

Press release
6 September 2018
Regulated Information

ThromboGenics Business Update – H1 2018

Positive Topline Results for Diabetic Eye Disease Portfolio

Shareholder approval for company name change to Oxurion NV

€10 million equity investment from Novartis Pharma AG

Total cash & investments of €101.4 million as of June 30, 2018

Highlights

Following shareholders' approval at an EGM held on September 3, 2018, and effective as of September 10, 2018, ThromboGenics NV is changing its corporate name to Oxurion NV. The new name Oxurion is designed to better reflect the company's ambition to deliver best in class therapies for back of the eye disorders, following recent progress made with the company's innovative diabetic eye disease pipeline.



Pipeline

- Positive Day 90 topline results reported from Phase 1/2 clinical study evaluating THR-317 (anti-PIGF) for the Treatment of Diabetic Macular Edema (DME). Day 150 topline results reported in July reinforced the positive Day 90 results by confirming safety and tolerability and indicated durability of clinical activity.
- First patient enrolled in Phase 2 clinical study evaluating the efficacy and safety of intravitreal THR-317 (anti-PIGF) administered in combination with Lucentis® (ranibizumab, anti-VEGF) for the treatment of diabetic macular edema (DME), including treatment resistant patients.

- First patient enrolled in a Phase 1 clinical study (THR-149-001) evaluating the safety of THR-149 (plasma kallikrein inhibitor) for the treatment of DME.
- THR-687 (pan-RGD integrin antagonist), under development for the treatment of diabetic retinopathy (DR) and/or DME, is expected to enter a Phase 1 clinical study in Q3 2018.
- Oncurios Phase 1/2a study with TB-403 for medulloblastoma: evaluation of 3rd (out of 4) dose level is running towards endpoint. Initial data by mid-2019 with progress update in Q1 2019.

Financial

- On 26th January 2018, the completion of an equity investment of €10 million by Novartis Pharma AG in ThromboGenics' capital was confirmed.
- In H1 2018, ThromboGenics reported overall revenues of €3.8 million.
- Cash and investments were €101.4 million as of the end of June 2018. This compares to €115.7 million as of 31st December 2017.

Leuven, Belgium – 6th September 2018 – ThromboGenics NV (Euronext Brussels: THR), a biopharma company focused on developing novel treatments for back of the eye disorders, with an innovative pipeline in diabetic eye disease, today issues its business and financial update for the six-month period ending 30th June 2018.

Following shareholder approval, ThromboGenics NV has changed its name to Oxurion NV effective 3 September 2018 and will execute the name change in the coming weeks. The new name will better reflect the Company's mission of delivering best in class therapies for back of the eye disorders. The new Company name will also result in a change to the Company's stock ticker symbol from 'THR' to 'OXUR'.

ThromboGenics is currently developing a broad pipeline of disease modifying drug candidates for the treatment of diabetic eye disease, including:

THR-317 – a PIGF neutralizing monoclonal antibody being developed for the treatment of DME. THR-317 is in a Phase 2 study evaluating the efficacy and safety of intravitreal THR-317 administered in combination with Lucentis[®] (ranibizumab).

THR-149 – a plasma kallikrein inhibitor being developed for the treatment of DME. THR-149 is in a Phase 1 open-label, multicenter, dose escalation study evaluating its safety.

THR-687 – a small molecule pan-RGD integrin antagonist being developed to treat a broad range of patients with diabetic eye disease. THR-687 is expected to enter the clinic in Q3 2018.

These products all have different modes of action allowing the Company to address the key segments of the rapidly growing diabetic eye disease market.

Further drug candidates are currently being explored for the treatment of diabetic eye disease and it is expected that at least one additional pre-clinical candidate will be moved into clinical development in 2018.

