



ThromboGenics Conference Call – FY 2017 Business Update & Results

Thursday 15.03.2018 – 18u30 CET

Speakers: Patrik De Haes, MD, CEO and Dominique Vanfleteren, CFO

Call Duration: 19:05

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 2017 full year results.

On the call with me is Dominique Vanfleteren, our CFO. I will begin the call by providing a brief overview of our business operations, before running through our 2017 highlights. I will then hand over to Dominique who will provide a review of the 2017 financials.

After that, I will focus on providing a more detailed update on areas of important progress and wrap-up with an overview of upcoming Newsflow.

Slide two. So, before starting the presentation I would like to draw your attention to the disclaimer on slide two.

And moving to slide three, as you can see, ThromboGenics' main area of strategic focus is the development of our promising pipeline candidates as disease modifying treatments in diabetic eye disease, an area of significant unmet medical need.

Our current pipeline will allow us to target all key segments of the diabetic eye disease market including non-proliferative diabetic retinopathy as well as a more advanced proliferative form of it, which is a sight-threatening form of the disease. The pipeline covers diabetic macular edema. Many DR sufferers indeed experience diabetic macular edema or DME and that's due to leaking of fluids from vessels within the macula, which then can progress to cause blindness.

We do believe that we can generate significant value from these sizeable and fast-growing markets based on the competitive profiles of our drug candidates. Our pipeline is progressing well and I will provide an update shortly. We are well-positioned to progress clinical development of these candidates, with €115 million in total cash and investments as of January of this year. That leaves us fully funded for at least the coming two years.

In addition to this pipeline, we own the global rights to Jetrea, the first and only pharmacological vitreolysis drug approved to treat VMA or vitreomacular adhesion in the US and VMT or vitreomacular traction in Europe. We maintained Jetrea as a cash-neutral business in the US in 2017 and are integrating and developing a commercial strategy for the global business following our agreement with Novartis to regain the non-US rights.

We also own 82% of Oncurious, a company with a promising immuno-oncology pipeline led by VIB, a leading life science research institute in Flanders, Belgium. Oncurious is also developing a candidate in oncology for the treatment of medulloblastoma TB-4.3 in a Phase I/II. This trial is led by Beat Childhood Cancer BCC in the US, and this trial is performed together with BioInvent.

Slide four. 2017 has been a year of important developments as we remain focused on generating value through our novel diabetic eye disease pipeline.

We have completed treatment of all patients in a Phase I/II trial in diabetic macular edema with our most advanced pipeline candidate, THR-317, following completion of patient enrolment in December last year. We will report top-line results from this study shortly by the end of Q1.

THR-317 is a recombinant human monoclonal antibody directed against the receptor-binding site of human placental growth factor. Two other pipeline candidates in late stage preclinical development are set to enter the clinic very shortly; THR-149, a plasma kallikrein inhibitor, for DME and THR-687, an integrin antagonist, for DR and DME.

We also plan to bring at least one new drug candidate into preclinical development for the treatment of diabetic eye disease in the course of this year. We are well-funded to achieve these pipeline milestones

having received €53.7 million in cash and €10 million in equity investment from Novartis. These were received as part of ThromboGenics regaining non-US rights to Jetrea from Alcon, a Novartis company, as we announced in September last year.

As mentioned, we now own global rights to Jetrea following this agreement. ThromboGenics is seen as a better fit to build a smaller and sustainable long-term business with Jetrea. Vinciane Vangeersdaele took up the role as our Chief Commercial Officer in November and will lead commercial strategic efforts related to the newly formed Global Jetrea business unit. Vinciane joined us from Novartis, where she was Head of the Ophthalmology Franchise, Europe. She has over 15 years of experience in sales and marketing leadership in the pharmaceutical industry.

Oncurios reached an important agreement with VIB in September to acquire five novel immunoncology assets based on work from different VIB labs. I'll cover this agreement in more detail later on in the presentation. We also strengthened the leadership team of ThromboGenics on the clinical side with the assignment of Susan Schneider as the Chief Medical Officer. Susan is developing and executing our global clinical and medical programmes and she joined us from Allergan where she served as Vice President & Therapeutic Area Head, Retina & Glaucoma and she has nearly 15 years of experience in clinical drug development.

