

# FINAL TRANSCRIPT

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## **CRXLF.PK - Q1 2010 Crucell Earnings Conference Call**

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**Ronald Brus**

*Crucell - President and CEO*

**Cees de Jong**

*Crucell - COO*

**Leon Kruimer**

*Crucell - CFO*

## CONFERENCE CALL PARTICIPANTS

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*Madison Williams - Analyst*

**Guillaume van Renterghem**

*UBS - Analyst*

**Mutlu Gundogan**

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**Brigitte de Lima**

*Merrill Lynch - Analyst*

**Fabian Smeets**

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**John Gibbons**

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## PRESENTATION

**Operator**

Good day and welcome to the Crucell Q1 2010 results conference call. At this time I would like to turn the conference over to Oya Yavuz, Vice President, Corporate Communications and Investor Relations. Please go ahead.

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**Oya Yavuz** - *Crucell - Director of IR*

Thank you for joining us today. Welcome to our first quarter 2010 results presentation. Our presentation this afternoon will be given by our CEO, Ronald Brus; our COO, Cees de Jong; and our CFO, Leon Kruimer. The presentation will be followed by a Q&A session, and it's also being simultaneously audio webcast by our website.

You should all have our press release from this morning. I'd like to ask you to read the forward-looking statement, which is also on slide two of the presentation. With that, I'll hand over to Ronald, who will start by giving you a business review of the first quarter of 2010.

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**Ronald Brus** - *Crucell - President and CEO*

Thank you, Oya. Good morning and good afternoon, and thank you for listening in on this first quarter results call. As you have seen, the first quarter has been negatively influenced by pacing of deliveries of Quinvaxem. However, having seen the figures of April, we noticed that in this first month of the second quarter we have sold more pediatric vaccines than in the entire first quarter. We therefore expect a very strong second-quarter for Crucell.

In addition, we have announced last week new contracts for Quinvaxem, bringing the total awards since 2006 to \$910 million. Today we also announced the start of a new study in Burkina Faso to test our malaria vaccine in the setting where malaria is endemic. This quarter we also announced and started to collaborate with GlaxoSmithKline on a combination of their RTSS vaccine and our AdVac vaccine as given as a prime boost for the prevention of malaria worldwide. The companies aim to start clinical studies already within a year with this combination of RTSS and AdVac.

We also started a new Phase II study with our tuberculosis vaccine to test this in HIV-infected individuals. As guided earlier, our R&D expenses were up 31% and we posted good progress on our pipeline.

The influenza antibody for clinical use has been produced in a FlexFactory, which basically means in a fully disposable way, leading to shorter development times and significantly lower investments and cost of goods. We have made significant progress in upscaling our Swiss Epaxal plant for the US market, and here we are ahead of our schedule.

I'll take you to page number five. The same holds true for our Taiwanese partner for our additional flu antigen supply. We are ahead of schedule. We have already reached technical completion on our hep B and Quinvaxem facilities in Incheon, Korea. So this facility could already be operational this year. And this facility has a capacity of over 100 million doses of pentavalent vaccine. Three new licenses for PER.C6 have been signed this quarter.

The company has appointed Dr. Jerry Sadoff as Chief Medical Officer. Jerry has a tremendous track record in bringing vaccines to licensure and will allow us to faster develop our pipeline.

Finally, I'm happy with the fact that we could nominate Bill Burns, James Shannon and George Siber for our supervisory boards.

With that, I'll bring you to page number six, where you see the quarterly results. And like I have indicated, the first quarter has been negatively influenced by phasing of deliveries of Quinvaxem. And since we have seen already the figures of April, we expect a very strong quarter for Crucell in the second quarter.

And with that I'd like to hand it over to Leon Kruimer to discuss the financial -- oh, sorry -- to Cees to discuss the operations.

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

Thank you, Ronald, and I would like to take you immediately to sheet number eight and update you on product sales.

Product sales for the first quarter were EUR49 million, and our sales in this quarter were impacted by some large shipments of Quinvaxem moving into April. In addition, we need to remember that we compare against a very strong first quarter of last year. Last year's quarter was one of the strongest ever with very large shipments of Quinvaxem into Pakistan and Ethiopia. And this year, as said, we saw some shipments of quarter one move into April, and I'll come back to that in more detail in the next sheet.

In our travel franchise, three products formed the core of our offering -- Epaxal, our aluminum-free virosomal hep-A vaccine; Vivotif, the live attenuated vaccine for oral immunization against typhoid fever; and Dukoral, our oral inactivated cholera vaccine.



