

# FINAL TRANSCRIPT

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## **CRXLF.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call**

Event Date/Time: Feb. 05. 2009 / 8:00AM ET

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

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## PRESENTATION

**Operator**

Good afternoon, ladies and gentlemen, and welcome to the Crucell fourth quarter and full-year results for 2008 conference call. My name is Wendy, and I'll be your coordinator for this conference. Throughout the presentation you will be on listen-only. However, at the end of the call, there will be an opportunity to ask any questions. (Operator Instructions).

I will now hand you over to Oya Yavuz, Director of Corporate Communications and Investor Relations, to begin today's call.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

**Oya Yavuz** - *Crucell - Director of Corporate Communications & IR*

Thank you, Wendy. Thank you all for joining us today. I'd like to welcome you to our fourth quarter and full year 2008 results presentation. This afternoon's presentation will be given to you by our CEO, Ronald Brus, and our CFO, Leon Kruimer. Also here is our COO, Cees de Jong, who will give you an update on our operations.

The presentation will be followed by a Q&A session, and is also being simultaneously audio webcast via our website. You should all have the press release from this morning. I'd like to kindly ask you to read the forward-looking statements, which is on slide two of the presentation as well.

With that I'd like to hand over to Ronald, who'll start by giving you a business review of the fourth quarter and full year 2008. Thank you.

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**Ronald Brus** - *Crucell - CEO*

Thank you, Oya. Ladies and gentlemen, I'm very happy to announce that 2008 was profitable for Crucell. We've posted a net profit of EUR14.6 million compared to a net loss of EUR42.9 in 2007. The net profit per share was EUR0.22 compared to a loss per share of EUR0.66 in 2007. Wyeth withdrew from friendly discussions on a potential combination of the companies, and we reported on that.

Additional contracts worth about \$140 million were awarded for supplies of Quin vaccine in our Hepatitis B Hepavax-Gen, bringing the total for the period 2007 to 2009, to about \$0.5 billion. We're very happy to announce that the Chinese Authorities approved Hepavax-Gen for the use in the Chinese private market.

Also happy to announce that we had great progress with our influenza monoclonal antibody that we demonstrated to do much better than the gold standard, Oseltamivir, also known as Tamiflu.

Our rabies and tuberculosis vaccine entered into Phase II clinical testing throughout the world, and we concluded two Phase II tests for rabies.

Important advances were made in antibody production using the PER.C6 human technology platform, and our first licensee, Ark Therapeutics, entered into Phase III studies with a product produced on PER.C6. We closed several new license agreements, including agreements with CSL, GlaxoSmithKline and Talecris.

Brings me to the next page, and there depicted our revenue growth over the last four years. And you see a nice slope, and finally, we're coming at 2008 at EUR283 million. What you see on the pie is how that has been divided, and you see about approximately 50% is now coming from the Pediatric arena. What you also can note is that Respiratory is a much smaller segment compared to what it was in 2006 and 2007. Hence, although we still see seasonality in our product portfolio, it is a bit more balanced in 2008 as it was in 2007.

What you can also see is the build up in the two boxes on the right side where you see the build up of product sales, license fees, service fees and grants and other, in 2007; and you see a big growth of product sales, but also in license revenues, and we're very proud that we have achieved that.

When it comes to the next slide, to the product highlights, we saw a nice increase of product sales in the fourth quarter, and it went to EUR76.5 million, which represents a growth of 20%. In the Paediatric segment, we saw particularly strong growth, but also in Travel & Endemic, we saw significant growth.

With respect to our flu sales, we had -- reported a very good Q3 in 2008 and hence, compared to 2007, our sales in Q4 were slightly down.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

That brings me to the next page, which is slide number seven, which deals with Quinvaxem. The supernationals have awarded us contracts totaling \$0.5 billion. If you look at the graph that is depicted on the left bottom, you see a significant increase going from 21.9 million doses to 39.6 million doses from 2007 compared to 2008. Well, if you do the math, you can conclude that we expect a further significant growth of this product in 2009. And this is for us a very important product also because it reduces child mortality throughout the world, and that is one of the main [millennium] goals.

I'd like to bring you to page, or slide number eight, where our pipeline is depicted, and there you can see where the EUR70 million that we invest in research and development is going to.

I just want to highlight just a couple of the programs that are depicted here, especially Flavimun, because you can see that's at the end of its development path and, therefore, we expect to file registration in the coming period in Switzerland and in Germany.

I also want to guide you to Tuberculosis, where which we have entered Phase II studies now with our new Tuberculosis vaccine. And, obviously, rabies and influenza are two things that I would like to discuss with you.

And I'll bring you to page number nine. With rabies, we've seen very good results in the Phase II studies that we have concluded, including the one in the United States, and the study is also completed in the Philippines in which we have studied our monoclonal in children.

What you can also see is that we're about to start a new Phase II study in India. Why do we do that? Because the results of the first two studies are as such that we think it's wise also to combine our monoclonal antibody, not just with the Sanofi vaccine, but also with the Novartis vaccine so that this could be sold everywhere in the world when Novartis has a high penetration of selling vaccines as well.

