THERACLION ANNOUNCES MAJOR ADVANCES AND REPORTS FIRST-HALF FINANCIAL RESULTS

On the strength of its progress on its 2023 and 2024 priorities (access to the US market, R&D and China), Theraclion is planning its commercial ramp-up for 2025 and 2026.

- **Pivotal study** for access to the important US market**: treatments completed in June 2024** as planned;
- **R&D and product development:** the SONOVEIN is reaching a new level of maturity in clinical effectiveness, as recently highlighted by numerous KOLs;
- **Preparing for the commercialization** of SONOVEIN in Europe and the Middle East.

Malakoff, October 30, 2024, 6:30pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing a robotic platform for non-invasive high-intensity focused ultrasound (HIFU) therapy for the treatment of varicose veins, reports on the implementation of its strategy for the first half of 2024 and the start of its commercial ramp-up.

Martin Deterre, Theraclion's Chief Executive Officer, states, *"During the first half of 2024, we achieved major milestones in Theraclion's strategy based on access to the US and Chinese markets and on advances in SONOVEIN® technology and clinical performance. This strategy is paying off: with over 2,700 veins treated and clinical efficacy demonstrated in the daily practice of numerous KOLs across Europe and publicly presented, SONOVEIN has reached a new level of maturity. Theraclion intends to pursue its efforts in these strategic areas, with further concrete advances expected in 2025 in regulatory and product development aspects.*

In parallel, and given the product's current performance level, the company is already preparing the next stages of its development, with commercialization ramp-up set to begin in 2025. This gradual targeted commercialization, with measured resources, will begin in Europe, where we are focusing on recurring revenues thanks to our installed base (sale of consumables), and in the Middle East, a buoyant market for system sales. We are aiming for a turnover of €2.5 million in 2025 and €5 million in 2026. After 2026, once FDA approval has been obtained, we expect sales to accelerate in particular through the search for a strategic partnership in the United States."

Access to the US market: a key stage in the FDA approval process for SONOVEIN® achieved on schedule

In the United States, treatments in the pivotal FDA (Food and Drug Administration) approved study for SONOVEIN® ended on schedule in mid-June, marking a key stage in the approval process. A total of 70 patients took part in the clinical trial, conducted at four leading centers in the United States and Europe. A 12-month follow-up period has thus begun, and final results should be available in summer 2025. The marketing authorization application should be submitted to the FDA in the second half of 2025, with approval expected in early 2026. These steps will pave the way to the largest market in the world and to high-impact strategic partnerships.

The maturity of SONOVEIN®'s clinical performance has been highlighted at leading medical conferences and in scientific journals:

- Professor Paolo Casoni and his team reported a 98.3% efficacy rate for SONOVEIN® on 188 treated limbs followed up for 12 months. Their results were published last April in *Phlebology, The Journal of Venous Disease*, a leading vascular pathology journal.
- Last June saw SONOVEIN®'s inclusion in the American Venous Forum guidelines, thanks to an article by Dr. Steve Elias in the prestigious *Handbook of Venous and Lymphatic Disorders, Guidelines of the American Venous Forum*.
- During the first half of 2024, 12 presentations by 10 opinion leaders practicing in 5 different countries took place during international conferences in several countries (USA, UK, Italy, Spain, Greece and Canada), based on follow-ups of up to 3 years with success rates in the order of 90 to 100% on cohorts comprising up to several hundred patients treated in routine activity[1].

A strong commitment to R&D and product development

Major progress has been made in recent months on specific SONOVEIN® functionalities, particularly in Artificial Intelligence, acoustics and 3D robotics, aimed primarily at significantly increasing treatment speed. These improvements will enable greater adoption by treatment centers and a sharp increase in the addressable market, ensuring that Theraclion's long-term growth prospects are both significant and sustainable.

Subject to the timely granting of new regulatory approvals, the deployment of these technological improvements in the field is scheduled for 2025 and 2026, underpinning the commercial development expected over this period.

