Event: ThromboGenics 2015 Full-Year Results Conference Call

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Operator: Good evening, good morning. My name is Laura and I will be hosting this ThromboGenics 2015 full-year results conference call. On today's call we have Dr Patrik De Haes, Chief Executive Officer at ThromboGenics, and Dominique Vanfleteren, Chief Financial Officer. Today's presentation part will take about 20 minutes before opening the call for a Q&A session. The presentation and transcript of this call will be made available on the investors' section of the ThromboGenics website.

Before handing this call over, I would like to remind you that the matter we will discuss during this call include certain statements relating to future results, or statements of our intentions, beliefs and expectations for the future, which are forward-looking statements. For this purpose, these forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from anticipated results.

With this introduction, I will now hand over to Dr Patrik De Haes.

Patrik De Haes: Thank you, operator.

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 full-year results. On the call with me is Dominique Vanfleteren, our CFO.

I will begin this call by running through the 2015 highlights, and I will then hand over to Dominique, who will provide a review of our 2015 financials. I then want to focus on providing more detail on the significant market opportunity for products targeting diabetic eye disease, and our exciting pipeline of disease-modifying drugs designed to treat diabetic retinopathy and diabetic oedema. We are very optimistic about the potential of this pipeline, which we think is one of the best in the industry today for targeting diabetic eye disease.

I would also like to briefly update you on our oncology spin-off, Oncurious, where we are making good progress, as evidenced by the announcement we made earlier this week covering our clinical development deal with NMTRC, a charitable clinical trial organisation that will be a key partner in the development of TB-403. I will then wrap up, before opening up the call for any questions that you may have.

I would like to take the opportunity to remind you all about our IR R&D day we have tomorrow in London, and we will provide there much more detail on the plans we have in diabetic eye disease. This meeting will also provide investors and analysts important background information on the disease from two distinguished key opinion leaders, Professor Schlingemann from Amsterdam and Professor Alan Stitt from the UK.

Before starting my presentation, I would like to draw your attention to the disclaimer slide that is in the slide deck for this call, which can be downloaded at the ThromboGenics website.

So, on slide three, 2015 has been a transformational year for ThromboGenics in which we have seen significant changes. These changes have resulted in us now focusing most of our resources on developing novel treatments for diabetic eye disease. This is the result of the significant progress we have made in the last 18 months in building our new diabetic eye disease pipeline. We have now four novel disease-modifying drug programs under development, which together will allow us to target all segments of the diabetic retinopathy and/or diabetic oedema markets. We believe we can generate significant value from these two significant and growing commercial opportunities due to the competitive profiles of our products in development.

In August 2015, we announced our decision to significantly reduce the resources that we were allocating to the commercialisation of JETREA in the US for the treatment of symptomatic VMA. We implemented this decision in the second half of 2015, and this will result in our US operations being cash-neutral in 2016 onwards. The changed financial profile of our US business, combined with our

current cash resources of over €100 million, plus the royalties we receive from Alcon based on sales of JETREA outside the US, means we have the resources to support our drug development activities for the next three years. During this period, we expect to deliver a number of important value-generating clinical and development pipeline milestones.

With this brief introduction, I would like to hand over to Dominique, who will run you through our '15 financials.

Dominique Vanfleteren: Thank you Patrik, and hello to all listeners.

In 2015, ThromboGenics had total revenues of €11.2 million, including €7.4 million of JETREA sales in the US and €3.2 million in royalties from Alcon based on the non-US sales of JETREA. In the corresponding period in 2014, ThromboGenics reported €8.8 million for JETREA sales in the US and a non-US royalty income of €3.4 million. As Patrik has outlined, the lack of sales momentum that we saw in the first half of 2015 led us to reduce the size of our US organization in the second half of the year.

During 2015, we have kept our R&D expenses in line with 2014 spending. We had 21 for – sorry, €21 million in 2015, compared with €22.6 million spent in 2014. This level of spending reflects costs of preparing for the CIRCLE phase II clinical study with THR-409, and the build-up of our new pipeline of disease-modifying medicines targeting the diabetic eye disease, and some preparatory work for the start of the forthcoming Oncurious TB-403.

2015 has brought a major decrease in sales and marketing expenses. Overall, sales and marketing expenses amounted to €17.6 million in 2015, which is a 41% decrease from the €29.9 million spent in 2014. This decrease followed our decision to right-size our US commercial approach for JETREA in the US, to ensure that our US operations are break-even for 2016 onwards.

In 2015, ThromboGenics reported a net loss of €37.9 million, or €1.05 per share, comparing to a net loss of €51.1 million or €1.42 per share in 2014. This is an improvement in the results of 25% – so, 25% less loss.

