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CORPORATE PARTICIPANTS

Oya Yavuz

Crucell - Corporate Communications and IR

Ronald Brus

Crucell - President and CEO

Cees de Jong

Crucell - COO

Leon Kruimer

Crucell - CFO

CONFERENCE CALL PARTICIPANTS

Mutlu Gundogan

RBS - Analyst

Alan Carr

Needham & Company - Analyst

Guillaume van Renterghem

UBS - Analyst

Brigitte de Lima

Merrill Lynch - Analyst

Jan Van den Bossche

Petercam - Analyst

Vincent Meunier

Exane BNP Paribas - Analyst

Peter Welford

Jefferies & Company - Analyst

Tony Campbell

Knott Partners - Analyst

Neil Wisproof

Kempen & Co. - Analyst

Rene Verhoef

Fortis Bank - Analyst

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and welcome to the Crucell fourth-quarter and full-year 2009 results conference call. My name is Dave and I'll be your coordinator for today's conference. (Operator Instructions). I'm now handing you over to Oya Yavuz, Vice President, Corporate Communications and Investor Relations, to begin today's conference. Thank you.

Oya Yavuz - *Crucell - Corporate Communications and IR*

Thank you, Dave. Thank you all for joining us today. Welcome to our fourth-quarter and full-year 2009 presentation. The presentation this afternoon will be given by our CEO, Ronald Brus; our COO, Cees de Jong; and our CFO, Leon Kruimer. The

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presentation will be followed by a Q&A session, and it's also being simultaneously audio webcast, which you can follow on our website.

You should all have the press release from this morning. I would like to ask you to read the forward-looking statement, which is also on the second slide of the presentation.

With that, I will hand over to Ronald, who will start by giving you a business review of the fourth quarter and the full year of 2009. Thank you.

Ronald Brus - *Crucell - President and CEO*

Thank you, Oya. Ladies and gentlemen, I would like to draw your attention to slide number 4. We've had a good last quarter and we've had a very good full year 2009. Our business is stronger than ever, and total revenues and other operating income increased by 26%. Operating profit increased more than fourfold to EUR39 million, whereas net profit increased almost 70% to EUR23.9 million. And we have ended the year with a very strong balance sheet, with EUR428 million in cash and short-term liquidities.

I would like to bring you to slide number 5, the highlights of 2009. With the largest healthcare company in the world, Johnson & Johnson, we have entered into a major research and development partnership with a potential value of over EUR1 billion. In this partnership, we started to work on our invention published in Science earlier that year to treat and prevent all strains of influenza with antibodies.

For this original research, we also received a grant up to \$69 million from the National Institutes of Health, and we are very excited about the results so far. We also reported detailed positive results of our rabies Phase II study and positive immunological data on our US HIV vaccine study. We started the collaboration with MVI and the US Army to accelerate a malaria vaccine program.

To fuel our pipeline further, we licensed intellectual property for a Hep-C antibody combination from Stanford University. For Quinvaxem, we received additional awards. And our new vaccine plant in South Korea has reached technical completion. Our partner, ADImmune, in Taiwan has started to produce a significant number of H1N1 flu shots, and our program for them to serve as our antigen supplier is on track.

12 new deals on the basis of our PER.C6 technology have been signed in 2009, which brings me to slide number 6, where you can see the revenue development over the last couple of years. With these revenues and operating results, we are now in the position to prepare our Company for the next jump in revenues and profits.

Now, this jump should come from the research and development programs that Crucell has financed by its own cash flow. These products and programs include a [Paxel] hepatitis A vaccine for the United States of America, new antigen doses from Inflexal out of our participation with ADImmune in Taiwan, tuberculosis now in Phase II studies, rabies gearing up toward Phase III, influenza and PER.C6, malaria, where we expect a data wrap-up, and influenza and monoclonal antibodies.

The products that I just mentioned are tapping into significant markets with a total value of several billions of euros. We are happy that Crucell has created the cash flow to significantly increase its power in the R&D arena of these significant programs. This can be done in parallel with expected healthy profits for the years to come.

And with that, I would like to hand it over to Cees de Jong.



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Cees de Jong - *Crucell - COO*

Thank you Ronald. If you please follow me to sheet number 8, as Ronald already mentioned, we realized strong operational improvements during 2009, leading to a very substantial increase in our operating profit. We've made great progress towards operational excellence, as evidenced in the EUR39 million of operating profit that we could deliver for 2009.

There were four key drivers for this improved result, three positive and one negative. First, product sales were up 35% compared to last year, and product sales margins were stable compared to last year. Secondly, our operational excellence program, Healthy Ambition, was completed during 2009, and we indeed achieved the targeted savings. Some key areas of savings include the operational excellence achieved within production and better yields, savings in overhead, and also lower marketing and sales costs, despite increased sales.

Let me tell you that in some of our key markets in Italy, Spain and Switzerland, the marketing and sales expense decreased compared to 2008, with 30%, despite a significant increase in sales in each of those countries. As you know, we've begun to expand Healthy Ambition initiatives into research and development, and, especially in our development groups, we're changing the way we work to increase capacity and efficiency.

Back to the key drivers, grants increased more than 20% compared to 2008, and licensing was somewhat lower than 2008. Overall, though, our improved performance is most visible when we look at the operational cash generated in the existing business. And I'm sure Leon will come back there, too. Our business is now so healthy that we can allow a very significant increase in our R&D spend for 2010 to accelerate the development of our pipeline.