[1] *References available on www.theraclion.com*

First-half 2024 results

In €K	30/06/2024	30/06/2023	Var. %
Turnover	**442**	**981**	
from equipment sales	108	597	-82%
from sales of consumables	287	314	-9%
from sales of services	46	69	-33%
Subsidies	138	0	
Other products	38	0	
Write-back of depreciation and provisions	11	0	
Total operating income	**628**	**981**	**-36%**
Purchases of goods and stock variation	170	532	-68%
Gross margin	**271**	**449**	**-40%**
% Gross margin	61 %	45%	
Other purchases and external expenses	1 640	1 115	47%
Purchases of goods and external charges	**1810**	**1647**	**10%**
Salaries and social charges	1 661	1 957	-15%
Depreciation expenses	102	103	-1%
Allocations to provisions	41	424	-90%
Other expenses		30	
Other operating expenses	**1 805**	**2 514**	**-28%**
Operating income	**-2 987**	**-3 179**	**-6%**
Financial result	84	-65	228%
Extraordinary result	16	263	-94%
Research tax credits	525	504	4%
Net income	**-2 363**	**-2 476**	**-5%**
Average headcount (FTE)	**28**	**30**	

**These accounts have been subject to a limited review by the auditors.*

Turnover for the first half of 2024

In the first half of 2024, sales of consumables to existing customers remained stable, while sales of new systems, which were not a priority, fell by 82% in the first half.

Operating income came to 628K€, including an operating subsidy of 138K€ received in the first half.

Until now, Theraclion has focused on supporting centers equipped with SONOVEIN® in order to improve their experience, rather than on prospecting for new customers. In the first half of the

year, the company focused its resources on improving products and treatment protocols, as well as on clinical trials with a view to ensuring the success of the US clinical trial.

From 2025 onwards, given the progress made in clinical trials and R&D, the Company will gradually be devoting resources to its commercial roll-out, with priority given to Europe and the Middle East.

Operating expenses

The increase in gross margin reflects a favorable product mix, with margin-generating services and consumables accounting for 75.3% of sales as against 39.1% in the first half of 2023.

External expenses of 1,640K€, compared to 1,115K€ at end June 2023 reflect expenditures linked to the clinical study in the United States (333K€). This increase is partly offset by a 15.1% reduction in compensation and benefits compared to prior year period

After taking account of allocations to the provisions to the tune of 41.5K€, operating income came to a loss of 2,987K€, down 6% compared with the first-half 2023.

The financial result amounted to €84K due to interest gained from long term bank savings.

After taking account of the Research Tax Credit (Crédit Impôt Recherche - CIR), amounting to 525K€, the net loss comes to 2,363K€, down 4.6% year-over- year.

Evolution of cash flow and going concern

On June 30, 2024, Theraclion had a cash balance of €5.9 million. This cash position will cover Theraclion's needs until the end of the first quarter of 2025.

Future short-term cash inflows include:

- Short-term cash inflows include payment of the 2023 Research Tax Credit amounting to 1,049K€.

- Second-half turnover forecast up on first-half.

The Company has already taken steps to secure the financing it needs to pursue its strategy and begin its commercial expansion.

About Theraclion

Theraclion is a French MedTech company committed to developing a non-invasive alternative to surgery through the innovative use of focused ultrasound.

High Intensity Focused Ultrasound (HIFU) does not require incisions or an operating room, leaves no scars, and enables patients to return to their daily activities immediately. The HIFU treatment method concentrates therapeutic ultrasounds on an internal focal point from outside the body.

Theraclion develops the HIFU, CE-marked, platform for varicose veins treatment SONOVEIN®, which has the potential to replace millions of surgical procedures every year. In the United States, SONOVEIN® is an investigational device limited to investigational use; it is not available for sale in the U.S.

Based in Malakoff (Paris), the Theraclion team is made up of some 30 people, most of them involved in technological and clinical development.

For more information, please visit www.theraclion.com and follow the LinkedIn account.

Theraclion is listed on Euronext Growth Paris
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