Patrik De Haes, MD, ThromboGenics CEO, said: *“We are pleased with the important progress we have made so far this year, as we focused on advancing our pipeline of novel drug candidates for diabetic eye disease. This progress has triggered our decision to change our name to Oxurion, to better reflect our ambition to transform the treatment of back of the eye diseases. We have progressed THR-317 into a Phase 2 study and THR-149 into the clinic, both for the treatment of DME. With our current cash resources, we are well positioned to continue to advance these clinical candidates, to progress THR-687 into the clinic, and to deliver on our multiple shots on goal strategy.”*

Progressing Pipeline of Novel Medicines Targeting Diabetic Eye Disease: Diabetic Retinopathy and Diabetic Macular Edema

According to the International Diabetes Federation, it is estimated that there are over 400 million adults with diabetes worldwide, and this number is expected to increase to over 640 million by 2040.

Diabetic retinopathy (DR) is an eye disease caused by hyperglycemia (high blood glucose levels) associated with diabetes and is the leading cause of vision loss among working-age adults, affecting over a third of all diabetes sufferers¹. DR progresses from mild, non-proliferative to more severe or even proliferative stages and can result in vision loss and blindness.

Diabetic macular edema (DME) is an accumulation of fluid in the macula which can occur at any stage of DR.

The total global market for drugs to treat DR and DME was \$3.2 billion in 2017. The market is expected to increase to \$4-5+ billion by 2026².

THR-317 – anti-PIGF antibody for treatment of DME

THR-317 is a recombinant humanized monoclonal antibody directed against the receptor-binding site of human placental growth factor (PIGF) that ThromboGenics is developing for the treatment of DME.

DME represents an area of unmet medical need as the current standard of care treatment with anti-VEGFs has been shown to result in suboptimal responses in up to 40% of patients.

In April, the first patient was recruited in a Phase 2 study evaluating the efficacy and safety of intravitreal THR-317 administered in combination with Lucentis® (ranibizumab), for the treatment of DME.

Patients are randomized to either a combination arm of THR-317 (8mg) + ranibizumab, or ranibizumab plus a sham administration. The study plans to enrol 70 patients, some of whom will be anti-VEGF treatment naïve and some will have had a suboptimal response to prior treatment with ranibizumab.

The rationale for this study is that the combination of the anti-VEGF (Lucentis®) and anti-PIGF (THR-317) may result in better efficacy than Lucentis treatment alone. Preclinical experiments have shown that the addition of an anti-PIGF to an anti-VEGF antibody enhances the inhibitory activity on the growth of new blood vessels (Van de Veire et al., 2010), a disease hallmark of DME.

The anti-PIGF component may also target inflammation, another hallmark associated with DME (van Bergen et al., 2017).

Initial results from this clinical study are anticipated by Q3 2019.

¹ International Diabetes Federation (IDF). (2017). IDF Atlas 2017. p.88

² Datamonitor Healthcare 2018

Initiation of the Phase 2 trial followed ThromboGenics' announcement of positive initial Day 90 data from the Phase 1/2 study evaluating THR-317 for DME in April. These data were reinforced by positive Day 150 data that were announced in July.

The Phase 1/2 study evaluated the safety and efficacy of 3 monthly intravitreal injections of 2 dose levels of THR-317 (4mg or 8mg) for the treatment of DME.

The study enrolled a total of 49 patients and included anti-VEGF treatment naïve patients (N=40) and anti-VEGF sub-optimal responder patients (N=9).

The study met its primary endpoint of safety for both the 4 mg and 8 mg doses. There was a low incidence of ocular adverse events, which were mostly mild and related to the injection procedure.

Whilst the focus of the study was safety, efficacy was also observed.

Overall, patients receiving the 8mg dose of THR-317 achieved better visual acuity outcomes than in the 4mg dose group at Day 90. Initial data reported for the 8mg anti-VEGF treatment naïve group at Day 90, 30 days after the last THR-317 injection, showed that 30% of patients achieved a ≥ 15 letter vision gain from baseline.

At Day 150, 90 days after the last injection, in the 8 mg anti-VEGF treatment naïve group, 30% of patients showed ≥ 10 letter vision gain and 10% showed a ≥ 15 letter vision gain, demonstrating the durability of the effect of THR-317.

In the 8mg group, there was a positive trend in the average change from baseline in central subfield thickness at Day 90. This positive trend was no longer observed at Day 150, 90 days after last THR-317 injection.