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First quarter sales in the travel franchise were especially positively impacted by [ETEC] sales into Korea. The more in general we are observing a recovery of the overall travel market. We've seen good sales growth for Vivotif in the US and also sales of Dukoral performed nicely, especially in Scandinavia.

For Inflexal, our flu vaccine, 2010 demand may be below last year's levels as, in the absence of another pandemic, overall demand for seasonal flu vaccines may be lower. In addition, we now know that production of this year's antigens for the seasonal product is more challenging than last year.

Last but not least, let me mention that during the first quarter our newly acquired sales team in the UK performed better than expected and exceeded last year sales into the UK significantly.

Let me update you on Quinvaxem, on sheet nine. For Quinvaxem, we expect a strong second quarter. We announced also last week that Crucell was awarded an additional \$110 million by UNICEF to provide Quinvaxem to additional countries in the developing world as a replacement for guaranteeing stocks of another manufacturer's vaccine. This additional award is for the period 2010 and 2011 and brings the total award to Crucell to \$910 million since its launch.

Crucell is now also and for the first time received orders to supply the vaccine beyond GAVI-qualified countries. This is therefore an important step as, in coming years, more countries will graduate from being eligible under the GAVI program and will then need to procure vaccines for national immunization plans. So these countries will soon be in a position to procure vaccines for immunization programs for themselves and giving Crucell a more sustainable opportunity to sell Quinvaxem to these additional markets.

As Ronald already said, in April alone we shipped the largest-ever quantity of Quinvaxem to a number developing countries to enable the immunization campaigns to continue. To be more precise, [until] April alone we shipped more Quinvaxem than during the whole first quarter. Or, as another comparison, these April shipments amounted to enough doses to vaccinate all newborns across the European Union for a full year. Obviously, we achieved such record shipments only thanks to a very strong and professional performance of our production and supply organization in Korea, and that is a nice lead-in to the next sheet on operations, sheet number 10.

In the last three years our Korean existing facility has supplied more than 150 million doses of Quinvaxem to more than 50 countries around the world, and that is significantly more than any of the other manufacturers of pentavalent vaccine. Crucell's track record with regard to on-time delivery and product quality and consistency is well-established. Our production performance in the first quarter of 2010 was at a similar high level as during 2009.

With the new state of the art production facility in Incheon we're further increasing the production capacity in order to meet the growing global demand for pediatric vaccines. Our facility is nearing completion, and we are starting the test runs this month. It is our expectation to start producing Quinvaxem in our new factory already in 2011, exactly according to plan.

As Ronald alluded to, several activities have already successfully moved to the site. Half of all the people we employ in Korea already operate from the new facility, and those activities were inspected by the Korean FDA recently, and we expect to receive the manufacturing license for our new facility very soon.

You don't see Switzerland on this sheet, and that is because production is stable. But I do want to mention that in the Netherlands we successfully went live with SAP without any major business disruption. The implementation of SAP is a good example of how we continue on our journey towards operational excellence.

Transfer of the fill-and-finish activities from Sweden to Spain is well underway, with the packaging line transferred in February, and that is ahead of our original plans.



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And then, last but not least, in Sweden a project was launched that is a good example of our various CSR initiatives. We've begun to reuse our distribution boxes. Those are our cool boxes used to distribute product from our Stockholm distribution center to all over Sweden. Customers are now returning the distribution boxes more than 90% of the time. The boxes can be reused four times without degradation, and they are then sent for recycling by us.

Let me take you to sheet 11, where I'll talk about process and product development. During previous calls I informed you that we were strengthening all the departments to play a role in product and process development. With the appointment of Dr. Jerry Sadoff as Chief Medical Officer and head of the product development group, we have made an absolute key hire to help accelerate the development of our pipeline.

We're making good progress with our promising new monoclonal antibody against a broad range of influenza. You will remember that last year the new [flu mop] as we call it, attracted the \$69 million NIH grant and resulted in a strategic collaboration with Johnson & Johnson.

With respect to process development and production for this program, we have successfully completed an engineering run at production scale, including the subsequent downstream purification in a fully mobile, fully disposable FlexFactory. We are now currently preparing for manufacturing for clinical Phase I material.

