortality rates.

I think what is important in terms of the competitive advantage you can have, it's the reliability of the delivery. So, we have quite large buffer stocks for this product, and meeting delivery deadlines and locations is key. Having said that, the strategy of UNICEF is to invite more competition -- foster competition, and drive prices down. That's what you know when you go into this game, with this product.

And I think given the fact that we have a relatively low cost base, a large capacity, we're in a pretty good position to take advantage of this market as it continues to grow over a few years.

Unidentified Audience Member

Could you describe your licensing agreement (inaudible-microphone inaccessible)?

LEON KRUIER - CFO

Yes.

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Unidentified Audience Member

(inaudible question - microphone inaccessible)

LEON KRUIER - CFO

For Quinvaxem, we will be at about \$100 million going forward.

Unidentified Audience Member

Overall?

LEON KRUIER - CFO

Overall, that's significantly higher, but it depends production facility per production facility. So in a place where we make hepatitis A, you can't make hepatitis B or Vivotif or -- so it's -- every product that we have has a dedicated production facility and the different capacity is varied. We're actually in the process, especially in Switzerland to Spain, to increase our production capacity, also an eye on exporting products in the United States, going forward, such as hepatitis A.

This is a picture of our key licensing agreement. Sanofi Pasteur for vaccines, for flu is one; antibodies with MedImmune, is another one. All licensing agreements basically consist of an upfront payment, of an annual payment in order to keep the arrangements alive, milestone payments if it's an exclusive licenseship, and finally as a royalty that's a percentage of net sales.

The royalty fee as a percentage of net sales varies. It could be as high as low double-digit for certain exclusive products, and for proteins and antibodies, it's usually 2% to 3%. But those markets that are much larger, usually their vaccines aren't.

And then finally, last but not least, there's something called service fees. If we perform additional development activities for a partner under this type of arrangement, then we bill for it, and that shows up as a separate line in our P&L.

Unidentified Audience Member

Do you have - are these exclusive agreements depending on product (inaudible-microphone inaccessible)?

LEON KRUIER - CFO

We have, I would say that, most of the arrangements that we have within vaccines are exclusive. And we're very careful that we slice and dice the market such that it doesn't compete with our own development plant. But for proteins and antibodies, it is basically what we call an -- sort of an open-license agreement; people can use it to make any product that they want, as long as they pay royalties once the product is there.

Unidentified Audience Member

When does the key patent on PER.C6 end?

LEON KRUIER - CFO

The question was, when does the key patent end on PER.C6? The patents still run until -- at this moment, until about 2025. Right? What we try to do is file additional claims each year on the original patent, thereby extending patent life. And also it's very important, PER.C6 is a production system. Once a company has embraced the system, taken into house and it has as made its facilities -- adapted its facilities to produce such a system that they're virtually locked in. They're going to change that for a certain time.

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Once you register a product on a production platform like PER.C6, the platform becomes an integral part of the product and of the registration file. So, you cannot change anymore. Interesting enough is if you think about biogenerics -- right -- that people talk about, then PER.C6 could be an excellent platform to make biogenerics because you can make it cheap, you can make it very high density, yet very few people have done that -- almost nobody has done it.

If you make an existing protein -- all right -- that a company has, but the patent has expired, such as [Epo] on a new production system, then by definition, from a regulatory standpoint, that becomes a new product. So you will have to go through a whole new registration process, and clinical trial, in order to get that process registered. So even companies like Teva or Sandoz or Dr. Reddy, and they're -- I think there are easier ways to make -- to copycat products than to make biologics at this (inaudible).

Unidentified Audience Member

Okay. Your original patent was filed when? 2025's a long time from now.

LEON KRUIER - CFO

For PER.C6? In 1998. In the United States.

Unidentified Audience Member

In 1998. Okay. A follow-on patent --.

LEON KRUIER - CFO

Yes.

Unidentified Audience Member

Added to process yield enhancement, things like that?