Let me take you to the next sheet, sheet number 9. Product sales were strong, especially towards the end of the year, ensuring again a strong fourth quarter. Full-year product sales were just over EUR304 million, which is 35% above 2008. At the guided currency, product sales would have been some EUR7.5 million higher, resulting in 38% growth in product sales over 2008.

Most of Crucell's growth in the pediatric segment was realized through the sales of Quinvaxem, our fully liquid pentavalent children's vaccine, especially Pakistan, Bangladesh and Ethiopia, with also a number of countries in Latin America that mean important sales markets for us during the year.

And as you know, the introduction of the pentavalent vaccine in Vietnam has been delayed as a consequence of additional requirements put up by local authorities. The delay in uptake in Pakistan, which caused Q3 to be somewhat weaker, was compensated in the fourth quarter with strong shipments of Crucell into that country. And ultimately, we met our own targets for Quinvaxem for the year.

In our travel franchise, we had a bit of a setback with one of our air carriers not sticking to our quality protocols. As a consequence, we had to retest a quite sizable shipment for Korea, and the material could not be released in the fourth quarter. In addition, we saw a slightly weaker market in the Nordics in the fourth quarter. If, however, we could have released the Epaxal Korea shipment, and correcting for the exchange rates that impacted the travel franchise, full-year sales in the travel segment would have been in line with 2008.

Sales and shipments for Inflexal, our flu vaccine, were, as you know, mostly completed in the third quarter. For the full year, we've seen a good performance of this business, with both price and volume exceeding 2008. Inflexal continues to command a priced premium due to its unique position in the pediatric segment. And it's important to add that we only sold seasonal flu vaccine and that Crucell did not participate in the pandemic vaccine sales.

Next sheet, sheet number 10, an update on Quinvaxem. During the third quarter, Crucell was awarded a portion of \$300 million worth of sales for Quinvaxem out of a tender for pentavalent vaccine. The tender, as you know, is for the next three years, so for the period 2010-2012, and brings our total award for Quinvaxem to about \$800 million.



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We expect additional awards in the upcoming periods and possibly already in 2010. Only half of the original tender volume has been awarded by the supernational organization at this time. And secondly, to date, Crucell has supplied over 130 million doses of Quinvaxem, which 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 both well known and recognized by the supernational organizations, as well as by many local authorities.

Our existing plant in Korea runs yields, line speeds and output levels that are truly best in class. Our colleagues in Korea have won a number of prestigious awards from the Korean government during 2009, and their contribution to our 2009 results has been significant. But also, the new site project is progressing very well. In a record 13 months, we went from groundbreaking to commissioning. And with commissioning, we mean that all equipment has now been installed in the facility, all connections have been made -- piping, cabling, air handling, the lot.

13 months is a fantastic achievement, taking into account that this is not a small factory. To remind you, the footprint of the factory has the size of two soccer fields. To get to such a milestone in most Western countries would have taken at least twice as long. We now enter the phase of commissioning and validation, and that will take most of 2010.

So, in summary, looking at Quinvaxem, whilst other producers have now been prequalified, we feel confident in our ability to supply additional volumes when requested to do so and in future will benefit from improved efficiencies, output and renewed tax benefits.

Sheet number 11 -- also, the European locations have been contributing to our excellent 2009 results. We further integrated and professionalized our operations in Europe. And as I said before, I feel that operations is now generally well under control, with good output and efficiency. There's still scope for further improvements in 2010, especially in our Swiss plants. To ensure these improvements will be realized, we have strengthened the organization in Switzerland, and we are already observing first results.

We've completed a number of orders during the year, and all inspections passed with success. In Switzerland, we implemented the Healthy Ambition new way of working and could make the savings as projected. In Spain, we've now brought the fill/finish capacity to overall 100 million doses. Thanks to the approval of the regulatory authorities, we've been able to use our new filling line already during the flu season.

Finally, in Sweden, the transfer of the fill/finish activities has started, with an early transfer of the packaging line complete in the first half of 2010. Last but not least, we continue to work on improving rCTB yields to increase our fill production capacity.

Let me take you to sheet number 12 and update you on both product and process development. We've used 2009 to significantly strengthen all departments that have a role in product and process development. For these groups that are mostly based in Leiden and Bern and for research, we've hired more than 120 new colleagues during 2009. We were capable to do so based on the significantly increased operational performance.

We brought process developments under a single leadership and brought on board new leaders. In Bern, we refurbished private plants and development labs to house our own projects. Also, during 2009, we were the first company to introduce the so-called FlexFactory concepts. A FlexFactory is basically a mobile cleanroom concept where the design is such that both upstream and downstream processing can be carried out in the same room. This new way of producing vaccines or antibodies has three main advantages. It allows for easier scaleup of production and hence faster clinical development and registration. The investment level is lower. And once in operation, turnaround times are shorter, leading to higher production efficiencies.

Let me also cover some of our most important pipeline projects and update you on progress. For Flavimun, we submitted our file for registration to Swissmedic, and while we await that review, we're preparing for the German registration.



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Our very promising monoclonal antibody against a broad range of influenza not only attracted the \$69 million NIH grants and J&J's attention; we also made good progress in the development of the new products. We've successfully manufactured the first lot in a FlexFactory, and that has significantly enhanced our confidence that we will be able to produce the clinical material ourselves early. We're currently scaling up to 200-liter scale.