On rabies, positive test results from the phase 2 trial in the Philippines were announced last year. This study showed that the antibody combination was safe, well-tolerated when given to children but, most importantly, it resulted in adequate rabies virus neutralizing activity levels. Discussions were initiated with the health authorities from the US, the Philippines, China and India to obtain alignment on the Phase III clinical evaluation of our antibody combination. And previously we informed you that the Indian Phase II trial was expected to start in the second quarter, which will now be later in the year, since we're in the process of amending the study protocol and, in addition, the best release procedure in India is progressing but taking longer than originally anticipated.

For Flavimun, we have received additional questions from Swissmedic, and our dedicated team are currently reviewing these and preparing the further registration strategy.

Epaxal US continues to progress very well, meeting or exceeding our in-house targets. We have made significant progress in our process scale-up and plan to submit the US IND by the end of this year. As you know, we aim for pivotal trials next year.

Let me take you to sheet 12 (technical difficulty) tuberculosis vaccine four Phase II studies were completed last year, (technical difficulty) the infant study in South Africa and a study in Portland. The infant study that started about a year ago, and it is a first in infants, is fully enrolled, and dosing has just been completed. Long-term follow-up is ongoing, and no safety issues have been identified to date.

The study in Portland is unique because it's designed in such a way that volunteers will donate a large number of human cells, allowing a more detailed analysis of the immune responses evoked by our vaccine candidates.

In addition, two Phase II studies are now ongoing with our TB vaccine candidates. The first Phase II study, in South Africa, is a dose escalation study and adults who have had active TB. This study completed enrollment in December of last year (technical difficulty)

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#### Operator

Ladies and gentlemen, we are experiencing a momentary interruption in today's conference call. Please stand by while we try to resolve the issue.



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Ladies and gentlemen, your line is reconnected. Please continue your conference.

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

Okay, it's my understanding that we got disconnected when we started with sheet 12, so I'll start over with that sheet that elaborates on TB and malaria.

For our tuberculosis vaccine, four Phase I studies were completed in 2009, while two are ongoing. The two Phase I studies currently ongoing are the infant study in South Africa and the study in Portland. The infant study, that started about a year ago and that is the first in infants, is fully enrolled, and dosing has just been completed. Long-term follow-up is ongoing and no safety issues have been identified to date.

The study in Portland is unique because it's designed in such a way that volunteers will donate a large number of immune cells, allowing more detailed analysis of the immune responses invoked by our vaccine candidate. In addition, two Phase II studies are now I'm going with our TB vaccine candidate. The first Phase II study, in South Africa, is a dose escalation study in adults who have had active TB. The study completed enrollment in December of last year and the last boost vaccinations were given in January.

To date, the vaccine has an acceptable safety profile in all the subjects enrolled, and preliminary data also indicate that the candidate vaccine induces CD8 cell immune responses. More recently, we announced the initiation of another Phase II study, but now in adults infected with HIV living in South Africa. Enrollment of study volunteers for the first stage of the Phase II trial has started. This is the first study testing the TB vaccine candidate amongst the study population and we consider this highly relevant because people with HIV living in countries with high TB prevalence, such as South Africa, are 20 times more likely to develop TB than those who are HIV-negative. According to the WHO, one in four TB deaths is HIV related.

For malaria I can inform you that the Phase I US study with our F35, the unblinding has been performed recently. Analysis of the unblinded safety data revealed an acceptable safety profile (inaudible) today's available unblinding immunogenicity data indicates that the F35 factor induces humoral and cellular responses.

Today we've also announced the start of a Phase I malaria study in Burkina Faso. This is the first study evaluating the safety and immunogenicity of F35 in a population residing in a highly malaria-endemic area. In fact, this study will enroll malaria semi-immune, healthy adult volunteers. And contrary to earlier Phase I study, enrollment is going very well so far.

Finally, we are extremely pleased to announce a strategic collaboration with GlaxoSmithKline on the development of a second-generation malaria candidate, where the technologies developed by Crucell and GSK will be used in combination. We will explore, together with GSK, the options to accelerate clinical development in such candidates.

And with that, I would like to hand over to Leon.

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

Will you join me to page 14, the financial highlights for the first quarter. The total revenues and other operating income came in at EUR65.7 million. Important here is that our product sales are very much determined by timing of Quinvaxem shipments and those shipments can be choppy from period to period. As a result, the number of shipments and the level of revenues can vary significantly, and we've seen that during the first quarter. And I said before also the levels of shipment and therefore the levels of recognize revenues in the second quarter is up significantly from the first quarter.

