

## **Regulated Information**

**Disclosure in accordance with the law of May 2, 2007**

### **ThromboGenics NV Announces 2010 First Half Results**

**Leuven, Belgium – 26 August, 2010** – ThromboGenics NV (Euronext Brussels: THR), a biopharmaceutical company focused on the discovery and development of innovative treatments for eye disease, cardiovascular disease and cancer, is today issuing a business update in conjunction with its financial results for the six months ending 30<sup>th</sup> June, 2010.

**Patrik De Haes, CEO of ThromboGenics, commenting on today's announcement said:**

“During the first half of 2010 we have delivered a number of key milestones that have greatly increased our confidence that we can achieve our goal of becoming a profitable fully integrated ophthalmology company. This view has been driven by the results from our successful Phase III results of the first pivotal study with our lead product microplasmin. These results showed that microplasmin has the ability to resolve VMA in close to 30% of patients and to cure a significant proportion of patients with macular hole without the need for surgery. Together these two very important clinical findings highlight microplasmin's potential to have a major impact on the treatment of retinal disorders. We are looking forward to announcing the results from our second Phase III study with microplasmin at the ASRS meeting in Vancouver next week as well as the pooled results from our Phase III program the week after at EURETINA, Paris

**Dr. De Haes continued,** “The successful implementation of our strategy also requires us to deliver on our other pipeline products. In the first half, Roche took the decision to progress our partnered anti-cancer antibody TB-403 into a further clinical study triggering a €6m milestone payment for ThromboGenics. We also reported positive Phase II results for our long acting anti-coagulant TB-402, showing superior efficacy compared to the most widely used anti-coagulant, enoxaparin. These positive results combined with the clinical advantages of TB-402 will be important in supporting our partnering discussions for this novel one-shot anti-coagulant.”

#### **Financial Update**

- ThromboGenics achieved revenues of €6.1 million during the first six months of 2010 versus €3.6 million in the same period of 2009. Nearly all of this revenue came from a milestone payment from Roche, as TB-403 entered a new clinical study. R&D expenses were €9.1 million during the first half, versus €8.8 million in the same period in 2009, as the Company invested in the development of its attractive product pipeline. In addition, €5.4 million of the costs related to the microplasmin Phase III clinical program MIVI-TRUST have been capitalized. This compares to €5.7 million in the corresponding period in 2009. ThromboGenics reported a net loss of €2.7 million for the first half of 2010 compared to €4.7 million in the same period in 2009.
- As of 30 June, 2010, ThromboGenics had €61.2 million in cash and cash investments. This compares to €76.7 million at 31 December 2009 and €52.6 million on 30 June 2009. The end June 2010 cash figure does not include the



€6 million milestone payment from Roche, which was received in July. This level of cash resources is expected to allow ThromboGenics to execute its operational plans for approximately the next two years.

- In March, ThromboGenics raised €0.6 million as the result of the exercise of warrants by a number of the Company's employees and advisors.

## **Business highlights**

### **Microplasmin – Positive Phase III Results Demonstrate Potential to Transform the Treatment of Retinal Disorders**

- **First Phase III trial of Microplasmin (TG-MV-006) achieved its primary end point for the non-surgical treatment of symptomatic vitreomacular adhesion (VMA). The study confirmed that microplasmin was generally safe and well tolerated with no increase in the rate of retinal tear or detachment in comparison to placebo.**
- **Detailed results from the TG-MV-006 study showing that a significant percentage of patients with macular hole could be cured. These results were received with excitement by the specialists at the World Ophthalmology Congress (WOC) in Berlin in June**
- **Results from second Phase III study (TG-MV-007) with microplasmin will be presented for the first time at the 28th Annual Meeting of the American Society of Retina Specialists (ASRS) meeting in Vancouver on 31 August**
- **The pooled results of the MIVI-TRUST program (TG-MV-006 and TG-MV-007) will be presented for the first time at the 10<sup>th</sup> EURETINA congress in Paris on 4 September.**

ThromboGenics announced in April that the first Phase III trial, TG-MV-006, with microplasmin for the non-surgical treatment of eye disease had met its primary endpoint and was generally well tolerated. 27.7% of microplasmin treated patients achieved resolution of their VMA compared to 13.2% of patients treated with placebo injection. The difference between the two groups is highly statistically significant ( $p=0.003$ ). The TG-MV-006 trial recruited a total of 326 patients in the U.S.