The same goes a bit for tuberculosis. We have multiple Phase I studies conducted for tuberculosis, all with the idea to cover all types of patients, the patients that have already got BCG primary doses, and the ones that don't, the ones that live in areas where tuberculosis is very highly prominent and the ones that are not living in those areas, thereby making sure that the potential label of such a vaccine will be as broad as possible.

We published in Nature, or actually I should say the Group of Harvard published in Nature, I think an important paper on our novel adenovirus technologies, and compared that basically with the outcome of the study that Merck has conducted with Type adenovirus 5 vectors.

I think the results were as such that it brings us to an encouraging note with respect of the possibilities to bring forward to the market T-cell mediated vaccines. And we're very proud that the group of (inaudible) did publish that in Nature, and we got a lot of positive report on that one.

Finally, I want to bring you down to the bottom of the page where we basically discuss a new approach of treating and preventing influenza with monoclonal antibodies. You might recall that it was an important thing to us to bring down the cost of goods of monoclonal antibodies produced on PER.C6 compared to those produced on CHO cells. The idea now is to bring monoclonal antibodies into a new segment, a segment of infectious diseases, and you can only do that when the cost of goods is under control. In the first studies where we compared our monoclonal mix or our monoclonal antibody with Tamiflu, we demonstrated superior efficacy both in preventing influenza, as well treating influenza. And it seems that just one antibody covers a wide variety of pandemic strains of the influenza, including the so-called Spanish Flu H1 variant.

Then I would like to take you to slide number 10. In the last three months we did approximately 12 deals with our PER.C6 technology, and I would just pick four of them as being important deals. Gedeon Richter, an important company because it's well known that the work on generic drugs as well as Biosimilars. Very important also Talecris Biotherapeutics in the United States, where we had a second exclusive PER.C6 commercial license agreement with on a plasma protein.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

Also important a great company from Australia, CSL; CSL is a great company, did tremendously well, and we're very proud that they took a non-exclusive license on PER.C6. The same goes for GlaxoSmithKline. And finally [off balance], Centocor signed a non-exclusive STAR research and commercial license agreement.

With respect to the outlook, and I'm now at page number 11, we expect strong vaccine sales for 2009, double-digit growth going forward. The outlook is as such that we expect 20% revenue growth, significant improvement of operating profit and a solid cash flow. We will continue to pursue key partnerships and focus on progress in clinical development, and continue to broadly license out our technology to our peers in the industry.

I'd like to discuss with you something that we brought forward to you not that long ago, and that's the Crucell ambition. We believe that we can accelerate the growth of our Company when we work on the organization and people, but also work on an operational excellence program that we call Healthy Ambition. That, together with a very stringent focus on infectious diseases, and an optimized delivering on promises, should be capable for us -- should it make possible for us to accelerate our growth.

And with that, I would like to hand it over to Cees de Jong, who will give you an operations update.

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**Cees de Jong** - *Crucell* - COO

Thank you, Ronald. In my presentation, I will a few items to cover. I will first give a short update on some of the changes and improvements that we've made to the Organization. I will then talk about Healthy Ambition and the progress that we've made during the last months. And, thereafter, share with you some of the key developments at our most important sites.

But let me start with Organization and people and share the improvements made to the Organization, as indeed, those form the basis under the Crucell ambition. Not only have we recruited five new leaders in operations, there's been significant leadership and organizational change, and we've brought in a number of experienced healthcare professionals in, in key positions.

In addition, and by deploying some true global HR tools, we've been able to better align all our leaders to our focused strategy and to the Healthy Ambition program. We further streamlined the Organization focusing on efficiency and particularly on delivery.

And finally, we're working towards an integrated one Crucell Company, and we've set up several forums where best practices are shared and further synergies identified. In all, we've made good progress on our organizational development agenda, and I think it's fair to say that the Organization's now more robust and more mature.

Taking you to the next sheet and updating you on Healthy Ambition, the stronger Organization is also ensuring delivery of the Healthy Ambition savings. As you will remember, Healthy Ambition is targeting savings of 15%, or about EUR30 million, on a 2007 cost base, excluding R&D. Study and design was completed in June of last year, and during the second half of 2008 the net savings amounted to EUR5 million, and that is ahead of earlier estimates.

We realized savings in overheads, we outsourced non-core business activities, and we rationalized our sales office infrastructure. In addition, we improved yields in production, and a part thereof is related to Healthy Ambition savings.

I think we're now very well on track to deliver the EUR30 million end this year, and our focus will be this year on reducing complexity, and that is standardizing our product offering and ensuring that small lots can and will be produced and sold in the most efficient way. And our focus will also be on streamlining the Organization further. And this is especially relevant for the operations and supporting functions in Switzerland, where last month we have started to implement optimized business processes. Obviously, the actions in Healthy Ambition are closely monitored and built into the budget.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

Let me then take you to some of the highlights of the most important sites in our network, and we're on sheet 16. I'm pleased with the progress that we've made during the year in both Switzerland and Spain, and a better performance in operations has contributed to the higher gross margins reported for 2008. As Leon will further explain, our gross margins have improved considerably, both for Q4 as well as for full year. In addition to higher product sales volume, higher license income, a key driver for the better margins has been an improved yield in operations, for both Inflexal and Epaxal.

