



Event: ThromboGenics half-year results 2015 conference call

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Speakers: Dr Patrik De Haes (CEO) and Mr Dominique Vanfleteren (CFO)

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OPERATOR: Welcome to the ThromboGenics half-year results 2015 conference call. For the first part of this call all participants will be in listen only-mode and afterwards there will be a question-and-answer session. Alternatively, you can use the webcast for your questions.

PATRIK DE HAES: Good evening to those listening in Europe and good morning to those in the US. I am Patrik De Haes, CEO of ThromboGenics, and I would like to welcome you to this conference call covering our 2015 half-year results. On the call with me is Dominique Vanfleteren, our CFO.

I will begin the call by running through the highlights for the first half of the year. I will then go into some more detail on the changes to our US organisation that we announced today, on the continuing rollout of Jetrea outside the US and on our development activities. I will then hand over to Dominique, who will provide a financial update, before we open up the call for any questions that you might have. However, before the start of my presentation, I would you to see our disclaimer. In the next slide, to begin with the highlights for the first half of 2015, we have delivered revenues of €6 million, of which €4.2 million came from Jetrea in the US and €1.7 million in royalties from Alcon on sales outside the US. This compares to €5 million of Jetrea sales in the US and royalty income of €1.7 million reported for the same period in 2014, and €3.8 million of US Jetrea sales and €1.7 million in royalty income in the second half of that year.

The absence of an improvement in sales momentum in the States, despite promotional efforts, has led us to take the decision to adjust the size and cost of our US organisation to match current market needs. As a result, ThromboGenics will become a leaner, customer-centric organisation and will target cash flow neutrality

from 2016 onwards. We ended the period with €113.3 million in cash. The decision to have our US organisation become cash flow-neutral means that this, plus the anticipated royalties from Alcon, will be sufficient to support our business plans for the coming at least three years, giving us the time to generate the important clinical data from a number of our development projects.

Looking to create longer-term value, we remain committed to developing Jetrea for other important indications and remain on track to initiate our phase II study assessing Jetrea for the treatment of diabetic retinopathy around the end of 2015.

This indication could be a significant commercial opportunity for a Jetrea, based on its ability to create a PVD or posterior vitreous detachment. By creating a PVD, we hope to prevent the growth of new blood vessels that are responsible for this sight-threatening condition. We are also evaluating the development of Jetrea for the enzymatic treatment of RVO, retinal vein occlusion, and continue to selectively invest in our pipeline as we have a very strong commitment to develop more innovative next-generation treatments for diabetic eye disease. In April, ThromboGenics spun out its oncology research activities into Oncurious NV, which will focus on developing TB-403 for the treatment of medulloblastoma, the most common form of brain cancer in children. Oncurious is on track to commence that phase I/IIa study before the end of 2015.

I would now like to explain in more detail the changes we are making to our US organisation and our commercial strategy for Jetrea going forward. In the first half of 2015, ThromboGenics generated sales in the US of €4.2 million. This was below the company's expectations. Whilst we remain convinced that in time Jetrea will be able to play a key role in the changed standard of treatment for patients with VMA, it has become increasingly clear that we needed to evolve our strategy if we are to generate significant returns for the shareholders.

We have therefore today announced a right-sizing of the US organisation to reflect the current market demand for Jetrea. A smaller US team will continue to provide

distribution, customer support and medical education services for Jetrea. It is important to point out that all US retina physicians will continue to have easy and timely access and support when they wish to treat a patient with Jetrea. We also intend to add capabilities in diabetic eye disease to support our planned clinical development activities in the States. The reduction in size of our US organisation is designed to make our US business cash flow-neutral, based on the current levels of sales, from 2016 onwards.

I would now like to turn to the activities of our partner Alcon and the rollout of Jetrea outside of the US. Alcon remains committed to building the sales of Jetrea outside the US, as is evidenced by the growing number of approvals that we are seeing around the world. In Europe the rollout is largely complete in terms of market introduction. Good progress has also been made in terms of gaining reimbursement in the major European markets.

Alcon also continues to rollout Jetrea in the rest of the world. In February, Jetrea was approved in Argentina, Israel and the Philippines and further approvals in Asia and Latin America are expected in the second half of 2015. Most recently, Jetrea was approved in New Zealand, the product's fifty-second approval outside the US. In parallel with our own efforts, Alcon is working to generate more real-world data with Jetrea. The first data from the Alcon so-called Inject study was presented at the ARVO conference in May and showed VMA resolution rates that were in line with those that were reported from the Oasis study, namely one out of two in the right patient population.