Finally, long-time non-executive director Thomas Clay was elected as our Chairman, effective as of June last year, succeeding Staf Van Reet. Thomas has been non-executive director since 2011, having replaced his father, Landon Clay, who led the first external investment in ThromboGenics back in 2001. I will now hand over to Dominique to give an overview of the financials. Dominique.

Dominique Vanfleteren: Thank you, Patrik. Good evening, morning to all. Let me now commence the 2017 financials. In 2017, ThromboGenics had a total income of €9.1 million, including €2.9 million of Jetrea sales in the US. Outside the US, we received €1.2 million in royalties from Alcon based on its ex-US sales of Jetrea up to 15 September last year, and we added to that €1.7 million in profit transfer as part of the transition period with Novartis from 16 September last year.

Additional income amounted to €3.3 million, which was received as a settlement from a previous dispute on vials pricing. This €3.3 million makes up part of the €53.7 million received from Novartis which is part of the agreement through which we regained the ex-US rights for Jetrea.

In the corresponding period in 2016, ThromboGenics reported €4.4 million of Jetrea US sales and an ex-US income of 2.7 million, including royalty income from €2.2 million. During 2017, our spending in R&D expenses was €23.2 million compared to €24.7 million in 2016. Our high level of R&D spending over the past two years are due to our re-focus on drug development activities through executing the development of our diabetic eye disease pipeline.

The spending for 2017 reflects the costs of the ongoing THR-317 Phase I/IIa study as well as costs of the CIRCLE Phase II study, for which patient recruitment was discontinued in December due to the slow recruitment rate. We have also continued to invest in preclinical activities to progress our two candidates THR-687 and THR-149 which are set to enter the clinic this year.

The final element of our R&D spend was on the ongoing Oncurios Phase I/II study with TB-403. Our sales and marketing expenses remained relatively stable year-on-year at €4.2 million and remained significantly reduced compared to 2015 figure of 17.6 million. And that was following the reduction of our commercial activities in the US in the late 2015.

The other income line you see of €50.4 million is primarily the remainder of €53.7 million received from Novartis, as said previously, and which is part of the rights agreement on the return of the rights of Jetrea. In 2017, we made a net profit of €22.6 million, boosted by this non-recurring income from Novartis, and that was compared to a loss of €60.4 million in 2016.

This resulted in diluted earnings per share of €0.62 versus €1.67 negative diluted earnings per share in 2016. 2016 results of negative €64 million included a one-off €26.6 million impairment that charge taken on the Jetrea sales.

If we move to next slide, I will talk about cash and investment which amounted to €115.7 million at the end of December 2017. That includes €10 million in restricted cash from Novartis, that is freed up following completion of Novartis' equity investment in ThromboGenics in January this year. This compares favourably to our position of €80.1 million at the end of 2016.

The key financial achievement in 2016 was that our operations in the US reached a breakeven/cash neutral situation, as a result of reducing the size of the US organisation in the late 2015, and we have maintained that status in 2017. With our cash discipline, our current levels of cash, we believe we have the resources to fund our business activities for the next two to three years.

This cash will allow us to generate significant value from our diabetic eye disease pipeline including achievement of several important milestones expected this year. With this, I would now like to hand over back to you, Patrik.

Patrik De Haes: Thank you, Dominique. So, let's move to slide eight. We're currently developing anti-PIGF as the candidate's name is THR-317 for the treatment of diabetic macular edema. For DME, DME is an important area of unmet medical need. The current standard of care treatment with anti-VEGFs has been shown in some cases to result in suboptimal and/or late responses in patients.

As I mentioned in our highlights, we have recently achieved important milestones with THR-317. This through completing enrolment and treatment of patients in a Phase I/IIa study for DME, evaluating its safety and efficacy. We will report initial results from this study shortly and expect to start of the Phase II study in the coming months.

We also continue to generate and present important preclinical data supporting the development of this candidate last year. We presented this data at ARVO in May. It was subsequently published in Experimental Eye Research. The data published showed that the murine form of THR-317 was able to reduce DR disease hallmarks and it may provide additional benefits versus VEGF inhibitors, and this with respect to reducing inflammation, fibrosis, without resulting in neurodegeneration.