On all our sites, we've had a number of audits, from both customers and regulatory authorities, and these orders were all successfully passed and confirmed; again, the robustness of our operations in general, and our quality systems and business processes in specific. And one of the most important audits was a recent inspection by the FDA for some of our facilities in Berne, and again, that audit was passed very successfully.

In our fill and finish center in Madrid, we have installed the new filling line, increasing the capacity to 100 million syringes per annum, and that line's been installed in a record time, and for a very limited investment.

Taking you to the next sheet, I'd like to update you on Korea where, during 2008, we more than doubled our output at the existing site. In addition, the Korean team have now increased their yields to world class levels, or in other words, the production losses that we have in Korea have been minimized to a point that is really state of the art.

Our Landlord at the Shingal site is leaving the site this year, and we had to create some own utilities. These utilities, such as water for injection clean steam, and even an own waste facility are now in operation and we can work fully independent.

As reported earlier, all legal and other disputes have been resolved and settled, and that means that production continuity is now guaranteed. In the meantime, the construction of the new site in a free economic zone, at Incheon near the airport has started. And just to remember, we are relocating our Hep B equipment, and we're duplicating our Quinvaxem production processes. Technical completion for that facility is targeted for early 2010, and thereafter, we will enter a phase of validation.

Now a picture says more than 1,000 words. On the next sheet, sheet 18, you see the layout of this new facility, and we are investing some EUR50 million, the majority thereof this year. The benefits of this new facility are better efficiencies, especially for Quinvaxem. It will enable to grow further -- it will enable us to grow further. And last but not least, having a factory in free economic zone will offer a substantial tax advantages.

Sheet 19, let me summarize. 2008 has been a year of focusing on delivering the promises, improving margins, and growing. We've seen significant change, stronger management controls are in place, our operation is in better shape, and Korea is making great progress. So in 2008, we have worked hard to build a more sustainable and more mature organization. In addition, we've eliminated several risks and uncertainties in our operations, and we are now much better positioned for the future.

During 2009, we will continue to improve, to share best practices, and to drive the implementation of our Healthy Ambition. With that, I'd like to hand over to Leon.

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**Leon Kruimer** - *Crucell - CFO*

Thank you, Cees. It's my pleasure to present the financial highlights, and I'd like to take you to slide number 21.

Ronald already mentioned, but 2008 has been a very, very good year for us financially, and Crucell is in better shape than ever. In addition to that, we have, during the year, eliminated a number of important risk factors, in the area of legal, IP and some of the other areas, like Cees just mentioned in Korea.

Our revenues overall grew 33% in 2008, and margins in the fourth quarter increased to 50%, which is an increase of 16 basis points, versus the comparable quarter in 2007. That increase was due mostly to increased volume, product sales, to license

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

revenues, which increased by a factor of more than 2.5, and drop immediately down to the bottom line, because they have -- they represent pure profit, to production performance and better yields, and last but not least, to currency effects, which basically can be attributed to a strong euro and a weakening dollar.

Our net profits amounted to EUR19.2 million for the fourth quarter. That compares to a loss of EUR4 million in the comparable quarter in 2007. That has resulted overall in a net profit of EUR14.6 million for the entire year.

We increased our cash and cash equivalent significantly by an amount of EUR67 million during the fourth quarter in 2008. That even exceeds the amount by which we increased it in the fourth quarter of 2007, bringing our total cash at the end of the year up to a level of EUR171 million.

The biggest contributor to this is the net cash from operating activities, which increased by EUR61.5 million during the fourth quarter. For 2009, we expect strong growth in Quinvaxem, and in order to anticipate that and to have the product ready for shipment in the first quarter and the beginning of the second, we increased our inventory significantly to a level EUR92 million by the end of the year, which also came out of our operational cash.

On the next page, number 22, we show an abbreviated profit and loss for the fourth quarter and the full year. Let me just highlight some of the points that are in there.

Revenues and operating income in the top left hand corner, Q4 2008, amounts to almost EUR94 million, a strong growth of 23% over the comparable quarter last year. And the total sales, total revenues and operating income for the full year came out to EUR83.3 million.

Gross margin for the fourth quarter represented 50% of the total revenues, and that is a significant improvement from the 34% which we realized during the fourth quarter of 2007. That strong performance also brought the overall margin for the year up a level of 45%. We promised you at the beginning of the year that we would improve our margins from 2007 level of 34%, and we have. We increased it more than 11 basis points.

Operating expenses were fairly stable, and the results for the period we've mentioned were 19.2% for the quarter and 14.6%, both profitable compared to losses in the previous year.

If you follow me to page 23, we detail the revenues and other operating income. Product sales, of course, is the vast majority of it; EUR76.5 million for the quarter and EUR226.1 million for the entire year, again both strong increases over comparable periods prior year.

License revenue, which amounted to EUR12.2 million for the full year 2007, were now EUR13.2 million. New contracts, a significant part of that is milestone payments on existing contracts with partnerships, which we reported on during the year. I'd also like to point out that one third of these payments are due to closing new contracts, and that shows how vibrant our research and development and our business development business is.

Grants came out at EUR5.4 million for the year, and other income at EUR10.8 million, which include important revenue parts for, among others, our Tuberculosis project. EUR93.7 million total revenues in operating income again is a record for any quarter that we've realized in the Company's lifetime.