Slide 8 provides further detail on the rollout of Jetrea in Europe. As you can see, approval and reimbursement is in place across much of Central and Western Europe, including most major markets. Reimbursement is currently under evaluation in many Eastern European countries and further announcements in this regard will be made over time.

In the next slide, we present the global situation with Jetrea. As you can see, the product is now approved in 53 markets globally and we expect to see further important approvals over the next 12 months in Asia and Latin America.

With slide 10, I would now like to update you on the clinical data on Jetrea that we have released in the last several months. All of this data continues to support our positive view of the benefits that Jetrea is able to deliver to patients with VMA. In particular, they show the importance of improved patient selection to generate higher rates of VMA resolution with the product and the longer-term follow-up data continues to support the safety of the product.

In March, we announced positive top-line results from our Oasis study. This was a randomised, sham-controlled, double-masked study that followed 220 patients with VMA for 24 months post-injection. The study was designed to provide long-term and well-controlled efficacy and safety data for Jetrea. The study showed that about 42 per cent of patients treated with Jetrea achieved VMA resolution at day 28 versus 6 per cent as compared to the sham injection. This was a very positive result given the fact that there was a 20 per cent misdiagnosis of epiretinal membranes, meaning that there were still 20 per cent epiretinal membranes in this study. Further analysis of all of the Oasis data will be presented at the American Academy of Ophthalmology in November later this year.

At ARVO, we presented the six-month data from our Orbit study. That study showed that 58 per cent of patients experienced resolution of their disease within one month post-injection.

Clinical data points out that careful patient selection should lead to higher resolution rates and increased patient outcomes. Side-effects reported have all been documented and mostly transient. They are also very similar to the side-effects experienced by patients following a vitrectomy for the treatment of their VMA.

In slide 11, I would now like to move to our development activities and the next couple of slides cover our work evaluating and developing Jetrea for important new indications.

Jetrea for diabetic retinopathy remains on track and we have to have the first patient in for that study around the end of 2015. DR represents a highly significant new indication of Jetrea where there is both a clear need for improved treatment options and a sound scientific rationale for the development of Jetrea and no surgical alternatives.

Research has shown that the presence of a PVD, posterior vitreous detachment, where the vitreous is separated from the retina, may prevent the growth of blood vessels that are causing the proliferation of the DR. This theory is supported by the observation that diabetic retinopathy is only rarely seen in patients with PVD. Jetrea is able to generate a PVD and could therefore offer a new and improved treatment option for the growing number of patients with DR. A recent report calculated that by 2020 it would represent over a million people just in the US alone.

To slide 13, in April, we began evaluating Jetrea for the treatment of RVO, retinal vein occlusion, also a disease that affects millions of people worldwide. What we are doing is locally applying the drug to lyse the blood clots that are responsible for the condition. The project will, in part, be funded by the Flemish Agency for Innovation and will be conducted in collaboration with the University Hospital UZ Leuven in Belgium. We also have a collaboration with the Mechanical Engineering Department of that university as we apply the drug via a robotics-assisted system, which can deliver ocriplasmin directly into the retinal veins. So the research is making good progress and a scientific publication is planned for 2016.

On the next slide are a few words on the new oncology spinout, Oncurious.

ThromboGenics is the majority shareholder there and the lead asset is TB-403, which is anti-PlGF, and the indication is medulloblastoma, a paediatric brain tumour.

Oncurios' lead product, on the next slide, is TB-403. Medulloblastoma is a life-threatening brain tumour that mainly affects children and it remains on track to start a Phase I/IIa trial in this indication with the enrolment of the first patient expected by the end of 2015. TB-403 is a humanised monoclonal antibody against PIGF. The ground-breaking research, where it is indicated that in medulloblastoma PIGF was upregulated, was published in a Cell paper in 2013.

I would now like to hand over to Dominique, briefly, who will run you through the financial highlights. Dominique?