In June more detailed results from the TG-MV-006 study were presented at WOC in Berlin by Dr. Matthew Benz, MD (The Methodist Hospital, Houston, Texas, U.S.). In his presentation Dr Benz presented the visual acuity data from the study which showed that at the end of the study 25.5% of the microplasmin treated patients had achieved at least a 10 letter (2 lines) improvement in VA without the need for vitrectomy. This compares to only 11.3% of the patients who received a placebo injection ( $p<0.005$ ).

Dr Benz also highlighted the significant benefit that microplasmin could provide to patients with full thickness macular hole (FTMH), a severe condition which can lead to irreversible vision impairment, if not treated by eye surgery (vitrectomy). In this group, 45.6% of the 57 patients were cured by a single 125 $\mu$ g injection of microplasmin without the need for a vitrectomy in the 6 months post treatment. This compares with 15.6% of the 32 patients in the placebo group ( $p= 0.005$ ).



The results from the second Phase III trial (TG-MV-007), which also recruited 326 patients in Europe and the US, will be presented by for the first time by Dr. J. Michael Jumper of U.C. San Francisco (California, USA) at the 28th Annual Meeting of the American Society of Retina Specialists (ASRS) meeting in Vancouver on 31 August.

The Phase III program with microplasmin has been executed in a remarkable timeframe, taking only 20 months from the start of patient recruitment in early 2009 to the presentation of the pooled data beginning of September 2010.

The primary endpoint of both of the Phase III trials is the non-surgical resolution of focal vitreomacular adhesion one month after a single injection of microplasmin. Both of these trials use 125µg of microplasmin. Vitreomacular adhesion is a condition in which the vitreous has an abnormally strong adhesion to the retina at the back of the eye. These adhesions can cause retinal distortion, which results in deterioration in the patient's vision. The only available treatment currently is invasive surgery.

- **Building awareness of microplasmin amongst retina specialists in the U.S., Europe.**

The positive results from the TG-MV-006 study with microplasmin, along with the upcoming results of the TG-MV-007, have provided ThromboGenics with an ideal opportunity to highlight the attractions of microplasmin to the global retina community. Over the next two months presentations on microplasmin will be made at a number of key ophthalmology conferences including:

- **28th Annual Meeting of the American Society of Retina Specialists (ASRS) in Vancouver,**
- **10th EURETINA Congress in Paris**
- **10<sup>th</sup> European Vitreo Retinal Society Congress (EVRS) in Seville**
- **American Academy of Ophthalmology in Chicago**

In addition, ThromboGenics is stepping up its pre-commercialization activities for this exciting new product which has the potential to transform the treatment of a range of retinal disorders. The Company has put in place a team to ensure the timely regulatory submission of microplasmin in the US and EMA by mid 2011. The Company is also starting to build a cross-functional launch team to ensure that microplasmin is correctly positioned to successfully launch the product when is approved.

#### **TB-402 – Unique, Long Acting, “One-Shot” Anticoagulant**

- **Superior efficacy to enoxaparin in Phase II VTE prophylaxis study in patients undergoing orthopedic surgery**

In May, ThromboGenics announced positive results from its Phase II VTE prophylaxis study with TB-402, (anti-factor VIII antibody). TB-402 is a novel, long acting “one-shot” anticoagulant that is being developed for the prevention of venous thromboembolism (VTE) following orthopaedic surgery. The positive Phase II results demonstrated that TB-402 had superior anti-thrombotic activity to enoxaparin (Lovenox®: sanofi-aventis) with comparable safety. Enoxaparin, which is given as a daily injection, is currently the standard treatment to prevent VTE in this setting. The Phase II study enrolled a total of 316 patients across 30 centers in Europe.



In the pooled TB-402 treated group, 47 out of 218 (or 22%) patients experienced VTE. This compares with the enoxaparin treated group where 30 out of 77 (or 39%) patients experienced VTE ( $p < 0.05$ ). The difference between the two groups is statistically significant. The study also showed that TB-402 and enoxaparin had a similar safety profile.