On rabies, positive results from the Phase II trial in the Philippines were announced in June. The 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.

During 2009, discussions were initiated with the health authorities from the United States, the Philippines, China and India to obtain alignment on the Phase III clinical evaluation of our new products. In our Q3, update we informed you that the start of the Indian Phase II trial is imminent, and we indeed expect this trial to start in the second quarter of this year.

For tuberculosis, four Phase I studies were completed in 2009. The first three were evaluating BCG plus our vaccine candidate in [prime dose] regimens in adults in the US. Data from these studies specifically indicate that two injections of our compound are immunogenic with an acceptable safety profile up to the highest dose tested. The fourth study was conducted by Walter Reed in Kenya, and its main objective was to test the safety of the [Canada] vaccine in BCG-vaccinated adults, with or without latent tuberculosis. And also, this study has been completed, and no safety issues were identified.

In April of last year, Aeras and Crucell announced the start of the first Phase I TB study in infants in South Africa. The study is now fully enrolled and dosing is ongoing. No safety issues have been identified to date.

And in December of 2009, we completed the enrollment of the third cohort of the first Phase II study of the Crucell compound. And this study in adults who have had active TB, to date, no safety issues have been recorded in a dose-escalating design. And even preliminary analysis of immunoresponses for the first two cohorts shows that our vaccine candidate induced cell-immune responses.

For malaria, I'm pleased to say that in December last year, we completed all vaccinations for the final group of volunteers in the US, the NIH-sponsored Phase I trial. Ongoing safety monitoring has revealed no significant safety concerns to date. Preliminary examination of the still-blinded data from the four cohorts indicated that the vaccine is probably immunogenetic. Detailed analysis of the data is ongoing. Unblinding is expected in the second quarter this year.

And in July 2009, we announced a new collaboration with MDI to accelerate the development of a promising new type of malaria vaccine. Through funding from the USAID, we will conduct studies to determine the effectiveness of Crucell's novel prime boost vaccine approach using two vectors as delivery.

And last but not least, Epaxal US continues to progress well. We meet our in-house targets, and in the second half of this year we will start to produce clinical trial material, and we have then planned the pre-IND meeting with FDA. As you know, we aim for pivotal trials next year.

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

Leon Kruimer - *Crucell - CFO*

Thank you very much, Cees. It's my pleasure to present the financial highlights for 2009. And please join me to slide number 14.



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Our total revenues and operating income increased by 26% to EUR358 million. If we would have had a constant exchange to \$1.35 at which we guided, the total revenue growth would have been 29%. So the increase was mostly driven by strong sales of pediatric vaccines, as was mentioned before.

Our gross margins reached 42%, and that compares to 45% in 2008, for two reasons that affect the margin level. Number one is currency movement, mostly the currency movements of the dollar vis-a-vis the euro, as well as the timing of milestones.

Our operating profit reached EUR39 million. That is more than five times the level that we achieved in 2008, which was EUR7.4 million. Our net profits was EUR23.9 million, and our net results per share were EUR0.34, and that is compared to EUR0.22 per share in 2008.

Probably the most significant financial transaction that we had was a payment by Johnson & Johnson of in excess of EUR300 million for our development program partnership and a stake of 18% in Crucell shares.

Our cash and cash equivalents increased by over EUR150 million during the year to EUR327.8 million, and that excludes any deposits which have been deposited for longer than 90 days, which are accounted for as short-term assets, financial assets.

If you join me to page 15, in a graph -- in a couple of graphs, we already began to show the different financial parameters that we achieved. And I think next to the increase in topline of 26%, we're very proud that both on operating profit, profit before tax, as well as profit before the period, we all show positive numbers over both years, and we show from 2008 to 2009 significant increases, especially in operating profit, profit before tax, but also total net result for the period increased 68%.

On the next page, page 16 is summarized statement of income, with, on the left-hand side, the comparisons for the fourth quarter 2008 versus 2009, and on the right-hand side, the full year of 2009 and 2008. Basically, it shows in each column and by comparison the numbers we've mentioned.

I would like to point out that for the quarter, EUR111.3 million income, revenue and operating income, is a record for the Company, and doing so, we have achieved margins of 47%. We've kept our operating expenses in the fourth quarter very much in line with that of last year. And our profit before tax then went to EUR20.4 million vis-a-vis EUR10 million the year before. And what you do see, that we have a tax charge in the fourth quarter, as well as for the full year, whereas in 2008 we had a positive tax income, and that had to do with capitalizing net operating losses in Switzerland.

On the next page, page 17, is our tax situation in a little bit more detail. It shows that in the Crucell group, excluding The Netherlands, we've had profits before taxes of about EUR82 million. Of that EUR82 million, we paid EUR14 million in taxes, which corresponds to a tax rate, effective tax rate of 17%.

The operating profit before tax elsewhere in the world is offset by a EUR44 million loss in The Netherlands, which is mostly due to research and development expenses taking place and activity taking place in The Netherlands. There is no compensating tax benefit for this operating loss. And therefore, the consolidated profit before tax comes out to be EUR37.9 million, with the net tax charge of EUR14 million, translates consolidated in an effective tax rate of 36.9%.

On the next page, number 18, we see the revenues and other operating income split out by product sales, license revenue, service fees, grants and other. And I would like to point out that for the full year 2009 versus 2008 in the right-hand columns, you can see that the license revenues were higher in 2008. Most of that was due to the timing of milestones, which has affected profitability and margins in that particular year.