DOMINIQUE VANFLETEREN: Thank you, Patrik. In the first half of 2015, ThromboGenics had total revenues of €6 million, being €4.25 million of Jetrea sales in the US and €1.75 million in royalties from Alcon based on its non-US sales of Jetrea. In the corresponding period in 2014, ThromboGenics reported €5 million of Jetrea sales and an ex-US royalty of €1.7 million. In the second half of 2014, the US sales of Jetrea were €3.8 million and the royalty again €1.7 million. As you are now aware, the sales performance of Jetrea in the first half of 2015 in the US was below expectations and a lack of sales momentum has led to the changes to our US organisation that we are announcing today.

In the first half of 2015, our R&D expenses were €10.3 million, including a €3.4 million amortisation of the ocriplasmin phase III programme. This compares with €11.6 million of R&D expenses in the same period for 2014 with the same level of amortisation. This lower level of spending reflects the ending of the Oasis study and some additional grant funding.

In the first six months of 2015, selling and marketing expenses amounted to €10.2 million compared to €14.3 million in the first six months of 2014. The reduction is related to the commercial organisation demanding fewer resources in the third year after launch. We would also expect the level of spending on sales and marketing to decline further in 2016.

For the first half of 2015, ThromboGenics reported a net loss of €19.2 million or €0.53 per share. In the corresponding period in 2014, the company reported a net loss of €23.9 million or €0.66 per share.

Let us move to the next slide. I would now like to turn to our cash resources. At the end of 2015, we had cash and investments of €113.3 million, compared to €127.1 million at the end December 2014. The declining rate of cash usage reflects our much tighter cash management.

Looking ahead to the remainder of 2015, we keep our previous cash position guidance for the yearend and this will include the costs of the US right-sizing that we have announced today. As announced, this right-sizing of our US operation is designed to ensure that this business is cash-neutral in 2016. So, with a streamlined US organisation, our current level of cash and the continuing Jetrea royalty income, we now believe that we have the resources needed to fund our business as well as product development activities for the next three years at a minimum.

With this message, I would like to hand over to you, Patrik.

PATRIK DE HAES: Thank you, Dominique. I would like to start by emphasising again the point that you just made that, with the changes we are making to the US organisation, we will have cash for at least the next following three years. This time allows us to generate the important clinical data from the two trials that we plan to start later this year. Again, that is the Jetrea in diabetic retinopathy study, which if successful would open up the opportunity to further develop the product for this significant commercial opportunity; and the second trial is a phase II trial, as mentioned before, on TB-403 in patients with medulloblastoma, the most common form of brain cancer in children. In addition to these clinical activities, we will continue to progress and build our earlier-stage pipeline which is focused on diabetic eye disease. We expect to be

able to provide you with more updates on the progress with our preclinical pipeline later this year.

In the final slide we have taken the opportunity to recap ThromboGenics' key value drivers, which are centred on our research and development activities.

I would now like to open the call for any questions that you might have.

OPERATOR: Ladies and gentlemen, we will now begin our Q&A session. If you wish to ask a question, please press the code 01 on your telephone keypad and you will enter a queue. After you are announced, please ask your question. If you find your question is answered before it's your turn to speak, you can dial 02 to cancel. So, once again, please press the code 01 on your telephone keypad to ask a question or 02 if you need to cancel.

Okay. Our first question is from Richard Vosser at JP Morgan. Go ahead, sir. Your line is open.

RICHARD VOSSER: Hi. Thanks very much for taking my questions. A few, please. Just in terms of projecting forward Jetrea's US sales growth, with the cuts to the salesforce that you're doing, should we be thinking of no further growth or very limited US sales growth in Jetrea until the new indications are available?

The second question: could you give us an idea of what size of salesforce you're retaining in the US?

Then, moving to the pipeline with Jetrea, I'm just wondering about whether you will have a reference arm in the diabetic retinopathy trial where you would look at the efficacy versus Lucentis or Eylea or some sort of VEGF product?

Then, just thinking about the mechanism with the detachment of the vitreous, in VMA I think the efficacy when epiretinal membranes were removed in the best case was about 40 per cent of patients had an improvement. Is there any evidence to suggest the removal - forgive me if I'm thinking about this wrongly - of the vitreous

from the retina in diabetic retinopathy would be higher than that sort of level or is that the sort of thing we should be thinking about? Thanks very much.

PATRIK DE HAES: Okay. Thank you, Richard. With regard to the sales growth in the States, what we basically have done is we have set ourselves a target that by 2016 we are going to have a cash-neutral operation.