LEON KRUIER - CFO

It's a patent family of over 30 patent groups, and close to 500 patents surrounding this whole system.

Unidentified Audience Member

That you want approved?

LEON KRUIER - CFO

Well, in addition to the basic patents. Right? What I said about the biologics master file, when you become a licensee, you pay partly for the use of the patent estate, but you also pay for the use of the know-how in the biologics master file, and the safety data. Right? The way to grow up these cells, the medium that is used, et cetera, et cetera.

So even as the patents expires -- right -- a licensee would still be eligible to pay a certain amount of royalty -- pays for the know-how. So, it's not really one of the short-term concerns.

Yes, sir?

Unidentified Audience Member

(inaudible question - microphone inaccessible)

LEON KRUIER - CFO

Well, ten years out is a long way. I -- I might be retired at that time. But if you look at a couple of years, I think we envision the Company to -- the sales of the Company in the medium term -- three to five years, to be driven by at least one product that makes it to clinical trials and adds significantly to sales base -- 3 to \$500 million of sales per year. Right? And that could be a rabies product, antibody product.

We also envision that in, say -- somewhat longer term five years plus, there will be products from licensees that will add to our royalties and add to our profitability in that way. Plus, we think that there are still significant and important strategic partnerships that we can close and forge very profitably around products that we have.

The hepatitis C antibodies, the flu antibody, the tuberculosis product. So I think, all together, we see enough opportunities in the next, indeed, zero to five years, to continuously and profitably grow forward with the mix of things that we have.

Yes, sir?

Unidentified Audience Member

(inaudible question - microphone inaccessible)

LEON KRUIER - CFO

Well, it -- we had discussions with Wyeth earlier in the year - right -- which were leaked out to Wall Street Journal and not by us. I think there was -- with Wyeth, there was a -- the team at Wyeth vaccines, we knew extremely well, which there is a team that came from Merck at the time when they are making their HIV vaccine. So, it's Marie Armenio and a number of those type of people.

There were a lot of -- they were relatively between two companies, a few areas overlapped -- right -- and we explored opportunities to see what would happen if we put those companies together. And while we're in the middle of it, Pfizer came along and took out Wyeth, so that was the end of that exercise.

And what we are left with -- we basically said, look, the Company is not for sell. End of story. Right? We are growing at a rate that is 30% plus per year. We're profitable. We throw off cash. We have close to 180 million in cash in the bank. And we have a great technology and we have a number of pipeline products, which are progressing actually quite well.

So let's make it very transparent to the market that this Company has great assets and revenue. And I think that's exactly what we're doing and it's fun to run this Company, this is sort of the year where the whole company's really consolidated -- all comes together. We're a public company. And on the other hand, if somebody comes along with an offer that the shareholders can't refuse, then that can happen, but we're not soliciting bids at this moment.

Unidentified Speaker

Would you consider joining forces with another vaccine company? If it becomes larger and more competitive?

LEON KRUIER - CFO

We look at anything opportunistically, but there are not that many vaccine companies left. So I think we have a lot -- we have a plateful with all kinds of things that we're doing. We're quite happy with it and busy enough, so -- but let's keep it at that for the moment.

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Unidentified Speaker

I think we have time for one more question. One at the back?

LEON KRUIER - CFO

Yes.

Unidentified Audience Member

(inaudible - microphone inaccessible)

LEON KRUIER - CFO

In terms of -- the people -- it's also a production cell. Right? Like CHO, Chinese Hamster Ovary cells was a production cell or vehicle cells or MDCK cells. I don't have the specifics on the (inaudible) cells, (inaudible) cells, but there are a number of production cells that can support the growth of proteins, of antibodies, et cetera and in biology. So it is, in that sense, it is a competitive system.

Unidentified Speaker

Okay. I think we'll have to finish here. Thank you very much.

LEON KRUIER - CFO

Yes. Absolutely.

Unidentified Audience Member

For coming. Thank you very much, [Leon], for being here.

LEON KRUIER - CFO

Thank you.

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