Gross margins came in at 40%. That compares to 45% in the first quarter of '09. The margins are primarily impacted by foreign exchange effects and that has to do with the currencies in the countries that we produce in, like Korea and Switzerland, vis-a-vis

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the euro and vis-a-vis the dollar. Fundamentally, we believe that in the long run our margins will reach industry levels, and the short-term fluctuations in currencies, right, therefore impact the margins but not fundamentally in the long run.

The increase in R&D expenses to EUR20 million compared to EUR15.3 million is in line with our prior guidance. Our operating loss came in at EUR4.3 million and a net loss at EUR2.3 million, which translates into net loss per share of EUR0.03. Cash and cash equivalents during the period decreased by EUR45.8 million to EUR282 million. That's EUR282 million in cash and cash equivalents does not include another EUR100 million in deposits which are accounted as short-term financial investments because their maturities are beyond 90 days.

Last but not least, during the period we also filed our annual report and our Form 20-F.

If you join me to the next slide, number 15, it shows the statements of income, the P&L for the first quarter 2010 and comparing it to the first quarter 2009. And we see that the revenues, EUR65.7 million or 11% of that below the comparable quarter last year, again driven by the shipment, timing of the shipments of Quinvaxem.

Gross margins at 23.2, came in at 40%, and that is 5 percentage points lower than the level, the comparable number in the first quarter of 2009. Operating expenses slightly higher and driven by the increase in R&D expenses, offset by some decreases in sales and marketing expenses. The operating loss at EUR4.3 million, profit before tax at EUR2.4 million and the income tax is actually a positive charge of about EUR100,000. That is a one-time tax benefit due to further improvement in our tax holiday arrangement in Korea.

The loss for the period, then, came out to EUR2.3 million, and results per share, as said, EUR0.03 -- was a loss of EUR0.03 per share.

If you join me on the next page, number 16, it details the total revenues between product sales, license revenues and service fees. There you see that the product sales have decreased vis-a-vis the same period in 2009, but the license revenues are up, and that has to do with the revenue recognition on the development agreement we have at Johnson & Johnson and on other operating income. The grants, EUR3.9 million, up significantly from last year, also has to do with monies we received for performing work, among others, on the development program and, amongst others, on the flu monoclonal antibody.

The EUR3.8 million in other revenue includes both R&D contributions from partners as well as some one-time effects that we recognized. So that makes up the total revenue and operating income of EUR65.7 million.

Last for the cash flow, on page 17, looking at the operating activities, the cash used in operating activities was less than in the comparable period last year. That is mostly due to working capital movements and, specifically, to cash collections on accounts receivable. Investing activities, EUR16.5 million, includes the investments in CapEx and the fixed assets as well as on information technology.

Financing activity has used up EUR18.6 million. That is significantly more than last year, and that has to do with the fact that we are repaid approximately EUR15 million of loans during this quarter. The loans were variable loans. Given the return we get on our deposit, repaying some loans is a very sensible alternative. And as you can see, it has improved our financing income quite a bit.

The net decrease in cash, then, for the quarter was EUR45.8 million. And as said before, quarter and cash and short-term liquidity's amounts to just over EUR382 million.

If you join me on the next slide, the outlook for 2010, we would like to repeat and maintain our guidance for the year. We will use our continued strong operating cash flow to accelerate product development. And we've seen the first part of that in R&D expenses in the first quarter. We maintain a healthy operating profit, and we forecast that our revenues and the other operating income will be broadly in line with the levels of 2009.



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With that, I would like to hand it back to Oya Yavuz.

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**Oya Yavuz** - *Crucell - Director of IR*

Operator, we are ready to take questions. Could you prompt for questions, please?

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## QUESTIONS AND ANSWERS

**Operator**

(Operator instructions) David Moskowitz, Madison Williams.

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**David Moskowitz** - *Madison Williams - Analyst*

On the reduction in cash that we saw since year end, it looks like there was a reduction in the current liabilities area. Can you talk about whether or not that has to do with your cash reduction? Also, given that Shantha is not performing in the marketplace with their vaccine, if I recall, there was a potential for you to renegotiate the royalties with Shantha. Can you just give us an update on that situation and what Shantha's situation is in terms of being able to supply the market at this point?

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

I'll take the first one, on the short-term financial liability. That item amounted to EUR18.7 million at last December's balance sheet. That included the significant part of a variable credit facility that we had in Korea. Since then, we have indeed repaid approximately EUR15 million of that. We've paid the entire facility while keeping it. But, given the excellent situation with corporate liquidity, there is no use to pay interest at this moment at the external credit lines. So yes, that is indeed the amount that we have repaid.