Now, why is that? If you look at the company, we have basically three parts. First of all, you have Oncurious. For Oncurious, if we want to basically develop that company, we're going to do that with external funding, so no cash and - what is it - €113 million will go to Oncurious and that will come from the outside.

Secondly, we have a bucket of Jetrea and you have to split the bucket of Jetrea into the commercial part and, in the commercial part, we're basically going to go for a breakeven situation in the States, and then you have the development of new indications. There, we talk about diabetic retinopathy and that's the part we're going to fund with the Alcon royalties.

Then the €113 million that we have on the books since 2013, that cash is completely reserved for the development of our new product, on which we'll give later this year an update. So you have to look at Jetrea as, to the company, a cash-neutral bucket.

When it comes to the US specifically, as you know, we were having more expenses than revenues and were taking cheap euros and turning them into expensive dollars to cover that up, and we are no longer doing that. At this stage, we have made our sales projections from a level of 2,500 vials per year. It's simple: the first-half number we had is the number we expect to see also in the second half.

What we have seen, Richard, is - and you can see it in the numbers for the last three semesters - that the drug seems to be very insensitive to promotional push. We had episodes with more reps than others. We had good reps on specific accounts than others. The thing is that we see a scattered sales pattern. We don't

really see too high commercial sensitivity for the drug. So that was your first question.

DOMINIQUE VANFLETEREN: The salesforce.

PATRIK DE HAES: On the size of the salesforce, I don't think that we basically go forward with a salesforce as such. We have a group of five which we call business managers that distribute the tasks around the country and they're supported by four medical affairs people, but this is basically the field-based staff that we're going to retain. We're going to focus the marketing in the US on three pillars. First of all, we think that it is important that we move from pushing sales to making sure that our customers are well served, so a customer service orientation where we're going to explore new ways of doing that. Secondly, we're going to address also the fact that patient information is going to be facilitated, so whatever the doctor needs to make sure that the patients are aware and are objectively informed about the chemical alternative or the anti-medical(?) alternative to vitrectomy that is available. Thirdly, we want to position the company strongly as a medically and scientifically oriented company and focus on the research. With regard to the DR, as I said, we expect the first patient in by the end of the year and at that stage we're going to give you guys much more detail on what the real plan is. Now, with regard to the last question, if I got that correctly, we had 20 per cent of ERMs in that last study and that indicates that it's extremely difficult to diagnose an ERM on OCTs. That is just the way it is. We have proven that in different studies that, even though an ERM is an exclusion criterion for the study, having only an OCT it is just not easy, especially older OCT machines have difficulty in identifying those. What we see in the newer machines - and that's the good thing here - is that ERMs are easier to identify. But it all confirms all these studies that, in the right

patient population and definitely those without ERMs, you get into a response rate of one out of two.

I hope I covered your questions.

RICHARD VOSSER: Maybe I'll just follow up on the last one. What I was just wondering was whether you had any idea of the responder rate in diabetic retinopathy at this stage and whether it would be higher than in VMA. That's what I was asking.

PATRIK DE HAES: Okay. The answer is no, Richard, because we had diabetic patients in our phase III and, if anything, these are patients who are more difficult to treat. That's why we plan to do the DR study with multiple doses. But again, there'll be more information at the time we launch the study.

RICHARD VOSSER: Okay. Perfect. Thank you very much.

OPERATOR: Thank you. Our next question comes from Jan De Kerpel of KBC Securities. Go ahead, sir. Your line is open.

JAN DE KERPEL: Hello. Thank you for taking my questions. I'll maybe take them one by one. There's only three. First, on the diabetic retinopathy, apologies for asking this but there seems to be continuous slack on the timing to start this study. A year ago, it was said it would start in the first half. Now we're already at the end of the year. Could you help us understand why there is this timing difference?

PATRIK DE HAES: Yes. We had this pre-IND meeting with the FDA, out of which a new study design was born - let me put it like this - which had an impact on the timing.

JAN DE KERPEL: Okay. This is only for the US, is it? This study will be done only in the US geography, not the European?

PATRIK DE HAES: No, we plan to do that study in Europe and in the US.

JAN DE KERPEL: Okay. The study design that the US wanted to see - the FDA - was also okay for the EMEA, then?

PATRIK DE HAES: We're going to launch that study globally at once, Jan.