The results of this trial were presented by Professor Peter Verhamme (University of Leuven, Belgium) presented at the 21st International Congress on Thrombosis in July in Milan, Italy.

TB-402 has the potential to be an important new entrant into the anticoagulant market. TB-402 is a recombinant human monoclonal antibody that partially inhibits Factor VIII, a key component of the coagulation cascade. TB-402, which is given as a single injection post surgery, could potentially become part of the standard post-surgical approach to the prophylaxis of VTE. This is because of its ease of use for the surgeon and the efficacy and compliance benefits it brings to the patient.

With Phase II data demonstrating TB-402's superior anti-thrombotic activity compared with current therapy, ThromboGenics is now starting further discussions with prospective pharma partners to optimize the potential of this product. .

During these discussions the following key attributes of TB-402 will be conveyed: TB-402 is a long-acting anticoagulant agent it can be given as a single dose after surgery, ensuring 100% compliance and reducing the nursing time that is associated with current anticoagulants used in hospitals for the prevention of VTE. The effects of TB-402 can be reversed easily and quickly with factor VIII.

TB-402 is expected to reduce the risk of undesirable bleeding events and the need for patient monitoring (the two main drawbacks associated with other anticoagulant therapies) due to its novel mode of action.

### **TB-403 - Novel anti-cancer agent partnered with Roche**

- **ThromboGenics receives €6 million from Roche as it initiates a new clinical study with TB-403**

During the first half of this year, Roche began an imaging study with the novel anti-cancer antibody TB-403 (RG7334) in patients with metastatic, treatment-refractory, colorectal and ovarian cancers. As a result, ThromboGenics and its co-development partner BioInvent received a milestone payment of €10 million from Roche under the terms of the strategic alliance agreement signed in June 2008. ThromboGenics, which discovered TB-403, received 60% and BioInvent 40% of this milestone payment.

The trial being undertaken by Roche is a multi-centre, open-label (monotherapy), dose-finding study with intravenous TB-403. The primary objective of the study will be to establish the TB-403 concentration-pharmacodynamic (PD) effect relationship using DCE-MRI (dynamic contrast-enhanced magnetic resonance imaging) and to identify the minimally PD effective dose. The trial will recruit up to 50 patients across three European sites.

With the start of this study, Roche will assume responsibility for all future development of TB-403, continuing the work started by ThromboGenics and BioInvent.



TB-403, a humanized monoclonal antibody directed toward placental growth factor (PIGF), is expected to act by blocking the formation of the new blood vessels that are required for tumor growth. The novel mechanism of action of TB-403 represents a potentially promising cancer therapy.

## **Financial Overview**

### **Revenue and Results**

In the first half of 2010, ThromboGenics achieved total revenue of €6.1 million, nearly all of which came from a milestone payment from Roche. This was due to the decision to move TB-403 into a further clinical trial. In the same period of 2009, ThromboGenics had revenues of €3.6 million.

In the first half of 2010, gross profit amounted to €5.5 million. In the same period in 2009, ThromboGenics achieved a gross profit of €3.2 million.

ThromboGenics invested €9.1 million in its R&D activities in the first half of 2010, on its clinical and pre-clinical pipeline including the comparative Phase II study with the long acting anti-coagulant TB-402. In the first half of 2009 ThromboGenics invested €8.8 million in its R&D activities. Additionally, the Company capitalized the Phase III clinical trial costs relating to microplasmin for retinal disorders to the tune of €5.4 million in the first half of 2010 and €5.7 million in the first half of 2009.

ThromboGenics' general and administrative expenses declined to €1.5 million from €1.7 million in the first half of 2009. This reduction was due to higher (one-off) legal costs in part due to the merger of ThromboGenics NV with its subsidiary ThromboGenics Ltd that were incurred in 2009.

In the first half of 2010, ThromboGenics reported an operating loss of €2.9 million. This compares with an operating loss of €5.5 million in the corresponding period. This lower loss was largely due to the higher level of income from Roche in 2010.

ThromboGenics achieved net financial income of €0.2 million in the first half of 2010. In the first half of 2009, the Company had net financial income, including an exchange gain, of €0.8 million.

In the first half of 2010, ThromboGenics had a pre-tax loss of €2.7 million. This compares with a pre-tax loss of €4.7 million in the first half of 2009. In both periods, ThromboGenics paid minimal tax expenses.