On the next page, number 24, we talk about the cost of goods sold and operating expenses. All looks very stable. The cost of the goods sold decreased as a percentage of total revenues, giving us very significant margins.

The total cost of goods sold for the year, including the cost of service fees and license fees, was EUR145.8 million, and amounted to EUR44.8 million for the quarter in 2008, which can also see that the license -- the service of license -- sorry, the cost of service fees represent a portion of the income, and actually the service fees that we report are quite profitable.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

Research and development, very important investments that we make, and a significant investment we continue to make in order to drive our future business forward. We still invested just over EUR70 million this year. That is up from EUR64 million in the previous year, and is clearly demonstrating our commitment to bringing new products of our own inventions forward.

Selling and general administrative very much in line with the level last year, and we will show you during the year that also the Health Ambition project will have an impact on that. We benefited in 2008 by the reversal of an impairment in 2006 of a facility we started to use again. The amount of EUR4.9 million net, so our total operating expenses came out to EUR129.7 million.

Something about cash flow on page 25. First and fourth quarter on the complete left hand side you will see that the operating activities contributed strongly to the net increase in cash in the fourth quarter; EUR61.5 million out of EUR67 million total net increase in Q4 2008.

We invested some, we raised some by financing -- I'll get back to it in a minute -- and there was a minor exchange rate effect on cash of EUR0.6 million.

For the year as a whole, operating activities were just about even. It's actually EUR300,000 used, cash used in operating activities. The main reason for that was that in this amount is included EUR37 million investment in inventories that we made during the year. Again, this was a conscious decision to bring up our level of inventories since we are anticipating very, very strong sales in the first period also of 2009.

We invested all together in property plan and equipment EUR8.9 million, and that is a net amount of some other factors in there. Financing brought in EUR16.6 million. That consists basically of two parts. Number one, it is the proceeds from operational equipment leases. A policy we've had over the last eight years basically to spread the cost of our equipment purchases over a number of years. And second of all, we partly financed the strong increase in investment in inventory in Korea by a loan from a Korean bank. That has to do with holding issues, tax issues. The other good thing for us was that a company like us in today's very, very difficult credit environment was able to get both operational equipment leases from companies, as well as commercial loans to finance working capital.

The cash and cash equivalents, as said, during the year increased by EUR7 million -- over EUR7 million, from EUR163 million to EUR171 million.

And finally, the guidance for the year 2009; Ronald already mentioned some about that. We forecast 20% revenue growth, a significant improvement absolutely in operating profit and solid cash flow.

The revenues will be phased throughout 2009 in very similar way to those in 2008. Again, it was mentioned before, whereas our business was strongly influenced by seasonal sales, especially of flu vaccine in prior years, that effect tends to diminish, because the products like Quinvaxem are much more evenly spaced throughout the year.

We expect solid cash flow despite investments in a new facility in Korea. Those investments will total about EUR50 million, with the majority of that spent in 2009. Construction there, as Cees mentioned, has already commenced.

Crucell's business, very important, is not expected to be affected by the economic recession in 2009, so we're very confident of this outlook.

And with that, I'd like to hand it back to Oya Yavuz for the question and answer period.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

## QUESTIONS AND ANSWERS

**Oya Yavuz** - *Crucell - Director of Corporate Communications & IR*

Wendy, we'll take questions now. Please limit yourself to two questions per caller, and clearly state your name and company. Thank you.

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### Operator

Thank you. (Operator Instructions). Our first question comes through from the line of Marcell Wijmer from SNS Securities. Please go ahead.

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**Marcell Wijmer** - *SNS Securities - Analyst*

Yes, good afternoon. This is Marcell Wijmer speaking from SNS Securities. First of all, my congratulations for these great results. I've got two questions. It's regarding Quinvaxem. Can you tell me what is your view on the size of the market in the next few years for the Pediatric vaccines? And can you tell us something about when we can expect the new tender offer from UNICEF for these type of vaccines? Thank you.

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**Ronald Brus** - *Crucell - CEO*

Yes, Marcel, this is Ronald Brus. I think, very importantly, if you look at the market, and especially the market that's been served by UNICEF, you see that UNICEF is living up to its goals. You see a strong increase in the number of children vaccinated throughout the world, and a strong increase in countries that have allowed UNICEF to start vaccination programs throughout the world.

Now there's two things that it's very important to bear in mind. One is that there is a original UNICEF market that we see as being as big as about 150 million -- 140 million, 150 million doses annually, and I think very importantly, this is not a one time market, right? Every birth cohort needs to be vaccinated from [then out]. So we see a very sustainable market of about 140 million, 150 million doses.

On top of that, we see something emerge in India. What we see in India is although they're not considered to be one of the countries qualifying for UNICEF distribution, we see that India is also one to allow pentavalent vaccination throughout its country.

Now the Indian market by itself could be as big as 100 million to 120 million doses as well, so two segments of the market, Marcell, the 150 million that we know in the UNICEF territories, and approximately an additional 100 million in India. This is how we see the future, with respect to the market potential, for pentavalent vaccines. And with respect to the process, I'll bring it back to Cees, because he is involved there with his team on negotiating with UNICEF and the likes.