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**Ronald Brus** - *Crucell - President and CEO*

The second question, on Shantha -- actually, I can split the question into basically two separate issues. First of all, the problems that Shantha has to supply the market -- obviously, we are aware of that, and that's why the supranational organizations have come to us to see if we could continue that supply but producing extra supplies on a very short notice.

Second, and it is an independent issue, is that we had a change of control on Shantha, and when Shantha would be acquired by a foreign or western company we would have the possibility to withdraw our exclusive license to Shantha to produce pentavalent vaccines. Obviously, that had happened, and so we are in the process of remedying that with Sanofi-Pasteur, and as soon as we know more we will update you.

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**David Moskowitz** - *Madison Williams - Analyst*

Okay, so that process is ongoing; thanks. And I guess just one last question -- the obvious shortfall in the quarter relates to less pediatric vaccine than we would have expected. It seems a little strange, given that there's supply issues from competing manufacturers, and you guys stand ready, willing and able to supply. So can you explain why we did see that shortfall in the first quarter? And will you make it up in the second quarter?

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

David, indeed, we will make it up in the second quarter, I would say even more than the individual shipments in April alone were more than the full first quarter and, obviously, the quarter isn't over yet. What you have to remember is that for certain countries, individual shipments can be very bulky. And this year in the first quarter we saw shipments to Bangladesh and Pakistan phase out from Q1 into April. So in this quarter we've not seen any effect yet of the additional \$110 million that we've been awarded.

**Operator**

Guillaume van Renterghem, UBS.

**Guillaume van Renterghem** - *UBS - Analyst*

You mentioned that the new contract with UNICEF had seven countries. I was wondering whether you can list the seven countries or, if not, can you tell us whether India is included. As well, we see that your inventory has increased quite a lot, increased 23% over Q4. I was just wondering what part of that was due to the additional UNICEF contract and what level of inventory you think is sustainable. That's really my two first questions.

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

Regarding your first question, we would not like to disclose individual countries. I guess other competitors are listening in as well. However, India was not one of them, to answer that part of your question. As we have informed you before, we are building a sustainable inventory for the management of the changeover of the two facilities in Korea, the old to the new one. I think what you see is the ability of us, despite shipping sizable volumes of Quinvaxem, to continue to build that inventory, which is exactly in line with our plans.

**Guillaume van Renterghem** - *UBS - Analyst*

So maybe one last question, on the EUR110 million. Can you give us a speed, 2010-2011, in terms of what share do you expect in each year?

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

I expect about 75% to be done this year.

**Operator**

Mutlu Gundogan, RBS.

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

First on your guidance, I'm a bit puzzled because you say that you sold more Quinvaxem in April than you did in Q1. Obviously, you were awarded \$110 million award last week, of which 75% will be in 2010. And you could also maybe get perhaps more orders. So why not an upgrade in the guidance? That's my first question.



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Second question is on the gross margin. Obviously, a significant drop year on year, especially when you correct for license revenues and service fees. So I was wondering, could you provide us with a bridge between the Q1 '09 gross margin and the Q1 '010 gross margin and show how much of that is due to currencies and other elements?

Thirdly, on CapEx it seems that the new facility in Korea is pretty much finished. Can you tell us what the level of CapEx will be going forward?

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**Ronald Brus** - *Crucell - President and CEO*

I'll take the first question with respect to the guidance. You are absolutely right in what you have stated. However, I think everyone needs to note that we are still very early in the year, and this is a complex industry. There's examples enough of people that were not -- basically, had a little failure in the production processes, and therefore we'd like to stick with our guidance. And if we are more certain about what we can produce and etc., etc., we will notify you in due time if we feel it's prudent to [hire] that.

At this moment, early in the year, we still have a lot of work to do. We stick with the guidance.

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

Mutlu, let me -- the section about the margins. The difference between the margin in the first quarter 2009 vis-a-vis the first quarter 2010 is basically entirely due to currency exchange differences. And the majority of that is due to basically increasing cost of sales as a result of currency differences in Quinvaxem in Korea. That basically has to do with the fact that the Korean won has been appreciating significantly against the dollar. As you know, we buy a significant amount of ingredients in dollars. And the effect of it over the year, because you cannot compare -- it's basically quarter by quarter, since the inventories that we sell, the cost of goods sold, has been acquired anywhere from six to nine months before the moment it is sold. Right? It's in the system for quite a while.