ThromboGenics reported a net loss of €2.7 million in the first half of 2010, giving a diluted loss per share of €0.09. This compares with a net loss of €4.7 million and a diluted loss per share of €0.18 in the first half of 2009.

### **Financial Position and Cash Flow**

As of 30 June 2010, ThromboGenics had a strong cash position of €61.2 million. This compares with €76.7 million at 31 December 2009. The end of June 2010 cash figure does not include the €6 million milestone payment from Roche which was received in July. The Company's strong cash position is in part due to the successful €42 million fund raising in November 2009.



These funds will allow ThromboGenics to support its business for approximately the next two years. The Company's underlying cash burn is expected to increase given the continuing investment in the clinical trial program for microplasmin in eye disease, the regulatory activities that need to take place ahead of a planned filing by mid 2011 as well as its intensified pre-commercialisation activities. The funds will also be used, at the appropriate time, to start the building of ThromboGenics' own commercial sales force to ensure the successful launch of this exciting new product.

At the end of June 2010, ThromboGenics had total shareholders equity of €91.6 million, which compares with €93.7 million at the end of December 2009.

ThromboGenics experienced a €10.8 million cash outflow in the first half of 2010 which compares to a €4.6 million cash outflow in the first half of 2009. This increased cash outflow was due to a change in working capital as a result of the milestone payment from Roche being booked as a receivable prior to its payment in July.



## 1.1. Unaudited consolidated statement of comprehensive income

In €1,000	Half - year	
	2010	2009
<b>Income</b>	<b>6,058</b>	<b>3,609</b>
License income	6,000	3,549
Income from royalties	28	54
Other income	30	6
<b>Cost of sales</b>	<b>-540</b>	<b>-454</b>
<b>Gross profit</b>	<b>5,518</b>	<b>3,155</b>
Research and development expenses	-9,080	-8,842
General and administrative expenses	-1,455	-1,706
Selling expenses	-199	-223
Other operating income	2,311	2,092
<b>Operating result</b>	<b>-2,905</b>	<b>-5,524</b>
Finance income	348	1,033
Finance costs	-167	-179
<b>Result before income tax</b>	<b>-2,724</b>	<b>-4,670</b>
Income tax expense	-23	7
<b>Net result for the period</b>	<b>-2,747</b>	<b>-4,663</b>
Attributable to:		
Equity holders of the company	-2,747	-4,663
<b>Result per Share</b>		
Basic earnings per share (Euro)	-0.09	-0.18
Diluted earnings per share (Euro)	-0.09	-0.18

In €1,000	Half - year	
	2010	2009
<b>Result of the period</b>	<b>-2,747</b>	<b>-4,663</b>
Net change in fair value of available-for-sales investments	0	72
Exchange differences on translation of foreign operations	43	11
<b>Other comprehensive income, net of income tax</b>	<b>43</b>	<b>83</b>
<b>Total comprehensive income for the period</b>	<b>-2,704</b>	<b>-4,580</b>
Attributable to:		
Equity holders of the company	-2,704	-4,580



## 1.2. Unaudited consolidated statement of financial position

In €1,000	30 June 2010	31 December 2009
<b>ASSETS</b>		
Property, plant and equipment	901	1,042
Intangible assets	22,716	17,357
Goodwill	2,586	2,586
Other financial assets	60	53
Employee benefits	73	73
<b>Non-current assets</b>	<b>26,336</b>	<b>21,111</b>
Trade and other receivables	9,769	3,437
Investments	3,266	742
Cash and cash equivalents	57,962	75,929
<b>Current assets</b>	<b>70,997</b>	<b>80,108</b>
<b>Total assets</b>	<b>97,333</b>	<b>101,219</b>
<b>EQUITY AND LIABILITIES</b>		
Share capital	125,557	125,122
Share premium	46,660	46,520
Accumulated translation differences	44	1
Other reserves	-19,896	-19,896
Retained earnings	-60,776	-58,029
<b>Equity attributable to equity holders of the company</b>	<b>91,589</b>	<b>93,718</b>
<b>Minority interests</b>		
<b>Total equity</b>	<b>91,589</b>	<b>93,718</b>
Trade payables	4,326	6,688
Other short-term liabilities	1,418	813
<b>Current liabilities</b>	<b>5,744</b>	<b>7,501</b>
<b>Total equity and liabilities</b>	<b>97,333</b>	<b>101,219</b>