We now have the full control of THR-317 in terms of development and commercialisation in all the non-oncology indications. That results from changes to our agreement with BioInvent which is still entitled to a 5% royalty on this project. We believe that THR-317 has the potential to be used or as a stand-alone therapy or as an add-on treatment to anti-VEGF medicines for the treatment of DME or DR.

Next slide. An overview of the Phase I/IIa study for which we completed enrolment in December is provided on this slide. It was designed as a single-masked, multicentre study to assess safety and efficacy of THR-317. In total, we recruited 40 patients that previously had not been treated with anti-VEGF, the so-called VEGF-treatment naive patients, and we added also nine poor responders to previous anti-VEGF therapy.

The study is evaluating the safety of three intravitreal injections of two dose levels, four and eight milligram. The trial is assessing THR activity by evaluating the best corrected visual acuity as well as central retinal thickness as measured by OCT.

Slide 11 gives some more information on our next project, the THR-149, which is a plasma kallikrein inhibitor that is being developed to treat DME. Plasma kallikrein is considered the valid target for the treatment of DME through inhibition of the Plasma Kallikrein pathway. When this system is activated, it induces retinal vascular permeability, inflammation and blood vessel growth, all the hallmarks of DME.

As you can see from this graph, patients with DME have elevated levels of plasma kallikrein. And therefore, an inhibitor has the potential to be effective in the treatment of DME, again, or as a stand-alone therapy or in combination with anti-VEGFs in refractory patients.

Slide 12, THR-149 is targeting DME, aiming to impact disease on-set and progression in this sizeable market. Following its successful preclinical development, THR-149 is now expected to enter a Phase I clinical study in the first half of this year.

Slide 14 is on our next project, the THR-687, which is a small molecule integrin antagonist under development for the treatment of DR, with or without DME. The broad therapeutic potential of this candidate makes it particularly attractive, expanding the available market for this drug.

New preclinical data highlighting the potency and safety of THR-687 was presented at the European Association for Vision and Eye Research in September. The data highlighted its ability to inhibit pathologic blood vessel growth at various stages, an important factor leading to vision loss in DR. This data gives further support to THR-687's potential in the treatment of DR ahead of its entry into the clinic, expected also mid of this year.

Slide 16 now, moving to Oncurios, the oncology part of the company. Last September, we saw an exciting development for the company as it broadened its pipeline. Its pipeline now includes preclinical research and drug development programmes targeting a broad range of cancers, through the acquisition of five novel immuno-oncology assets from VIB.

VIB leads a preclinical development of this project and they will receive a royalty on future sales of any of those assets. In exchange, VIB increased the equity share in Oncurios to 18.33% remainder owned by ThromboGenics. ThromboGenics did commit a total of €2.1 million to be invested in Oncurios over the next three years, which will result eventually in an ownership of 85% of that company three years from now.

Slide 18. As you can see, 2018 is set to be an important year for us with three clinical trials expected to initiate over the coming months. And by the middle of the year we will have three clinical projects in the diabetic eye space. Our two late-stage preclinical candidates will enter the clinic, the THR-687, the integrin antagonist for DR and DME, is expected to enter Phase I around mid-2018, and our THR-149 is expected to enter Phase I first half of the year.

We expect the read-outs from these three clinical studies from mid-2019 onwards. We also expect at least one novel diabetic eye disease candidate to enter preclinical development during the course of the year.

Next slide, ThromboGenics remains extremely well-positioned to progress its promising pipeline of clinical and preclinical candidates targeting different areas of diabetic eye disease. Having received the recent cash boost from Novartis as part of regaining ex-US rights to Jetea, we now own the global rights to Jetea as we mentioned before.

Oncurios has a broad-ranging cancer focused portfolio, following the acquisition of the immuno-oncology assets from VIB. And with our experienced management team, we remain focused on generating value through the diabetic eye disease portfolio, with several important milestones expected this year. These milestones mark key developments towards our goal of becoming a leading player in the treatment of diabetic eye disease.

And with this, I would like to open for questions.

Operator: Thank you. Ladies and gentlemen, we will now begin our Q&A session. As we have no questions, this concludes today's web conference call. Thank you all for your participation. You may now disconnect.