The study also showed clinical activity in the THR-317 anti-VEGF sub-optimal responder group. However, due to the small numbers in this group, no firm conclusions could be drawn.

Full results from the Phase 1/2 study will be presented at an upcoming ophthalmology conference later this year.

THR-149 – a plasma kallikrein inhibitor for treatment of DME

In May, the first patient was enrolled in a Phase 1 clinical study (THR-149-001) evaluating the safety of THR-149 in the treatment of DME.

THR-149-001 will assess the safety of a single intravitreal injection of escalating dose levels of THR-149 in patients with DME. Approximately 18 patients will be enrolled, with initial (safety) results anticipated by mid-2019.

THR-149 acts through inhibition of the Plasma Kallikrein-Kinin (pKal-kinin) System. Activation of the pKal-kinin system induces retinal vascular permeability, inflammation and angiogenesis. Based on literature data, patients with DME have elevated levels of plasma kallikrein (pKal).

Preclinical studies involving THR-149 were published in *The Journal of Medicinal Chemistry* in March and presented by ThromboGenics' Senior Scientist Dr Tine Van Bergen at the Annual Meeting 2018 of the European Association for the Study of Diabetes Eye Complications Study Group (EASDec). The data demonstrate the potency and efficacy of bicyclic peptide inhibitors of pKal, such as THR-149, via a VEGF-independent pathway.

THR-687 – a pan-RGD integrin antagonist for diabetic retinopathy, with or without DME

ThromboGenics is developing THR-687, a pan-RGD integrin antagonist, for the treatment of a broad range of patients with DR, with or without DME.

Preclinical studies have provided evidence that THR-687 is a potent and safe treatment, highlighting its ability to inhibit various significant stages in pathologic angiogenesis, an important factor leading to vision loss in diabetic eye disease. These preclinical studies provide supporting data for moving THR-687 into the clinic.

THR-687 is on schedule to enter the clinic in Q3 2018.

Oncurious Update - TB-403 for Pediatric Brain Cancers

Recruitment is on-going in a Phase 1/2a study with TB-403, a humanized monoclonal antibody against placental growth factor (PlGF), in the US. PlGF is expressed in several types of cancer, including medulloblastoma. High expression of the PlGF receptor neuropilin 1 has been shown to correlate with poor overall survival.

The study, initiated in May 2016 and being conducted by Beat Childhood Cancer (formerly known as NMTRC), aims to recruit 27 patients with Relapsed or Refractory Medulloblastoma. The purpose of this study is to evaluate the safety and tolerability of TB-403 at the maximum tolerated dose in pediatric subjects with relapsed or refractory Medulloblastoma. Evaluation of the 3rd (out of 4) dose level is currently running towards its endpoint. For recruiting patients, Oncurious is partnering with Beat Childhood Cancer.

Initial data anticipated by mid-2019, with progress update in Q1 2019.

Medulloblastoma is the most common pediatric malignant brain tumor, accounting for 20% of all brain tumors in children. Treatment with TB-403 in relevant animal models for medulloblastoma has demonstrated beneficial effects on tumor growth and survival.

TB-403 is being developed by Oncurious in conjunction with BioInvent International.

Financial review

During the first six months of 2018, ThromboGenics' income amounted to €3.8 million resulting from JETREA® sales.

During the first six months of 2018, the Group reported a gross profit of €2.6 million.

ThromboGenics' R&D expenses were €13.3 million during the first half year, including an amortization of the intangible assets related to JETREA®'s Phase 3 program (VMA/VMT indication) of €1.6 million. In the same period of 2017, the R&D expenses were €10.5 million, also including €1.6 million amortization.

General and administrative expenses declined from €3.2 million to €2.9 million in the first half of 2018.

Selling and marketing expenses amounted to €2.5 million compared to €2.1 million in the corresponding period of 2017.

For the first half of 2018, ThromboGenics reported a net loss of €15.2 million (or €-0.39 per share). This compares with the corresponding period in 2017 when the Company reported a net loss of €15.2 million (or €-0.42 per share).