If we move to the next slide, the above has resulted in us continuing to have an excellent cash position. Effectively, at the end of December 2015 we had cash and investments of €101.4 million, compared to €127.1 million at the end of December 2014. This significant reduction in our usage of cash in 2015 reflects a much tighter management across the whole – management of expenses across the whole ThromboGenics organization. With this tight cash discipline, with our streamlined US organization, the current level of cash and also the royalties coming from JETREA, we believe we have the resources to fund – to fund our current business activities for the next three years. During this period, we are confident that we can generate significant value from our pipeline, as is going to be explained more tomorrow in London.

With this, I would like to hand back to you, Patrik.

Patrik De Haes: Thank you, Dominique.

I would now like to turn to why we have been investing in developing a pipeline of novel drug candidates targeting diabetic retinopathy. The reason is that the market for new treatments for diabetic retinopathy is expected to be one of the fastest-growing segments of the ophthalmic medicines market. Over the period to 2023, this market segment is forecast to grow at over 16% per annum from $1.6 billion to $4.2 billion, which is about double the growth rate of the overall ophthalmology market.

A key factor underlying this growth is the increasing number of diabetics. At present, there are over 400 million people with diabetes worldwide, and this number is expected to double over the next 20 years. Another reason for focusing on this market is that there is a clear need to improve on the treatments for both diabetic retinopathy and diabetic oedema currently available.

This growth in the number of diabetics is expected to significantly increase the number of patients suffering from diabetic retinopathy. It is estimated that approximately one out of every third diabetic will develop some form of diabetic retinopathy during his life – his or her lifetime. Diabetic retinopathy is a serious eye disease and is the leading cause of vision loss in working-age adults. It is important to recognise that diabetic retinopathy is a progressive disease, with patients experiencing different forms. As you can see, the most common form of the disease is non-proliferative diabetic retinopathy. It is important to treat patients with non-proliferative diabetic retinopathy in order to prevent their condition from progressing to proliferative diabetic retinopathy, a serious sight-threatening form of the disease. At present, there is no optimal treatment options for patients with NPDR, or non-proliferative diabetic retinopathy.

As you can see, a significant number of diabetics with diabetic retinopathy experience diabetic macular oedema due to leaking of fluid from blood vessels within the macula, and which can progress then to causing blindness. Again, there is a clear need for a disease-modifying option to treat this serious condition.

Having provided you with some background on the scale of the diabetic eye disease opportunity and the need for improved treatment options, I would now like to turn to the pipeline of novel drug candidates that we are developing to treat both diabetic retinopathy and diabetic macular oedema. This pipeline was created by the research team at ThromboGenics using cutting-edge science which has included the development of a number of proprietary pre-clinical models of diabetic retinopathy and diabetic macular oedema.

Our most advanced product for diabetic retinopathy is THR-409, or ocriplasmin. In January 2016 we initiated a phase II clinical trial called CIRCLE, assessing the ability of multiple doses of ocriplasmin to induce a complete PVD – a complete posterior vitreous detachment – and that in patients with non-proliferative diabetic retinopathy. It is thought that, by creating a PVD with ocriplasmin, we can prevent NPDR from progressing to proliferative diabetic retinopathy, a serious sight-threatening condition. Research has shown that the presence of a posterior vitreous detachment, where the vitreous is separated from the retina – it may prevent the growth of blood vessels that are the cause of the DR – of the proliferative diabetic retinopathy. This theory is supported by the observation that diabetic retinopathy is rare in patients with a PVD.

We would anticipate being able to announce initial clinical results of the CIRCLE study towards the end of 2017. These results will indicate whether multiple doses of THR-409 can achieve a PVD in this patient population.

Our second development candidate is THR-317, which is being developed for diabetic macular oedema either alone or in combination with anti-VGEF drugs. THR-317 has a novel mode of action, and we are confident that this product, which targets PLGF, will deliver important benefits to DME patients. We expect to start the clinical development of THR-317 later in the year.

We are also developing two further exciting new compounds. THR-149 is a plasma kallikrein inhibitor to treat oedema associated with diabetic retinopathy. And finally, we just signed an agreement with Galapagos for THR-687, a small molecule integrin antagonist being developed to treat a broad range of diabetic retinopathy or – with or without DME. This is a very interesting molecule, given the broad cross-section of patients with diabetic eye disease that it potentially could treat.

We intend to provide you with more details on our four disease-modifying pipeline projects at tomorrow's R&D meeting.

I would now like to briefly update you on Oncurious, our oncology spin-out in which we partner with VIB, a leading life science research institute in Flanders, Belgium. Oncurious is focused on developing orphan drugs for paediatric cancer treatment, and our strategy for Oncurious is to continue to develop

its lead asset, TB-403, for the treatment of paediatric cancers. Oncurious' lead product is TB-403, which is a humanised monoclonal antibody against placental growth factor (PlGF). PlGF is expressed in several types of cancer, including medulloblastoma, and its expression is required for the growth and spread of medulloblastoma. This groundbreaking research was published in *Cell* in 2013.