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**Cees de Jong** - *Crucell - COO*

Yes, Marcell, we expect the tender request any day now. We haven't gotten it yet, but it's due any day. Then what would happen is during the second quarter of this year, there will be the interactions with UNICEF, and a decision would be during the second half of this year. So decision to be expected second half of 2009.

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**Marcell Wijmer** - *SNS Securities - Analyst*

Okay, thank you very much.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

**Operator**

Thank you. Our next question comes through from [Sachen] Soni from Kempen. Please go ahead.

**Sachen Soni - Kempen & Co - Analyst**

Good afternoon. This is Sachen Soni from Kempen and Co. in Amsterdam. Congratulations on profitable full year. I have two questions. One is on the growth margin of 50%. My question is how sustainable this high growth margin is. What do you think is the realistic growth margin going forward?

And another question is on the FluCell and Epaxal Junior and Yellow Fever. Can you give some update on these questions -- these products? Thank you

**Cees de Jong - Crucell - COO**

Sachen, let me take the growth margin question first. In the fourth quarter, the gross margin has been also very high due to high license income as you've seen. What I can say, on our margin on product sales, our gross margin on product sales, that is very sustainable going forward as our portfolio is now settled.

In terms of -- I think you were asking for both Inflexel, Epaxal and even Flavimun. Let me say that FluCell -- let me take Inflexal and Epaxal first. You've seen that on Inflexal, we've been able to have a very nice position in the European markets due to the fact that our product is truly unique. We expect that position to be sustainable.

Epaxal is a nicely growing product, and in our view, not prescribed enough, so we would consider further growth. And with regard to FluCell, Ronald, I think you should take that one?

**Ronald Brus - Crucell - CEO**

Yes, as you might know, FluCell has been partnered, except for Japan, to Sanofi Pasteur. And we are not at liberty to talk you through the progress of that program because it's entirely in the hands of Sanofi Pasteur.

But in order to give you a better flavor on the programs and what we expect for the products that we're currently selling, how we could move forwards, I think it's important to note that we have active sales forces in a limited number of countries. In those limited number of countries where we do the selling ourselves, we have reached market shares that are quite significant and in the order of about 19% to 20%.

If you now look at the fact that we do sell with distributors in an additional 60 countries, you can see that we're striving towards better penetrating those markets as well, because we know it's feasible, we know it's doable and we know that the products are good.

Just give you an example of Epaxal. Epaxal is the only Hepatitis A vaccine that does not use aluminum as an adjuvant booster. Now in order not to use aluminum, you should have a very strong immunogenic response, that's one thing. And second, you can do away with [last] of the -- about half of the volume that you inject.

Now these are very important things, and we started to market that product in several countries in Europe, and we see that we easily achieved very high market shares there. So we also feel that with having better distribution deals in place, these are typical products that should be able to grow our Company further. With that, I'd like to take it back to Oya.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

**Oya Yavuz** - *Crucell - Director of Corporate Communications & IR*

Next question, please.

**Operator**

Thank you, our next question comes through from [Tom] Campbell from Knott. Please go ahead.

**Tony Campbell** - *Knott Partners - Analyst*

Yes, two questions. Can you just remind us the extent of the NOL? And the second question is, the plant that you're manufacturing, something for Wyeth, has that plant been written off, or is that a fully approved plant? And is there something from an accounting basis that could come back here? Because I think that plant was written off.

**Leon Krumer** - *Crucell - CFO*

Yes, Tony, this is Leon. Let's take the second one first. The plant where we produce for Wyeth was a plant that we completely impaired, written -- wrote off in 2006. But 50% of the value has been capitalized again, which is called the reverse impairment, right, which is the effect of about EUR5 million you've seen during this year. It's a positive effect. And that was because that plant's generate a cash flow again; that's the criteria for impairing or not.

So the plant itself is a brand new plant. It's a world class facility. As long as we keep on using it, we should be able to normally appreciate it, and the more business comes in the more reverse impairment you can take.

Second question, or the first question actually, what's the status of the NOL, the net operating losses? The net operating losses per our annual report 2007 were about EUR250,000 million. What we have done with those during the year, a significant part has been capitalized, because otherwise it would evaporate over the next few years through a deal and through tax provisions in the Dutch tax [law], so we can capitalize the tax losses and offset future license and royalty incomes with them for a long time to come, 15 to 20 years.

And the second part of it, a big part of it, was an operating loss which related to Switzerland. And since administratively we have made Switzerland into a distribution center, so products are distributed administratively through Switzerland we generate a profit there, and are able to use our operating tax losses there effectively. So nothing would go to waste.

**Tony Campbell** - *Knott Partners - Analyst*

Thank you.

**Operator**

Thank you. Our next question comes through from Mutlu Gundogan from RBS. Please go ahead.

**Mutlu Gundogan** - *RBS - Analyst*

Yes, hello. Two questions. The first is on the travel vaccines that you want to expand to the US. My question is, since you have entered the discussions with Wyeth and those have been canceled, has that project been on a hold back then, or has it started again? So that's my first question.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

Second question is on your adviser, Morgan Stanley. They are no longer advising you. It was in the press a couple of days ago, a week ago. Does that mean that you don't have an adviser at the moment? Those are my questions, thank you.