As of 30th June 2018, ThromboGenics had €101.4 million in cash and investments. This compares to €115.7 million as of the end of December 2017. Both figures include the €10 million equity investment received from Novartis. It was accounted as restricted cash in ThromboGenics' accounts as of on 31st December 2017 and became unrestricted on the completion date of 26th January 2018.

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About ThromboGenics

ThromboGenics is a biopharmaceutical company focused on developing novel treatments for back of the eye diseases with an innovative pipeline in diabetic eye disease. The company's pipeline of disease modifying drug candidates is targeting the key segments of the diabetic eye disease market.

ThromboGenics' clinical pipeline consists of THR-317, a PIGF inhibitor, for the treatment of diabetic macular edema (DME), which is in an ongoing Phase 2 clinical study in combination Lucentis[®], and THR-149, a plasma kallikrein inhibitor which is in a Phase 1 clinical study for DME. THR-687 (an integrin antagonist) is in late-stage preclinical development for the treatment of diabetic retinopathy and DME. THR-687 is expected to enter the clinic in Q3 2018. Further new drug candidates are currently being assessed and developed for the treatment of diabetic eye disease.

ThromboGenics owns the global rights to JETREA[®] (ocriplasmin), the only pharmacological vitreolysis drug approved for the treatment of symptomatic vitreomacular adhesion (in the US) and vitreomacular traction (outside the US).

ThromboGenics is headquartered in Leuven, Belgium, and is listed on the NYSE Euronext Brussels exchange under the symbol THR. More information is available at www.thrombogenerics.com

Important information about forward-looking statements

Certain statements in this press release may be considered "forward-looking". Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason. Additional information concerning risks and uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the Company's Annual Report. This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of ThromboGenics in any jurisdiction. No securities of ThromboGenics may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. state securities laws.

Consolidated key figures as of June 30, 2018

Unaudited consolidated statement of financial position

In '000 euro (for the period ended on)	June 30, 2018	December 31, 2017
Property, plant and equipment	764	991
Intangible assets	22,027	23,603
Other non-current assets	127	126
Non-current tax credit	2,325	1,434
Inventories	2,143	2,204
Trade and other receivables	3,729	4,295
Current tax receivables	2,048	2,054
Investments	25,640	49,555
Cash and cash equivalents	75,793	56,175
Restricted cash	0	10,000
Total assets	134,596	150,437
Total equity	128,076	133,357
Current liabilities	6,520	17,080
Total equity and liabilities	134,596	150,437

Unaudited consolidated statement of profit and loss

In '000 euro (for the period ended on June 30)	2018	2017
Income	3,752	2,746
Operating result	-15,664	-15,012
Finance income	571	67
Finance expense	-74	-273
Result before income tax	-15,167	-15,218
Income tax expense	-4	-3
Loss of the period	-15,171	-15,221
Result per share		
Basic earnings/(loss) per share (euro)	-0.39	-0.42
Diluted earnings/(loss) per share (euro)	-0.39	-0.42

Condensed consolidated interim financial statements

Unaudited consolidated statement of profit and loss

In '000 euro (for the period ended on June 30)	2018	2017
Income	3,752	2,746
Sales	3,750	1,886
Income from royalties	2	860
Cost of sales	-1,117	-1,996
Gross profit	2,635	750
Research and development expenses	-13,349	-10,544
General and administrative expenses	-2,874	-3,176
Selling expenses	-2,541	-2,062
Other operating income	465	20
Operating result	-15,664	-15,012
Finance income	571	67
Finance expense	-74	-273
Result before income tax	-15,167	-15,218
Taxes	-4	-3
Loss of the period	-15,171	-15,221
Attributable to:		
Equity holders of the company	-15,028	-15,214
Non-controlling interest	-143	-7
Result per share		
Basic earnings/(loss) per share (euro)	-0.39	-0.42
Diluted earnings/(loss) per share (euro)	-0.39	-0.42