On the next page, page number 19, at a high level, our cash flow provided from the different activities, you can see that the operating activities in the fourth quarter, as well as the full year 2009, yielded a very healthy positive operating cash flow. That was in spite of the fact that in 2009 we decided not to factor our receivables, which led to a net cash inflow in the year 2008 of



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approximately EUR30 million. So on a like-for-like basis, the operating cash flow for 2009 is even stronger than the numbers suggest.

In terms of investing activities, a very large number for the year, EUR154 million. Roughly EUR50 million of that is due to, indeed, purchasing property, plant and equipment, mostly for our new plant in Korea. EUR100 million of it is simply a financial investment, a deposit that we entered into for a period for more than 90 days, which is included in the balance sheet as short-term financial assets.

Then from the other financing activities for the year, an inflow of EUR231 million. That's of course related to the different payments made by Johnson & Johnson. We have a small exchange rate of cash. And to summarize, [74], we increased our cash reserves for the year by a number of EUR156.8 million. The year-end cash and short-term liquidities, short-term financial assets amount to about EUR428 million.

On the last page, the expected news flow for the year, first of all, a partnership for a malaria vaccine development. As Cees just mentioned, we have successfully completed our clinical trial in the United States, and we feel that with the strong technology base that we have for a T-cell malaria vaccine, it is a prime candidate for partnering and could actually grow to one of the most promising malaria vaccines in the world.

We expect further news on the J&J development targets. As you know, two have been mentioned, and we expect to announce other J&J -- with J&J development targets during the year. As mentioned also, we expect the start of a rabies Phase II in India in the second quarter and the eventual registration of Flavimun, a yellow fever vaccine, in Switzerland.

And on the last page, the outlook for the year, we intend to use our continued strong operating cash flow to accelerate product development. Therefore, we've made a conscious decision to increase R&D spending, and development spending especially, to as much as -- to increase by as much as one-third vis-a-vis this year while we maintain a very healthy operating profit. Last but not least, our revenues and our other topline we see broadly in line with the year 2009. Finally, the guidance also that we have made is given at a currency rate of \$1.41 of the euro against the dollar.

And with that, I would like to hand it over to Oya for the question-and-answer session.

Oya Yavuz - *Crucell - Corporate Communications and IR*

Dave, we're ready to take questions now. So please limit yourself to one question per caller, and if you could state your name and your company clearly, that would be great. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Mutlu Gundogan, RBS.

Mutlu Gundogan - *RBS - Analyst*

Two questions. First, on the outlook of revenues, you expect license revenues to increase in 2010 on the back of the J&J deferred income. And secondly, travel vaccines should go up as well. But for total revenues and other operating income, you expect flat development in 2010. So I was wondering what is coming down in 2010. Can you tell us that? That's my first question.



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And then secondly, on the gross margin, on product sales -- so not gross margin for the whole, but on product sales specifically, that is down year on year in the fourth quarter. Would you expect that to increase on the back of future efficiency gains or to decline as a result of lower Quinvaxem prices?

Cees de Jong - *Crucell - COO*

This is Cees. With regard to our revenue for 2010, we would expect the mix of our revenue and other income to be slightly changed somewhat, and that obviously has a positive effect on our overall margins. With regard to gross margin for product sales, what has significant impact there, of course, is the dollar effect that we face. With regard to Quinvaxem, we have I think outstanding margins, and it would be only for the new factory to be operational before we can make significant further improvements there.

Operator

Alan Carr, Needham & Co.

Alan Carr - *Needham & Company - Analyst*

I wonder if you could elaborate a bit on the guidance for 2010, again, that you expect revenue to be flat. You just expect the mix to change for 2010. And then what are your assumptions about Quinvaxem for 2010 in terms of revenues and contracts for 2010?

Cees de Jong - *Crucell - COO*

This is Cees. Let me answer your question. Indeed, as I said, we would expect in 2010 that the mix of both the revenue and other income will be slightly different compared to 2009.

With regard to Quinvaxem, as we've probably indicated before, it's very difficult for us to predict the exact timing of shipments. Single shipments can have a very considerable impact with regards to growth and phasing of sales. So, first, it's rather difficult to predict how Quinvaxem sales will develop, particularly also now that new entrants have been qualified.

As you know, and as I've presented, only half of the original tender holding seems to have been awarded at this time. We have an outstanding track record both in terms of quality as well as in service-level delivery. Normally, what you would expect is when new entrants come in is that start is always somewhat more difficult, but it's extremely difficult for us to predict when additional awards will be given out and whether Crucell can sort of obtain these. Hence the guidance that we've given.

Alan Carr - *Needham & Company - Analyst*

Would you characterize it as your guidance is on the conservative side, considering your -- I guess your lack of insight as to what may be happening with Quinvaxem?

Cees de Jong - *Crucell - COO*

I think the guidance is what it is. And I would not want to speculate on whether it is conservative or not.

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Alan Carr - *Needham & Company - Analyst*

So in terms of investing for the future, you mentioned that you're raising R&D by a third this year. What are your thoughts on acquisitions as well for 2010?

Ronald Brus - *Crucell - President and CEO*

Alan, this is Ronald Brus. For a company our size, with the cash flow that we just presented today, yes, we do have a very I would say magnificent balance sheet that we could, if we wanted to do that, use for acquisitions.