But over that period, the Korean won has been appreciating significantly against the dollar, and the effect of it is basically that the cost of sales is increasing vis-a-vis the dollar, and that causes the squeeze on margins that we see in the first quarter of this year.

Let me also take the issue on CapEx. The CapEx that we expect this year will be comparable to that of last year, approximately EUR50 million or so. 25% of that is maintenance, ongoing maintenance capital investment. About 75% of it is related to new projects that we have. It will be the tail end of the investment in Korea. It will be the investment in process development and FlexFactory that we are at this moment investing in. And part of it will be also in information technology systems, most importantly the implementation of an SAP/ERP system worldwide, of which the first phase, as Cees has mentioned before, has been successfully implemented in Holland.

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**Operator**

Brigitte de Lima, Merrill Lynch.

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**Brigitte de Lima** - *Merrill Lynch - Analyst*

A few questions on Quinvaxem as well. I'll start it with the guidance, though. I was just wondering, firstly, when you provided full-year guidance at the full-year 2009 results, did you already assume that you would be selling more Quinvaxem related to the SHAN5 suspension, or did you not know that? This is already also alluding to the fact that the guidance looks a little bit conservative to me.

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The second question is on the recent UNICEF award. Do you have any clarity why UNICEF may have not awarded a little bit more, given that it looks like SHAN5 may be out of the market for quite a while? And do you have any information at all or any feedback from UNICEF suggesting that the waiting for WHO prequalification of additional vaccines, local vaccines?

The third question is on pricing. Given that one of your competitors is out of the market, UNICEF will have recognized that you are the premier supplier for them. Do you think that could increase your pricing power over time? And I'll start with those three.

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

At the time when we provided the guidance to the market, obviously we were not aware of the problems that the other manufacturer was having are of such great nature that their product had to be guaranteed. So at that time we provided the guidance based on the information we had then.

Your second question, with regards to, could UNICEF have requested for more volume or awarded more -- the award that UNICEF has made and has made to us is for the period 2010-2011 only. So I think it's at UNICEF's discretion to make additional awards in the period to come.

With regards to other prequalifications, let me say this, that I think the level of quality that will be required from all manufacturers is probably going to be more strictly enforced.

And with regard to pricing, it's clear that there is a certain (inaudible) and that we would not want to bring the global immunization program at jeopardy by trying to push prices.

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**Brigitte de Lima** - *Merrill Lynch - Analyst*

Do you have any feedback from UNICEF, any updated feedback as to what sort of volume they expect for 2010? Last year I think they saw it was a total of 107. Do you have any clarity as to whether they intend to expand it, given there seem to be some supply issues at the moment?

Lastly, on India, do you have any further insight as to what status the government is in terms of deciding in favor or against vaccination with [pentavenamax] in India?

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

Let me take your last question first. I think the Indian situation is still a political one, and there is no full clarity as to how and when full immunization with pentavalent will start there and what role UNICEF will play.

With regard to full volumes for this year, again, that is something that is at UNICEF's discretion. We would envisage that, over time, be it either this year or next year, additional awards be made in order to supply the full pentavalent volumes. And as said before, based upon our track record we would be in an excellent position to be awarded such volumes.

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**Operator**

Fabian Smeets, Rabo Securities.

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**Fabian Smeets** - *Rabo Securities - Analyst*

First of all, on Quinvaxem, it is clear that you are going to be delivering additional doses into 2010. How do you expect this will affect the movement from your current factory to the new factory in Incheon, in Korea?

Secondly, how much inventory do you exactly want to build for the movement of your factory, because your current inventories already seem quite large. Could you indicate how many doses you currently have and how many doses you intend to have when you move?

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

I think we've mentioned before that our ability to supply additional volumes of Quinvaxem is a very solid one. The fact that the additional award has been made and has been made to Crucell only, at least to the extent we know, is a clear indication of that well-recognized capability to supply. So we don't see this impact our ability to move.

In addition, I informed you before that the construction activities have gone exactly according to plan, that the inspection activities are progressing very well at the new facility. So we see everything developing according to plan, and that continues to put us in a position to be able to supply additional volumes if and when they would be awarded.

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**Fabian Smeets** - *Rabo Securities - Analyst*

And related to my first question or my second, how much inventory do you expect to produce when you move?