### 1.3. Unaudited consolidated statement of cash flows

In €1,000	Half - year	
	2010	2009
<b>Cash flows from operating activities</b>		
(Loss) profit for the period	-2.747	-4.663
Finance costs	167	179
Finance income	-348	-1.034
Depreciation on property, plant and equipment	228	224
Depreciation on intangible assets	1	1
Equity settled share-based payment transactions	0	249
Change in trade and other receivables including tax receivables	-6.332	-85
Change in short-term liabilities	-1.757	508
<b>Net cash (used) from operating activities</b>	<b>-10.788</b>	<b>-4.621</b>
<b>Cash flows from investing activities</b>		
Disposal of property, plant and equipment	7	-6
Change in investments	-2.524	22.809
Interest received and similar income	320	894
Acquisition of intangible assets	-5.359	-4.908
Acquisition of property, plant and equipment	-94	-345
Acquisition of other financial assets	-7	0
<b>Net cash (used in) generated by investing activities</b>	<b>-7.657</b>	<b>18.444</b>
<b>Cash flows from financing activities</b>		
Proceeds from issue of share capital	575	3.025
Paid interests	-3	-3
<b>Net cash (used in) generated by financing activities</b>	<b>572</b>	<b>3.022</b>
<b>Net change in cash and cash equivalents</b>	<b>-17.873</b>	<b>16.845</b>
Cash and cash equivalents at the start of the period	75.929	30.356
Effect of exchange rate fluctuations	-94	-335
<b>Cash and cash equivalents at the end of the period</b>	<b>57.962</b>	<b>46.866</b>



#### 1.4. 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	Minority interests	Total
<b>Balance at 1 January 2009</b>	<b>111,338</b>	<b>15,837</b>	<b>28</b>	<b>-20,851</b>	<b>-43,959</b>	<b>62,393</b>	<b>0</b>	<b>62,393</b>
Net loss 2009					-4,663	-4,663		-4,663
Change to foreign currency translation difference			11			11		11
Conversion of warrants by ThromboGenics Ltd				2,783			2,783	2,783
Contribution in kind ThromboGenics Ltd shares	2,488			-2,488		2,783	-2,783	0
Share-based payment transactions				249		249		249
Conversion of warrants by ThromboGenics NV	171	70				241		241
Net change in fair value of investments				72		72		72
<b>Balance at 30 June 2009</b>	<b>113,997</b>	<b>15,907</b>	<b>39</b>	<b>-20,235</b>	<b>-48,622</b>	<b>61,086</b>	<b>0</b>	<b>61,086</b>
<b>Balance at 1 January 2010</b>	<b>125,122</b>	<b>46,520</b>	<b>1</b>	<b>-19,896</b>	<b>-58,029</b>	<b>93,718</b>	<b>0</b>	<b>93,718</b>
Net loss 2010					-2,747	-2,747		-2,747
Change to foreign currency translation difference			43			43		43
Conversion of warrants by ThromboGenics NV	435	140				575		575
<b>Balance at 30 June 2010</b>	<b>125,557</b>	<b>46,660</b>	<b>44</b>	<b>-19,896</b>	<b>-60,776</b>	<b>91,589</b>	<b>0</b>	<b>91,589</b>

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**About ThromboGenics**

ThromboGenics is a biopharmaceutical company focused on the discovery and development of innovative medicines for the treatment of eye disease, vascular disease and cancer. The Company's lead product microplasmin has completed its first Phase III clinical trial for the non-surgical treatment of back of the eye diseases. Microplasmin is also being evaluated in Phase II clinical development for additional vitreoretinal conditions. In addition, ThromboGenics is developing novel antibody therapeutics in collaboration with BioInvent International; these include TB-402 (anti-Factor VIII), a long acting anti-coagulant in Phase II, and TB-403 (anti-PIGF) in Phase Ib/II for cancer in partnership with Roche.

ThromboGenics is headquartered in Leuven, Belgium. The Company is listed on Euronext by Euronext Brussels under the symbol THR. More information is available at [www.thrombogenics.com](http://www.thrombogenics.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.*