Now, looking at our research and development pipeline, we also are candid enough to say, okay, with the right investments and the right people, we should be able to do things quicker. And that is, hence, why we -- and Cees had told you that earlier -- we did invest a lot in new leadership in that R&D arena. And we expect that we can basically grease the wheels quite significantly.

Now, with respect to acquisitions, we're not looking for acquisitions to fill our pipeline, because I think our pipeline has never been as full as it is today. And I think the way you should look at our Company is, currently, we are operating in markets where I would say the total market potential is rather limited. And once we are in a market like influenza, where there is a good market potential, we were hampered by a supply issues that we couldn't increase our market share rapidly enough.

Now, we've taken ourselves to task to repair these things. We did that over 2008 and 2009 by investing in a company like ADImmune, by investing in all kind of several means. But that now currently creates a kind of a company where we now are in a state that we say, okay, we have a full development pipeline that is tapping into segments that are billions of dollars worth of potential. Now we need to do that and we need the money that we make out of the cash flow need to work for us.

So if we do acquisitions, it wouldn't be acquisitions to fill our pipeline per se, because we feel we don't need it. If we would do acquisitions, it could be acquisitions that we have done in the past with Bruna that could significantly improve revenues and profits over the longer run, and in relatively shorter run than acquiring companies that demand extra money. We're not keen to do those kind of acquisitions.

Operator

Guillaume van Renterghem, UBS.

Guillaume van Renterghem - *UBS - Analyst*

Two questions, actually, if you don't mind. On your R&D spending, a 33% -- a third increase seems very high. On what actual project can you tell us you are going to invest?

You mentioned as well in Q3 that you may plan to stop actually the distribution agreement that you have in 2010 and may actually in-source your sales and marketing. Can you give us actually more guidance on what are the projects, where they're lying, in what countries, what the costs are going to be in 2010, please?

Cees de Jong - *Crucell - COO*

Let me take the questions. The increase in R&D spend we can allow ourselves, due to the fact that the operational business is performing so strong. And obviously, when a pipeline progresses, the intensity of spend increases. So when our pipeline is progressing with a number of projects entering Phase II and beyond, the spend increases. So the projects that have been mentioned in the presentation before are the lead candidates for such spend.

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With regard to bringing in house the marketing and sales activities, last year we brought in house the UK market, the largest travel market in Europe. And we're really pleased with the progress that we've been making there, exceeding our own targets and before year end already running a pretty profitable operation. You will see further announcements from us in due course. And for competitive reasons, I would not want to make any specific comments at this point in time. I hope you understand.

Guillaume van Renterghem - UBS - Analyst

Sure. Can you confirm, actually, that the J&J antibody is to enter the clinic in Q2 2010?

Cees de Jong - Crucell - COO

Let me respond to that in a slightly different way. As you know, with new compounds you first have to do tox studies. And we will indeed start tox studies in 2010. The material has been manufactured, and as I said before, we are currently upscaling to 200-liter scale.

Operator

Brigitte de Lima, Merrill Lynch.

Brigitte de Lima - Merrill Lynch - Analyst

I'll start off with four financial questions, please. The first one, just going back to the increase in R&D, should we expect step-ups in later years to be somewhat more modest than [those seen] in 2010? Or is this sort of a big jump, then followed by more moderate increases in R&D?

The second is, I notice there was an increase in accounts receivable of about EUR20 million versus September 30, and I was just wondering if you could clarify what caused that increase in receivables.

The third was on the tax rate. Could you provide any guidance at all on what tax rate you anticipate in 2010 and perhaps the level of the tax charge you're looking at?

And the fourth question, and I'll leave it there, then, is on CapEx. Given that you've nearly completed the new facility in Korea, or the bulk has been spent on that facility, could you provide some guidance on capital in 2010 and beyond? Should we expect a significant drop in CapEx? Thank you.

Cees de Jong - Crucell - COO

This is Cees. Let me take the first and fourth question. And I hope I understand your first question correct.

Indeed, next year we have a very considerable increase in R&D for -- in this year, 2010. We have a very considerable increase in our development spend, and we do so to accelerate the pipeline. We can only do so because the business is so healthy.

At this point in time, we don't make any forecasts on what will happen in 2011, although it would seem logical to expect slightly more moderate increase than the up to 30% that we now forecast for 2010.

I will also take your fourth question on capital expenditure. You're correct that a majority of spend for our new Korean facility has been in 2009. In 2010, the portfolio of CapEx changes somewhat towards our development projects. And we're gearing up

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to bring Epaxal to the US and create the facilities necessary to provide the clinical trial material, later the launch material for our pipeline products.

I'll leave it to Leon to answer your second and third questions.

Leon Kruimer - *Crucell - CFO*

Yes, regarding the accounts receivable level of the end of the year, it is significantly higher than it was in September and also significantly higher than it was December 31, 2008. That is specifically due to the fact that our shipments in the fourth quarter were very strong. So the receivables that result from it have increased. And we've decided consciously not to factor our receivables like we have done in previous years, due to costs and due to the fact that we have adequate cash on our balance sheet, so we can afford to finance that ourselves this year.

In terms of tax, our tax rate, as you can see, this year was approximately EUR14 million. The bulk of that was payable in Korea and also partly in Switzerland, where we are incurring tax expense but not paying taxes, because we're using up our net operating losses from previous years.