Unaudited consolidated statements of other comprehensive income

In '000 euro (for the period ended on June 30)	2018	2017
Loss of the period	-15,171	-15,221
Exchange differences on translation of foreign operations	-58	7
Other comprehensive income, net of income tax	-58	7
Other comprehensive income that will not be reclassified to profit or loss	-58	7
Total comprehensive income for the period	-15,229	-15,214
Attributable to:		
Equity holders of the company	-15,086	-15,207
Non-controlling interest	-143	-7

Unaudited consolidated statement of financial position

In '000 euro (for the period ended on)	June 30, 2018	December 31, 2017
ASSETS		
Property, plant and equipment	764	991
Intangible assets	22,027	23,603
Other non-current assets	127	126
Non-current tax credit	2,325	1,434
Non-current assets	25,243	26,154
Inventories	2,143	2,204
Trade and other receivables	3,729	4,295
Current tax receivables	2,048	2,054
Investments	25,640	49,555
Cash and cash equivalents	75,793	56,175
Restricted cash	0	10,000
Current assets	109,353	124,283
Total assets	134,596	150,437
EQUITY AND LIABILITIES		
Share capital	137,485	151,991
Share premium	0	157,661
Cumulative translation differences	-393	-335
Other reserves	-13,193	-13,141
Retained earnings	3,593	-163,546
Equity attributable to equity holders of the company	127,492	132,630
Non-controlling interest	584	727
Total equity	128,076	133,357
Trade payables	3,850	3,298
Other short-term liabilities	2,670	13,782
Current liabilities	6,520	17,080
Total equity and liabilities	134,596	150,437

Unaudited consolidated statement of cash flows

In '000 euro (for the period ended on June 30)	2018	2017
Cash flows from operating activities		
Profit (loss) for the period	-15,171	-15,221
Finance expense	74	273
Finance income	-571	-67
Depreciation on property, plant and equipment	256	379
Amortization of intangible assets	1,577	1,579
Equity settled share-based payment transactions	-52	88
Change in trade and other receivables including tax receivables and inventories	-258	1,756
Change in short-term liabilities	-10,560	-3,469
Net cash (used) from operating activities	-24,706	-14,682
Cash flows from investing activities		
Disposal of property, plant and equipment (following a sale)	58	48
Change in investments	23,915	97
Interest received and similar income	90	10
Acquisition of property, plant and equipment	-88	-139
Acquisition (divestments) of other non-current assets	-1	41
Net cash (used in) generated by investing activities	23,974	57
Cash flows from financing activities		
Proceeds from issue of share capital	10,000	0
Paid interests	-4	-5
Net cash (used in) generated by financing activities	9,996	-5
Net change in cash and cash equivalents	9,265	-14,630
Cash and cash equivalents at the start of the period	66,175	58,251
Effect of exchange rate fluctuations	353	-204
Cash and cash equivalents at the end of the period	75,793	43,417

Unaudited consolidated statement of changes in equity

	Share capital	Share premium	Cumulative translation differences	Other reserves	Retained earnings	Attributable to equity holders of the company	Non-controlling interest	Total
Balance as at January 1, 2017	151,991	157,661	-185	-13,317	-186,334	109,816	43	109,859
Loss of the period 2017	0	0	0	0	-15,214	-15,214	-7	-15,221
Change to foreign currency translation difference and revaluation reserve	0	0	7	0	0	7	0	7
Share-based payment transactions	0	0	0	88	0	88	0	88
Balance as at June 30, 2017	151,991	157,661	-178	-13,229	-201,548	94,697	36	94,733
Balance as at January 1, 2018	151,991	157,661	-335	-13,141	-163,546	132,630	727	133,357
Loss of the period 2018	0	0	0	0	-15,028	-15,028	-143	-15,171
Change to foreign currency translation difference and revaluation reserve	0	0	-58	0	0	-58	0	-58
Capital increase	9,796	204	0	0	0	10,000	0	10,000
Capital decrease	-24,302	-157,865	0	0	182,167	0	0	0
Share-based payment transactions	0	0	0	-52	0	-52	0	-52
Balance as at June 30, 2018	137,485	0	-393	-13,193	3,593	127,492	584	128,076