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**Ronald Brus** - *Crucell - CEO*

Okay, let me take your first question on travel vaccines. During the friendly discussions that have been held with Wyeth, we've conducted business as usual, so that means that the planning that was ongoing and is ongoing with regard to that project has continued, and has not been affected by those discussions.

The second question --

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**Mutlu Gundogan** - *RBS - Analyst*

What do you expect then -- that this will finalize? Do you have an agenda?

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**Ronald Brus** - *Crucell - CEO*

We will finalize our plans this year, and when there is news to share with you, we will do so during a quarterly update or an analysts meeting.

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**Mutlu Gundogan** - *RBS - Analyst*

Okay.

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**Leon Kruimer** - *Crucell - CFO*

This is Leon. With respect to the discussions with Wyeth, as we reported, those have been stopped, so we are not actively seeking advice. And for the rest, we don't comment on the relationships with advisers.

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**Mutlu Gundogan** - *RBS - Analyst*

Okay, thank you.

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**Operator**

Thank you. Our next question comes through from Alan Carr from Needham and Co. Please go ahead.

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**Alan Carr** - *Needham and Co. - Analyst*

Hi, good afternoon, everyone; a couple questions, one on Quinvaxem. Could you -- you mentioned that second quarter you -- I guess a series of meetings with UNICEF to discuss contracts for the next three year period. Could you characterize those? What sort of -- what you expect to happen? If you could characterize those, and then also describe, I guess, what [your all] take on the competitive environment, the extent that that there might be a pricing pressure for the next three years, the next round of contracts.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

The second question is on taxes. Can you give some guidance on what those will look like going forward now that you're profitable? Thanks.

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**Cees de Jong** - *Crucell - COO*

Alan, this is Cees. Let me take that question on Quinvaxem. The way the tender is organized is that we will get tender documentation sent literally any day now, and we will be requested to submit our offer, and then indeed an interaction takes place. I would not like to comment too much about such interaction.

The way this is organized though is that it's an absolute level playing field for all players that are involved. And with regard to competitive pressure, you've heard Ronald describe the characteristics of the market. You've seen that there's new players on the market, new Indian players on the market, yet there's also an Indian market that is developing very, very quickly now. So we might face some competitive pressure. I cannot rule that out, obviously, but we think there's very good prospects for Quinvaxem as a product in our portfolio.

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**Leon Kruimer** - *Crucell - CFO*

Second one, Alan, this is Leon, relates to the tax burden that we experience. As you've seen, this year, we have a net positive tax effect that actually is a combination of a number of one-time effects, which I will explain, and actual taxes that we pay in various countries.

The one-time effects come from capitalizing net operating losses in Switzerland, since we now have a probability of sustainable profits there. That's the criteria for capitalizing that. The second part of it relates to the situation in Korea where, due to the fact that we make a significant investment, we are eligible for a period, a five-year period in first instance of reduced taxes; a so-called tax holiday. Therefore, a liability that was on the balance sheet for future Korean taxes could be reduced, because now that liability was recalculated against lower taxes that we will experience for certain.

We do meanwhile also pay taxes in a number of countries like Spain, the United States, Sweden, and also in Korea. So as our business progresses and the volume and the profits would increase, obviously, in absolute terms, you would pay more taxes. That will be offset again for a significant part by a tax holiday again that we will experience, that we will get in Korea, and there are a number of things that are still under discussion with the tax authorities, so I can't comment on that. But I think that it is important to look at our EBIT line going forward, and the tax burden of I think on Crucell on average will be very moderate.

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**Alan Carr** - *Needham and Co. - Analyst*

I guess you're suggesting that might be relatively -- that the taxes would balance out. There wouldn't be much of a net tax going forward in '09. Is that fair to assume?

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**Leon Kruimer** - *Crucell - CFO*

Yes.

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**Alan Carr** - *Needham and Co. - Analyst*

Okay. Thanks very much.

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Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

**Operator**

Thank you. Our next question comes through from Mark Clark from ING. Please go ahead.

**Mark Clark - ING - Analyst**

Yes; good afternoon, everyone; a couple of quick questions. Just on Quinvaxem, the 39.6 million doses, do you have a feel for the market share that represented, or if that is still the absolute size of the endemic market?

And secondly, can I just ask what your cumulative Quinvaxem sales are in dollar terms? I calculate that it's a little over EUR250 million, but I don't know what your rates, your various lots of sales, your dollar rates occurred at. So I wonder if you could give us that figure so we can calculate how much of that EUR500 million is left to be fulfilled this year. Thank you.

**Cees de Jong - Crucell - COO**

Hi, Mark. This is Cees. Good afternoon to you as well. Mark, we think that the doses that we sold in 2008 represent slightly over 50% market share, and I think your calculation on the cumulative doses sold to date is about right; in dollars it's about right. It might be slightly, slightly higher, but not lower.

**Mark Clark - ING - Analyst**

Thanks very much.

**Operator**

Thank you. Our next question comes through from Fabian Smeets, from Rabo Securities. Please go ahead.

**Fabian Smeets - Rabo Securities - Analyst**

Good afternoon, Fabian Smeets, Rabo Securities. I have two questions, one regarding guidance. Can you give guidance on the total expected CapEx and potential milestone payments?