I think the main -- one of the main reasons for our investment in Korea is also that it gets us a seven-year tax holiday, which will reduce taxes by an expected level of 70%. So it's a very significant tax holiday, it's a very significant financial benefit, and that starts when the plan becomes fully operational, which could be sometime next year, if maybe the year after. We expect that for the total taxes that we will pay next year would be in the range of EUR13 million to EUR15 million -- this year, sorry, in the year 2010.

Brigitte de Lima - *Merrill Lynch - Analyst*

Can I still ask you a very quick question on the pipeline? I was just wondering firstly, on the malaria vaccine, why have you decided to partner it, given that it is quite early stage and you've definitely got the balance sheet to finance development yourself?

And the second one is on flu sale. Is there any update at all from Sanofi? Have they just dropped the project, or are they continuing on the Phase II studies, and do you have any idea when they might be starting a Phase III trial?

Cees de Jong - *Crucell - COO*

Let me answer the question on malaria. You've seen the positive results that we had in Phase I and the new collaboration that we announced. Forming a partnership, we would do to accelerate time to market or obtain better access to markets. So it might mean that we create combinations with other parties' products to get even better products than the ones we have in the clinic. I think, Brigitte, you will have to wait until we come with the announcement so we can further clarify why we would have formed such partnerships.

Ronald, I think you wanted to take the question on flu sale?

Ronald Brus - *Crucell - President and CEO*

Yes. I think, Brigitte, everyone knows that we have said publicly that a deal that we have done with Sanofi Pasteur in the year 2004 on PER.C6 with respect to flu sale was a kind of a deal that at this day and the current stage of development of the Company we wouldn't do again. This is typically something that we have done when we're a small biotech outlet where we didn't have the salesforces throughout the world and we did not have the ability to sell in 60 countries like we do have to date.

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Therefore, we are also not pleased with the speed of development that our large partner, Sanofi Pasteur, demonstrates in this arena. And we will try to do whatever we can to remedy that as forcefully as we can, because it's now in our best interest to make this program as successful as possible. And given the power that we currently possess as a sales organization, but also as a research and development organization, we will do our utmost to get the maximization of this project.

With respect, I would just like to come back on the malaria. I think if you look into what is currently going on in malaria, we see that GlaxoSmithKline is doing tremendously on a vaccine that they currently are developing in Africa. And I think basically what that demonstrates, it is doable to come up with a malaria vaccine, because the T-cell responses and the clinical responses surely suggest that it is much better than placebo.

However, looking at the preventive rates that we observe, it's clear that it needs to be improved, that a 40% efficacy is clearly not good enough on the longer run. And I think you've seen public statements of [Andrew Witty] on this subject. You know that there's a lot of movement in this arena; hence, our Company would like to position ourselves as being at the forefront of what is going to happen in malaria. And therefore, we know that we need one day to join forces with the other leader in this pack. And that's why we're positioning ourselves, and that's what we're trying to achieve.

Operator

Jan Van den Bossche, Petercam.

Jan Van den Bossche - *Petercam - Analyst*

First of all, on Flavimun, could you give some kind of an indication on what's the typical review period in Switzerland for a registration file?

And then secondly, on the increased R&D spending -- how should I put it -- what was the reason that you decided in 2010 to increase the spending by this amount? What event triggered you that an additional EUR20 million or so was necessary for the process development? Was that linked to the result that you had from a number of studies in different programs, or is it -- I can't imagine that it's simply because you do have the money available from the Healthy Ambition that you're increasing the spending. So I'm just wanting to know, what was the strategic decision that triggered or the strategic event that triggered the necessity for increased spending? Thank you.

Ronald Brus - *Crucell - President and CEO*

Jan, I will do the latter part of your question. And the answer is basically twofold. The results of the program that we have run so far are for us -- and also the markets -- and the diseases that they intend to prevent are so significant and so, for our, the way we look at it, so promising that we decided to invest more to accelerate and to keep more of the value in those markets.

The other thing -- and that's very important -- is also that we better and better understand how we could make major improvements in the manufacturing in order to make antibodies available to a better cost to large numbers of people in the world. Driving down the cost of goods has been a very significant leitmotif over the last couple of years within our Company, and we ultimately succeeded in that.

I think about five years ago, we told you that a gram of antibody, cost of goods was roughly \$1000. We're now capable and able to bring that down to a level under \$50. And I think in the years to come, that can go even down to \$25 a gram. And you know that antibodies are originally intended to treat infectious diseases.

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Now, bringing that together, tapping into larger markets, we decided that it's now the time to invest. Hence, we need to have the money to invest. And obviously, cleaning up and making the Berna organization as streamlined as we have, we do have the cash flow now to pay for these kind of extra R&D investments.

So I see that as a very important step towards building and gearing up for the next jump in revenues. And we hope that that jump is even more significant, obviously, than the jump that we have created in the year 2004, when we acquired Berna -- sorry, in 2006 when we acquired Berna.

The other question, I would like to hand that over to Cees, if he still remembers what it was.

Cees de Jong - *Crucell - COO*

I actually remember the question. The question was on Flavimun. Jan, there is no such thing as a typical timeline for Swissmedic. However, I can say that towards the end of 2008, beginning of '09, Swissmedic has announced an eight-month waiting period for any new file that was submitted. And you remember -- probably remember me saying this before. We have been faced with that waiting period and are now in interactions with Swissmedic. But it is extremely difficult for me to predict when the file will be approved.