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

I'm sorry; I don't want to be specific on the inventory that we keep when we move. What we will do is we will keep sufficient safety stock to make sure that our excellent supply track record will be sustained also during the period of the move. I think that is well recognized by the supranational organizations. We have shared with them those details. I'm not prepared to share them on this call.

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**Operator**

Alan Carr, Needham & Co.

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

Can you review for us current Quinvaxem capacity and when in 2011, towards the beginning or middle or late in the year, that you expect to have that new facility up and running?

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

That capacity will be well over 100 million doses. We all know that when you start up a facility you won't be immediately at that level. But the way the factory is designed is that we can supply well over 100 million doses.

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

And your current capacity?

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

Is just under that.

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

Can you tell us a bit more about this transition that some countries are making from the GAVI program to their own vaccination programs? How can we expect that transition -- what's the timing around that transition and the scale of that transition [that] you guys expect to take place over the next couple years?

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

Well, let me explain because I think it's a very good question. Many countries today are 100% dependent upon the GAVI funding. What is happening over time is that GAVI would expect those countries to also partly or in full start to pay for their pentavalent vaccines or for their large immunization programs. As I have explained, we have now, for the first time, received orders from those countries to supply our vaccine.

So you can imagine that, once you start supplying in those countries, you establish a track record of use, of service levels that makes it more difficult for competitors to come in. This is not the simple tender with [big block] volumes; it's now also about established relationships with individual countries. So we are very excited about being able to supply to those countries. And from our announcement you can infer that that changeover is sort of a continuous process that is already happening.

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

Can you give us a sense of the scale of this, or is it -- what sort of details can you give us around that?

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

No; that would be too detailed that this call. Maybe we can take that off-line.

**Operator**

(Operator instructions) Guillaume van Renterghem, UBS.

**Guillaume van Renterghem** - *UBS - Analyst*

Based on your inventory, the current one, do you think you have enough doses to provide what you think UNICEF is going to ask you in 2010?

Second question is, do you expect to start hedging your cost of goods sold?

And the last question is related to your last comment on the new countries starting to order directly from you guys. I was wondering whether you could give us any indication on the pricing for those you get paid this year.

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**Ronald Brus** - *Crucell - President and CEO*

Let me take the two questions, one on pricing and the other one on enough doses. I think it's good practice that we don't give comments on individual prices and definitely not for individual countries. However, as you see, price levels have been broadly in line for most of those shipments.

Your first question is an interesting one. Do you think you have enough doses for if and when UNICEF will ask? Well, obviously, I don't know what UNICEF will be asking. However, their award of the additional \$110 million is a clear vote of confidence on our behalf. In addition thereto, we have shared with the supranational organizations our full ability to supply both from the existing as well as from the new facility as well as from our stock build. That situation would, indeed, allow us to fulfill additional awards, if and when they would come, in the next 18 months or so.

The other question, Guillaume, you asked about hedging and why not hedge the entire cost of goods sold -- first of all, we do hedge whatever economic risk that we can reduce. So any cash flow that we can reasonably accurately predict in the future we will hedge so it doesn't affect -- the currency fluctuation doesn't affect the result. However, to fully hedge your cost only is dangerous without not also hedging your top line. And by doing both it would be quite unusual and it would be very expensive.

Rather, what we have chosen for is in certain countries we are planning to change the functional currency of the country to euro. And by doing so we will basically eliminate the fluctuations in foreign currencies against the dollar and against the euro because the entire currency of the country will be changed. And we think and expect that that will take a lot of the fluctuation out of the results, currency fluctuation out of the results, and that should be, at least for important countries, should be effective somewhere in the second half of the year.

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**Operator**

[John Gibbons], [Oden Parsons].

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**John Gibbons** - *Oden Parsons - Analyst*

I just wonder if I could get a little more clarity on the rabies which we've been following. I'm puzzled why we haven't got a Phase III design and ready to go. What was the issue with production issues in the Philippines [with this] rabies trial?

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

Basically, we would've wanted our Phase II study in India to have kicked off already. But what we had to do there was change the potency measurements of our products. It's a bit of a technical story, but what you need to recognize is that the current products, which are polyclonals, either from horse or from human, contain more than 99% of nonspecific immunoglobulins that do not recognize or do not neutralize rabies virus.

Our product, though, is a very pure monoclonal antibody. And in the process of designing our subsequent clinical trials, we found that we needed to come to a different measurement of the product to be administered, that the potency measurement needed to be different basically because our product is so good. It has caused a delay, but I think we are now well on track for the further development of this product.