As announced earlier this week, Oncurious signed an important collaboration with the Neuroblastoma and Medulloblastoma Translational Research Center, a non-profit US organisation and clinical trial network, with the mission to bring forward new effective therapies against both diseases. NMTRC operates a network of 25 clinical centres across the US. This agreement will provide Oncurious with access to the patients who are needed for the planned phase I/IIa study with TB-403, which will start in the coming months.

In the final slide I would like to wrap up what we have covered on today's call.

ThromboGenics is clearly focused on delivering shareholder value as a drug development company, focused on a pipeline of innovative treatments targeting diabetic eye disease. We are now working on novel treatments for diabetic retinopathy, both the non-proliferative and the proliferative form, as well as diabetic macular oedema. These are conditions where there is a clear need for improved treatment options.

Our pipeline, which we believe is one of the most exciting in the industry, contains four novel disease-modifying products. The exciting pipeline will allow us to target all segments of the fast-growing diabetic retinopathy market. We are confident, based on the clearly differentiated drug candidates, that we will be able to both improve the lives of patients with diabetic eye disease and to generate value for our shareholders. We are in the fortunate position that our current cash resources of €100 million will allow us to finance our clinical development plans for the next three years, and we are confident that during this period we can deliver a number of potential value-generating milestones.

I would like to take this opportunity to remind you about our IR R&D day tomorrow in London, where we will provide more insight into the unmet medical needs in diabetic eye disease and the science behind the novel products in our development pipeline. With that, I would now like to open the call for any questions that you may have.

Operator: Thank you. 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. So, once again, please press the code 01 on your telephone keypad.

Our first question is from Jan de Kerpel, KBC Securities.

Roderick Verhelst: Yes, good evening. It's actually Roderick Verhelst of DeGroof Petercam. Just to zoom in a bit on the molecule licensing from Galapagos, was there a specific reason why you – were you looking for this type of – this class of drug? Why did you end up at Galapagos, because they were – they didn't really put it in their pipeline? So I was really wondering how you arrived at that – Galapagos – in light of this product. Thank you.

Patrik De Haes: So, integrin inhibition in back-of-the-eye disease has been studied for quite a few years now. I think initially it was even Bausch & Lomb who had the initial research in this area. We also have been following what has been presented by a company in the US that is also developing an integrin inhibitor and been listening at our key opinion leaders, and they clearly found it an interesting avenue. Our internal research also has shown that it would be interesting to look into this category of drugs, and then we looked at the number of companies who had integrin inhibitors in their pipeline. These were a group of drugs that had been studied a few years ago for the treatment of rheumatoid arthritis. Galapagos was one of those companies and, as you could have read, we have made a deal with them.

Roderick Verhelst: Okay. Thank you. Very clear.

Jan de Kerpel: This is Jan de Kerpel here, KBC. Thanks for taking also my questions, a little bit more on the financial side. In 2015 we see the sales going down from – for JETREA in the second half of the year versus the first half. What kind of sales levels do you expect in 2016? And linked to that, in fact, can you clarify if the US operation will be cash-neutral in – for full-year 2016, or as of 2017? Thank you.

Patrik De Haes: Well, you know, we – as we said, we reconfirmed that the US operation will be cash-neutral, independent of the top-line level we gain there. All the money we make in that first indication in the US, we will invest in that market. We have communicated that before, and we stick to this line.

Jan de Kerpel: Sorry, Patrik. The question was if it's – if it's cash-neutral in 2016 already, or in 2017. It's unclear.

Patrik De Haes: Sorry, in 2016. This year it will be –

Dominique Vanfleteren: By the end of the year.

Patrik De Haes: Yeah, by the end of – cash-neutral.

Jan de Kerpel: Okay, that's – and what kind of sales do you expect? Because if sales would go down, your costs may have to go down. Do you have that flexibility?

Patrik De Haes: Yes, we do have that flexibility.

Jan de Kerpel: Regarding the R&D pipeline, it will be elaborated on tomorrow. The – should we assume that the R&D expenses will go up, or how do we have to look for that?

Patrik De Haes: Dominique, you want to –?

Dominique Vanfleteren: Yeah. Well, for the year 2016, the projects that we foresee are going to be within the budget that we have foreseen, and this is – sticks within the – what we have said, that we have enough funds to go out a further two, three years – like, from – this year included, of course.

Jan de Kerpel: Okay. This three-year cash spending, should we assume that this will be equally spread over the next three years, or will there be a ramp-up in spending over the years? Can you guide a little bit on that?

Patrik De Haes: I would say that they are reasonably equal, with a little acceleration towards the third year.

Jan de Kerpel: Okay. Thank you.

Operator: Thank you. There are currently no more questions in the queue. Ladies and gentlemen, let me remind you that you can ask a question by pressing the code 01 on your telephone keypad.

There are no more questions. Do you wish to begin closing comments?

Patrik De Haes: So, if there are no more questions, I would like to thank everybody on the call again. Tomorrow in London, much more detailed on the future of our R&D pipeline. Hopefully we can welcome some of you or – live, or via the webcast. Good evening and good morning

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