Jan Van den Bossche - *Petercam - Analyst*

Okay. Maybe one other question on the news flow for this year. You're mentioning the partnership for malaria. You're not providing or you're not putting on that slide the fact that you will have the Phase II data available I would assume also in the course of 2010. Is that because you will not publish those data, or is that something that I was missing?

Cees de Jong - *Crucell - COO*

Yes, so help me, Jan. You refer to the page 2 data on which project?

Jan Van den Bossche - *Petercam - Analyst*

On the malaria vaccine, sorry. And you mentioned in the press release that the unblinding of the study, of the Phase I, sorry, was expected in the second quarter of this year. I expect or I think we can expect those data to be published in the course of this year?

Cees de Jong - *Crucell - COO*

That's correct, Jan. The US study, the unblinding will be expected in Q2 this year. So that will be indeed a news item. You're fully correct. Thanks for that.

Operator

Vincent Meunier, Exane BNP Paribas.

Vincent Meunier - *Exane BNP Paribas - Analyst*

Looking at your margins and the trends, I'm trying to understand where you will be able to maintain what you call healthy operating profits in your guidance, because if your R&D increases, maybe the COGS will decrease, but you already said that the

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South Korean plant will not be online before 2011. Maybe the selling, general and administrative costs will be drastically reduced, if that's right -- would you consider this?

Cees de Jong - *Crucell - COO*

Let me take that question. As you know, the vaccine business is generally a very healthy business with very good margins. We've been focusing very much on operating results in recent years. Indeed, there is going to be a change in mix in our total revenue and other income that will have positive contribution on our margins in 2010.

Vincent Meunier - *Exane BNP Paribas - Analyst*

But is it correct to anticipate a reduction of the cost of product sales and also a reduction of the SG&A?

Cees de Jong - *Crucell - COO*

I think, Vincent, that what will happen in fact in 2010 is definitely a different exchange rate to the dollar, and there will be some ongoing improvements in our margins from operational excellence efforts.

Operator

Peter Welford, Jefferies.

Peter Welford - *Jefferies & Company - Analyst*

Two questions. Firstly, can you just outline for the Johnson & Johnson EUR69 million up front that you're conferring as revenues, over what period will that EUR69 million be recognized, please?

And secondly, just on Inflexal, can you just talk a little bit about what the volume and pricing trends you saw in 2009 for that were, i.e. were volumes broadly flat, and should we anticipate that until you get more antigen, and therefore was all the growth driven by price or not? That would be great. Thank you.

Leon Kruimer - *Crucell - CFO*

This is Leon. Let me take the question on the premium on the J&J deal. The amount is actually a little bit higher than the EUR69 million, because there were some subsequent payments. The total is about EUR75 million. And it will be amortized as deferred income basically over a four-year period, which resembles the development time of the flu monoclonal.

And, Peter, let me take your question on the Inflexal. If I'm correct, that was the product you were referring to. For 2009, we enjoyed better yields in production and slightly higher prices in the market. The volume of antigen that we were supplied to it was roughly same.

Operator

Tony Campbell, Knott Partners.



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Tony Campbell - Knott Partners - Analyst

Just a clarification, as the first question. The Korean plant will not be, then, onstream until 2011? Is that correct? Because we had -- I had difficulty hearing responses to a number of the questions because of the quality of the phone call. You were going in and out.

Cees de Jong - Crucell - COO

Let me take that question on the Korean facility. As I mentioned before, the facility is now commissioned, meaning that all the equipment is in. But the way it works with pharmaceutical and biopharmaceutical products is that after a facility is complete, you go into a fairly lengthy phase of validating. And that means that although we produce some first material this year, that is basically used for nothing else than stability studies and validating that the product we manufacture in this new facility is exactly the same as we've manufactured in our previous facility. That testing will take most of this year, probably all, and the production is expected to commence 2011.

Tony Campbell - Knott Partners - Analyst

Okay, that's fine. I understand that, then. I just wanted to clarify it.

Now, if we were to look at margins, your margins, and let's just talk in constant currency. Let's forget about the currency fluctuation. So your margins are, let's say, 42%, 45%. And those are still kind of historically sort of low relative to margins in the vaccine business. So presumably, the Korean plant is going to improve your margins by some percent. So if we were to look out two to three, four years, what is it reasonable -- what sort of margin level -- give us a range, because I don't want to pin you down, but what do you think is a reasonable range that you can get your margins to?

Cees de Jong - Crucell - COO

I really appreciate your question, but you're not going to get a range out of me. What I'm willing to help you with is a couple of things. One, the margins of Crucell are --

Tony Campbell - Knott Partners - Analyst

Let me, let me -- all right. Go ahead. Then I have a follow-up.

Cees de Jong - Crucell - COO

The margins that Crucell enjoys are a function of the mix of our operating income and other revenue, i.e. license income within that that mix has, of course, a very strong positive income on our margins. Product sales has of course a different impact. That mix is going to change in 2010 compared to 2009 and hence has an impact on our margins.

Exchange rates always have a significant impact on our margins. In general, there's no reason to believe that Crucell cannot move up its margins to margins that are common in the vaccine industry. At this point in time, as I said in my opening statement, I'm not willing to give a range where we could be.