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**John Gibbons** - *Oden Parsons - Analyst*

So will the Phase III start in the Philippines? Are you still -- is it going to have to wait until the Phase II start in India first?

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

We will do India first. We will do India this year, and the work is ongoing for the preparation of the Phase III, but that won't start this year.

**Operator**

Rene Verhoef, Fortis Bank.

**Rene Verhoef** - *Fortis Bank - Analyst*

First, regarding Flavimun, you said you are preparing a new registration strategy following the questions from the Swiss authorities -- medic. Do you expect an approval still, this year, a registration? Or is there some serious delay?

And, secondly, you are reporting in your press release three one-time items. First of all, in your tax line, do you -- can give, provide guidance for the remaining three quarters a normalized tax rate in your Korean production business?

And, secondly, in SG&A and in services business, there was a one-time benefit as well. Can you quantify that for me?

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

I'll take the Flavimun question. What we need to remember is that the Flavimun is a product we are working on that, as we called it before, won't move the needle. It's a small product that we are developing. Additional questions have been asked by Swissmedic, and we are currently studying how to best take Flavimun forward. Given the base at which registration is going, I'm not optimistic that we will come to registration this year. Leon, you want to take the other?

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

Rene, regarding the tax item, the tax item has to do with the fact that our facility in Korea, our tax facility, provided for a three-quarter tax holiday, so three-quarters of income exempt over a five-year period. And now that has changed to 100% over a five-year period and 50% over an additional two years. So we expect to pay fewer taxes in Korea in the future, and therefore the item called deferred tax liability was reduced and the freefall produced a one-time result, a positive tax result.

The tax that we pay in Korea will be normal corporate rates for the rest of the year, just over 20%, and we expect that our total tax burden to come out slightly lower than last year as a result. The one-time effect in the SG&A line had to do with settlement of license revenues with certain partners [of us] that was regularized, and we recognize some one-time cost reductions on there, or license income on that, as well as the reduction in the number of doubtful accounts. So both of them were good news, but our one-time effect that had the results to reduce the overall SG&A costs.

**Rene Verhoef** - *Fortis Bank - Analyst*

And in the services business, let's say cost of goods sold were extremely low, (inaudible) about 3 million there. Usually, this was at -- gross margin is about 20%. So there was a one-time [element]?

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

No, that very. That really varies from contract to contract and from period to period. And basically the service business is income for work that we've performed for certain partners such as some contract manufacturing, and the relationship between the



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revenue line there and the cost of the license revenues, it's not a constant. It's really a project-by-project type of income and cost story.

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**Operator**

David Moskowitz, Madison Williams.

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**David Moskowitz - Madison Williams - Analyst**

Just a question on any milestones from J&J in the period, and are you expecting milestones this year? And if so, what line item would they be reported in?

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**Cees de Jong - Crucell - COO**

Any milestones that we receive from J&J would be accounted for as license revenues, and there have been no milestones, at least in this quarter, that we accounted for.

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**David Moskowitz - Madison Williams - Analyst**

And do you expect any milestones, perhaps, this year?

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**Cees de Jong - Crucell - COO**

That really depends on the progress in development, and I don't want to give any guidance on that yet.

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**Operator**

Brigitte de Lima, Merrill Lynch.

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**Brigitte de Lima - Merrill Lynch - Analyst**

I just have a very quick follow-up question on Inflexal. Can you just quickly, very briefly, elaborate on the challenges you are experiencing with the vaccination? Is it that you are seeing low yields for the strains that you are growing?

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**Ronald Brus - Crucell - President and CEO**

There's two items that we mentioned. Obviously, with no pandemic threats existent, we expect the demand for -- the overall demand for seasonal flu vaccines to be impacted. And although we did not participate in any pandemic sales last year, we may have some impact on our seasonal sales. In addition, we know that for everyone this year, the manufacture of these seasonal antigens is more difficult. That is basically the yields of the three strains and, unfortunately, it's of all the three strains, seems to be lower than in previous years. And that will impact overall availability of vaccine.

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**Operator**

(Operator instructions). We have no further questions at this time. I would like to hand the conference back over to your host today for any additional or closing remarks.

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**Oya Yavuz** - *Crucell - Director of IR*

Thank you very much. Also, on behalf of management, thanks for joining us. If you have any further questions, you know where to find us. Have a nice day. Thank you.

**Operator**

Ladies and gentlemen, that does conclude today's conference call. Thank you for your participation today. You may now disconnect.

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