JAN DE KERPEL: Okay, good. Two smaller ones, financially. I see there is still €7 million of inventory on the balance sheet. Your product has a shelf-life, I think, of 24 months at maximum. Are you expecting some impairments to be taken there?

DOMINIQUE VANFLETEREN: The major part of this €7 million is a prepayment for the next batch of drug substances, which is prior to the vials, which still have to arrive, so that's one. But nonetheless, without having the details to give here, there will potentially be some impairments, yes, but not on a high level. We take them as they come and this year we have had something like €800,000 that we have taken out (Inaudible).

JAN DE KERPEL: Okay. Just on that, do you also expect to take some impairments in the intangible assets given the anticipated size of the US market versus what you were banking on previously?

DOMINIQUE VANFLETEREN: Yes, there was a signal that we should be looking at whether we have to impair assets. Look at our capitalisation. But we have been doing the evaluation of the assets with the value and use and we believe there is no need for impairment at this stage. But we will follow up on this by the end of the year.

JAN DE KERPEL: Okay, thanks. Then, on the reorganisation and the way you are going to do it in the US, two sub-questions, in fact. First of all, what kind of costs are we looking at that will come into the company? Then we'll have the next one.

DOMINIQUE VANFLETEREN: So, on reorganisation costs, you mean the restructuring not --

JAN DE KERPEL: Exactly, yes.

DOMINIQUE VANFLETEREN: It will be included in our costs and we have an estimate today that it will cost us around €2 million.

JAN DE KERPEL: Okay, thank you. Then, more strategically on what you are doing in the US and the way you are going to approach physicians and so on and also reach out to patients, is that in fact aligned and is it similar to what Alcon is doing in its territory?

PATRIK DE HAES: I'd prefer that you ask Alcon directly what they are doing in their territory. It's a bit difficult for us to talk about it. But as you know, we have strategic committees together and we agree on common things. Of course, the local application can be different, but all I can say is Alcon is also looking to as efficiently market this product as possible.

JAN DE KERPEL: Okay. Thank you, Patrik and Dominique.

OPERATOR: Thank you very much. At this point, ladies and gentlemen, there are currently no questions in the queue. Let me remind you that if you wish to ask a question, you can do so by dialling the code 01 on your telephone keypad now to enter the queue.

We have a follow-up question from Richard Vosser of JP Morgan. Go ahead, sir.

Your line is open.

RICHARD VOSSER: Thanks. It's just about the resources to do a phase III trial in diabetic retinopathy. If I understood your answer, essentially, that would come out of the royalties from Alcon to fund the phase II and then potentially a phase III. Do you think you would need extra funding or do you think you would have enough funds to do a large phase III trial? I'm just thinking that, for example, Eylea with Regeneron or Lucentis with Roche did quite large DME trials, which I think is a pretty similar area to diabetic retinopathy, so just your thoughts there would be great.

PATRIK DE HAES: There's a fundamental difference between what the anti-VEGFs are doing and what we try to do. We basically are going to treat - let's say - severe NPDR. At a certain moment, those NPDRs move into PDR and within one or two years their vision can be threatened quite dramatically. That is when the vessels start growing into the vitreous. What we try to do with Jetrea, which we know we already have proven in non-diabetic patients, is to basically take the scaffolding away so that the vessels no longer grow into the vitreous. That's why people with a PVD have no PDR. They have no progression in this diabetic retinopathy, so it's a fundamental difference. If anything, those two drugs can be combined, but the way that this drug works and the part of the market that we try to address is a different part of the market than the anti-VEGFs do. It's also, actually, a bigger part of the market.

But again, on your question, whether we would have to go to the market to raise money at this stage is a very difficult question to ask. We're going to have to wait a few years before we can judge that. We hope not.

RICHARD VOSSER: Thank you very much.

OPERATOR: Okay. Once again, if there are any further questions, please dial 01 on your telephone keypad now.

Okay. There seem to be no further questions. Speakers, do you wish to begin your closing comments?

PATRIK DE HAES: We thank the audience for participating in this call. Today, clearly, it was not an easy decision that this company had to make, but we firmly believe it's the right decision. Thank you very much.

OPERATOR: Thank you, Dr Patrik De Haes and Mr Dominique Vanfleteren. This concludes today's conference. Thank you all very much for attending.