And two, on the sustainability of gross margins, do you expect it's reasonable that the Q4 gross margins, or the costs of goods sold, are those sustainable for the full year 2009?

**Leon Kruimer - Crucell - CFO**

Yes, Leon. Yes, the abstract guidance that you were given, it's clear, and we will not give guidance on any specific lines. On the CapEx, as I've said, the biggest project by far is the EUR50 million investment in the Korean facility. The majority of that will be spent in 2009, so you can expect that the CapEx in 2009 will significantly exceed the level of about EUR15 million that we experienced in 2008. Part of that will come out of our operational cash flow, and part of that will be financed by mortgage loan in Korea.

In terms of the sustainability of the margins, in the fourth quarter, margins were very high, about 15%, and approximately -- it's somewhat hard to calculate -- but approximately 4% to 5% of that can be attributed to currency differences that we have experienced during that particular quarter, particularly a weak dollar and a weak Korean won, which accounts for the majority of our operational production costs in Korea, which is an important part.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

As Cees said before, the average margins for the year significantly increased versus the year before, and we strive to keep those margins at that level, or even improve them.

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**Fabian Smeets** - Rabo Securities - Analyst

Okay, thanks.

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**Oya Yavuz** - Crucell - Director of Corporate Communications & IR

Next question, please.

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**Operator**

The next question is from Peter Welford from Jeffries. Please go ahead.

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**Peter Welford** - Jeffries - Analyst

Hello, I've got a couple questions. Firstly, can you just highlight why I guess you brought the results forward from last week -- from next week, sorry, to this week, today? And also, just go through the 2007, I think there was a slight restatement relative to what you reported before.

And then the second question just on the Wyeth news. I guess we're sort of catching up with events here. Did Wyeth out of interest approach you, or did you go out to seek potential buyers or interested parties, and discussions then started from there?

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**Ronald Brus** - Crucell - CEO

I can take both questions. Our fourth quarter results were substantially better than expected, and also if you look at the consensus. So our legal advisers advised us basically to release that now, and that means earlier than planned. And I think no one should be reading anything else into this early release.

Second question about why we really cannot comment on who approached who, it's very -- we have lots of interactions throughout our businesses with all pharmaceutical industries, and we cannot comment on who approached who. I can just tell you that all deals and all dealings that we have with pharma tend to be extremely friendly.

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**Leon Kruimer** - Crucell - CFO

Peter, this is Leon. Regarding the restatement in 2007 numbers, that is indeed, to those that have analyzed the balance sheet, but also the effect on P&L, there is a change in accounting principle that we have applied that relates to IFRS, IFRIC, IFRIC number 14, which relates to the valuation of pension assets. And the revaluation of pension assets in 2007, to bring it on the same basis with the rule when introduced in 2008, leads to a valuation upwards of the pension assets, and leads to a positive impact on the 2007 P&L reducing the losses from about EUR45 million to EUR42 million.

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**Peter Welford** - Jeffries - Analyst

That's great. Thanks very much.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

**Operator**

Thank you. Our next question comes through from Jan Van den Bossche from Petercam, Please go ahead.

**Jan Van den Bossche** - Petercam - Analyst

Yes, good afternoon, a few questions. First of all, on the R&D budget. I don't know whether you can give some guidance on whether we should expect similar growth rates in '09 as we've seen in 2008 for the R&D budget.

And then secondly, on the Indian market segment for Quinvaxem, could you highlight a little bit whether Crucell can tackle this potential, or whether it is up to Novartis to address this market, and whether that could have any impact on the margin, I would say, for Crucell? I know you have arms length deals with Novartis, but maybe you could give some clarity on that business. Thank you.

**Cees de Jong** - Crucell - COO

Jan, in terms of the R&D budget, what is important to understand is that R&D in Crucell is not calculated as a percentage of sales. We have gone through a complete exercise to analyze a strategy in the projects belonging to that, and basically we invest a certain amount each year, and that was a little bit more in 2008 than it was in 2007, in the specific projects, in the limited number of focused projects that we work on.

In 2008, that number will be similar, a little bit higher probably due to the intensity of the programs that we have, but don't draw it forward in terms of percentage of sales.

**Ronald Brus** - Crucell - CEO

Jan, as an answer on your second question with respect to countries that are more or less outside the UNICEF territories, with respect to the profits for Crucell, there is no difference whether or not those are being tackled, so to say, by Novartis or by ourselves. There is a tendency, since we are quite well equipped in providing services to our clients throughout the world for Quinvaxem, that there is a tendency that we take somewhat more territories to ourselves in a very good relationship with Novartis, and that has to do with that our teams have worked quite well over the last three years in coming out with the right strategy for Quinvaxem and know exactly what buttons to push, so to say.

So for us, it doesn't matter that much whether those areas are being tackled by Novartis or ourselves. We have a very good steering team in place that really looks at the map of the world on a regular basis between us and Novartis, and these discussions are very friendly and are just aimed to make sure that the market share of Quinvaxem throughout the world is optimized.

**Jan Van den Bossche** - Petercam - Analyst

Okay, thank you!