Tony Campbell - Knott Partners - Analyst

Okay. Let me ask the question a different way. Where are the plants that are producing these low margins? Everybody knows the Swiss, for instance, and particularly Berna, they weren't running the business for profitability. So where are the sort of, if I

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may be so bold, the problem plants, the problem facilities? And I assume, and I would love to just talk product sales -- forget about licensing, because I understand that is pure profit. Where -- you've got to -- give us some guidance as to what you're doing, okay, and where you're moving production. And obviously, Korea is one of those places.

Cees de Jong - *Crucell - COO*

Tony, I don't think we have any problem sites. All our sites are contributing to our margins, and so are all of our products. Again, the margins that Crucell enjoy are a mix between the product sales and the license income that we obtain. And on a year-to-year basis, the exchange rates have significant impact.

And again, when our mix starts changing, there is no reason not to assume that we can't move our margins up to industry levels. We have been guiding operational results for 2009. And we very specifically did so because we feel that is a much better measure to appraise the performance of the Company by.

Tony Campbell - *Knott Partners - Analyst*

Okay, then one final question. For Quinvaxem tenders, it takes -- what is the timeframe between issuing a tender and actual delivery, just in general?

Cees de Jong - *Crucell - COO*

There's different source of tenders, Tony. The tender of the largest supernatural organization is being held once every three years, and it is about roughly half a year prior to the period for which it is. So as you remember, we announced the awards for that large supernatural organization I think in Q3, in August of last year, and the tender period is starting in January.

However, tenders for other geographical areas, for instance with the Pan American Health Organization are on an annual basis. But I think your question is more pertaining towards when do you expect additional awards.

Let me repeat what I've said before. Only half of the originally tendered volume has been awarded today. Some of the other companies entering the field may have difficulty in supplying the originally awarded volumes. So when you're an optimist, you would expect additional awards to be granted already this year. And as I said in my presentation, we do not rule that out.

Tony Campbell - *Knott Partners - Analyst*

So really, I guess, well, it's a matter of semantics, but essentially your guidance is conservative, then. Thank you very much.

Cees de Jong - *Crucell - COO*

There is a conclusion, Tony, that is completely on your account and not something we would support.

Operator

[Neil Wisproof, Kempen & Co.]

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Neil Wisproof - *Kempen & Co. - Analyst*

What I would like to know is, how much of the R&D 2010 budget of approximately EUR90 million will be reimbursed by your partners?

Leon Kruimer - *Crucell - CFO*

I will take that question. As I said before, the strong increase in R&D is made possible because of very extremely strong cash flow performance, which allows us to do that. Part of our topline -- so it is a growth number -- part of our topline will include research income that we will get and that we will indeed use for R&D expenses. But the overall connection, I think that it will be a minority part of the R&D costs that are covered by direct infusions of cash for R&D.

Neil Wisproof - *Kempen & Co. - Analyst*

A minority part being in what range?

Leon Kruimer - *Crucell - CFO*

You'll find that money back in license income, and you'll find it back in terms of programs where we get paid for, for instance, by governments or the NIH in the United States. It will show up as grants and other income. So it will -- the money that comes in actually shows up at two different line items in the P&L.

Operator

Guillaume van Renterghem, UBS.

Guillaume van Renterghem - *UBS - Analyst*

My question was with regard to the premium on J&J, but it has been answered. Thanks.

Operator

Rene Verhoef, Fortis Bank.

Rene Verhoef - *Fortis Bank - Analyst*

I've also questions regarding Inflexal. ADImmune, let's say, is starting production of influenza vaccines at substantial scale. Will they also supply Crucell with antigen in 2010 and further, and will that imply that you can supply more influenza vaccines in 2010 than in 2009? And in case yes, by how much?

And the result of participations, I assume that reflects ADImmune, was once about EUR8 million positive. Is that a trend? I know the seasonality in the business, but the improvement in those results, are those sustainable?

Cees de Jong - *Crucell - COO*

Leon will take the last part. Let me take the first part of your question, which I think is an excellent question.



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When you look at the Inflexal product, let me restate it -- is the unique flu vaccine, due to the fact that not only it's thimerosal-free, but it's also aluminium-free. So it is one of the best-positioned products for the pediatric segment and hence it enjoys a price premium in the market. As you know, unfortunately, thus far, we have antigen constraints. The volume of antigen that we've been supplied with is more or less constant on a year-to-year basis.

On ADImmune, I'm pleased to say that ADImmune has already produced flu shots for the local Taiwanese and some local Asian markets during 2009. They have participated in the sales of pandemic vaccines, and they've done so very successfully. So the facility is ready. And again, same as with our new facility for Quinvaxem in Korea, in order to qualify the product for the European market, that facility needs to do test runs, which will be done during this year. And as of 2011, we would expect to obtain antigen from ADImmune. Ultimately, we would expect that volume to go up to like 10 million doses of Inflexal, bringing up our sales significantly.

Leon Kruimer - *Crucell - CFO*

In terms of the results, investments in [non-2008] companies, that is indeed ADImmune, but it also reflects the investment in [Proshedia], our development center in the United States. As Cees has just said, ADImmune has had a good year because they started production of pandemic vaccines, and hopefully going forward that would be continued by producing regular seasonal vaccines.

Operator

I will now hand back to your hosts to wrap up today's call. Thank you.

Oya Yavuz - *Crucell - Corporate Communications and IR*

Okay. Also on behalf of management, thank you very much for your questions. You know where to find me if you have any further questions. Thank you all very much.

Operator

Thank you for joining today's call. You may now replace your handsets.

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