**Operator**

Thank you. Our next question comes through from Rene Verhoef from Fortis. Please go ahead.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

**Rene Verhoef** - Fortis - Analyst

Yes, good afternoon; two questions, one regarding the cost reduction program, EUR25 million left. Can you give some clue that will -- the cost savings, will they be realized in SG&A cost or cost of goods sold? Can you give some information about the split?

**Cees de Jong** - Crucell - COO

Yes, Rene, this is Cees. As we've I think mentioned before, there indeed is some 40% of savings that will have an impact on our gross operating margins, and some 60% to come out of SG&A. Fair to say that what we achieved in 2008 was more on of 50/50 basis, but going forward, we look to 40/60.

**Rene Verhoef** - Fortis - Analyst

Okay, and regarding sales achieved in the -- all the vaccine segment, that business is growing quite nicely. Can you give some color, what is driving growth there, and also is it related to the Talecris protein sales? What do you expect going forward for that business?

**Ronald Brus** - Crucell - CEO

Well, Rene, this is Ronald Brus. This business is doing well. Indeed, the Talecris relationship is paying off, I would say. And, obviously, we started to sell, apart from vaccines also proteins and monoclonals, because we're gearing up our own distribution network once we can sell rabies, and maybe on the longer term flu antibodies throughout the world. We cannot give you the specifics though, and we will not do so. But, indeed the business is doing well there.

**Rene Verhoef** - Fortis - Analyst

Okay.

**Oya Yavuz** - Crucell - Director of Corporate Communications & IR

And we will take the last question, please.

**Operator**

Thank you. Our final question comes from the line of Steve McGarry from Goldman Sachs. Please go ahead.

**Steve McGarry** - Goldman Sachs - Analyst

Hi, good afternoon; just a couple of quick questions. Obviously, as the Company gets larger and larger, then the impact of currency is going to be potentially -- have a greater impact in terms of forecast. Can you give us any feel for what you expect in the next 12 months in terms of the split of revenues in euros versus dollars? And also, your cost base, euros versus, say for example, Korean won, with the facility you're obviously building there?

**Leon Kruimer** - Crucell - CFO

Yes, Steve. In terms of revenues versus dollars, if you look at the impact of pediatric vaccines on overall sales, product sales, you see that's about 50%, and the vast majority of that is dollar based. What we have done during the year, especially because we're

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

faced with strongly fluctuating currencies, and especially the dollar versus the euro, we have started very diligently to buy forward currencies for the cash flows that they are basically well known. And although we don't hedge positions, we do hedge certain cash flows, cash flows that are certain. And that has blunted the impact of all the currency differences significantly.

If you look at the overall P&L, then you will see that the currency impact, which was still about EUR4.5 million loss in the first quarter has been reduced to near zero for the year as a whole.

In terms of our cost base, it's important to see that a significant part of our cost of goods sold, namely the ingredients that we buy for flu and for Quinvaxem, are also dollar based. So actually, there is quite a nice natural hedge between the revenue and the cost, both in dollar and dollar based type of currencies, but we do very carefully monitor the progress of the dollar and the effects of that versus our eventually reported consolidated result.

In terms of Korea, the plant that we're building and the write off that will occur on that will be in Korean wan. What we've seen in the past that the Korean wan has been remarkably stable against the dollar, but also that has changed in the past year with the Korean wan significantly depreciating against the dollar, and then appreciating a little bit. For us, that actually has been a good development, because it means that our fixed operating costs in Korea have gone down.

Again, that is also something where we will hedge the cash flows that will go into that, and something that we will also do in this financing part of it. And a significant part of the investment will be Korea based financing in order to circumvent part of that currency issue. But I think that it's something that affects a lot of companies in the world. It also affects us, and we've taken our precautions in terms of treasury management.

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**Steve McGarry** - *Goldman Sachs - Analyst*

Okay, thank you. And just one final thing just to ask. Obviously, you've made it clear that Crucell hasn't really been impacted by the macro-environment here. Have you got any hints, for example, from any of your suppliers that there's any pain likely to come through the pipeline at any point over the next couple of months?

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**Ronald Brus** - *Crucell - CEO*

Steven, this is Ronald. Could you please repeat the question, because I didn't understand?

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**Steve McGarry** - *Goldman Sachs - Analyst*

What I'm asking is if you get any indication from any of your suppliers at any point over the last few months that even now that the macro-environment is beginning to impact your business in any way?

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**Cees de Jong** - *Crucell - COO*

Steve, this is Cees. To the best of my knowledge, none of our major suppliers have given any of those signals. Now as you may recollect from earlier discussions, we've got a huge supplier base of various small services, so I cannot rule out that there is suppliers in between that. But for major services, either in goods or services, none of those signals given.

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**Steve McGarry** - *Goldman Sachs - Analyst*

Thank you.

Feb. 05. 2009 / 8:00AM, CRXL.F.PK - Q4 and Full Year 2008 Crucell Earnings Conference Call

**Oya Yavuz** - *Crucell - Director of Corporate Communications & IR*

Okay, well, thank you also on behalf of management. Thanks a lot for joining us today, and your interest in Crucell. If you have any further questions, you know where to find us, and have a nice day. Thank you!

**Operator**

Ladies and gentlemen, thank you for joining today's call. You may now replace your handsets.

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