THERACLION DELIVERS A STRUCTURING YEAR IN 2025 AND PREPARES TO SCALE UP

Malakoff, January 29th 2026, 6:30 pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing Sonovein®, a robotic platform for non-invasive High-Intensity Focused Ultrasound (HIFU) varicose vein treatment, provides an update on its key achievements in 2025 and has built strong foundations for 2026.

- Clinical efficacy validated through the FDA pivotal study and major new scientific publications
- Three key regulatory milestones achieved in the United States, Europe and China
- "Pay per Use" (PPU) business model showing traction and ready to scale up

Martin Deterre, Theraclion's CEO, states, "*In 2025, we proved that our technology is no longer a promise but a clinical and commercial reality. Theraclion offers a genuine non-invasive, robotic technological breakthrough, providing access to the surgery of tomorrow. Strong regulatory, industrial and commercial foundations have been built, ensuring Sonovein's® ramp-up in the years ahead. Commercial momentum has taken hold, with stronger organization, several dozen new centers added to our prospect list, and several new contracts signed in recent weeks. We are ready to change scale. 2026 also looks very promising, with new milestones expected, including FDA clearance, tangible progress on U.S. reimbursement, and stronger commercial traction across all our target geographies. The teams and I are fully committed to delivering on these objectives.*"

A Strategic Regulatory Trio: United States, Europe, China

United States: In December, following the success of the pivotal study demonstrating 96.8% efficacy for Sonovein®, Theraclion submitted a De Novo application to the FDA for go-to-market authorization of the system. Discussions have started and a decision is expected around mid-2026. All these milestones were achieved in line with the plan previously communicated. Preparatory activities for U.S. market access and reimbursement—in particular the process for obtainment of a CPT (Current Procedural Terminology) code—are progressing actively.

Europe: CE marking for Sonovein® was obtained under the new, stringent MDR (Medical Device Regulation, EU 2017/745) in September 2025. This achievement marks the culmination of several years of continuous product improvement and, combined with pivotal trial results, provides a decisive boost to commercialization in Europe as well as in other MDR-covered markets. It also enables faster introduction of Sonovein® upgrades, some of which have already been validated under MDR and are currently being rolled out. This momentum, driven by user feedback, simplifies operation, improves user experience, and supports broader uptake.

China: Validation of technical tests (GB 9706.1-2020) paves the way toward a key varicose vein treatment market that is both large and growing very rapidly. Discussions have been initiated with the competent authority, the NMPA (National Medical Products Administration), to access the Chinese market for Sonovein® via a regulatory filing on behalf of the Theraclion-China joint venture.

Stronger International Visibility and Consolidated Clinical Evidence

In 2025, Sonovein® enhanced its visibility with presentations at 25 international conferences by 15 speakers across 14 countries. In parallel, 4 new peer-reviewed publications[1] consolidated the clinical evidence base, reporting efficacy rates ranging from 94% to 100% across several vein types (great and small saphenous veins and perforator veins). These real-world clinical data further reinforce momentum by corroborating the U.S. pivotal study's results.

R&D: Acceleration in AI, Acoustics and Robotics

Theraclion is making sustained R&D efforts in AI, acoustics and robotics with a view to improving treatment speed and ease of use for physicians. New features integrating AI algorithms, designed to assist physicians and reduce the learning curve, are expected in the near term. In 2025, the first patients were treated using SpeedPulse, an innovative technology designed to significantly accelerate treatment, as part of a clinical study in Prague.

Pay per Use traction: more treatments and new contract signings

In 2025, Theraclion strengthened its commercial organization with the arrival of a Chief Commercial and Marketing Officer at the end of the first half. The Company also accelerated rollout of Sonovein® around the Pay per Use (PPU) model, which is very popular on the market: a use-based offer with defined minimum consumables that facilitates adoption by centers and supports the ramp-up of recurring revenues. The model provides increased financial visibility as adoption by centers no longer depends on heavy capital expenditure (CAPEX) budgets. Traditional system sales, while more immediately cash-generative than PPU, remain less predictable due to long decision cycles.

The PPU model's commercial momentum is reflected in:

- 30% growth in recurring revenues from PPU centers and consumables (in line with first-half performance and similar seasonality effects),
- 20% growth in the number of treatments,
- an expanding installed base with the opening of several new centers in the second half of 2025,
- several new PPU contracts signed in recent weeks with installations expected in the coming months,
- a prospect list that has expanded significantly in recent months, with several dozen new centers expressing strong interest in Sonovein®.

Theraclion expects all these indicators to accelerate in 2026.

[1] Rodríguez Carvajal *et al*., in *Phlebology* , Izquierdo Lamoca *et al.*, in *Journal of Vascular Surgery*, and two from Casoni *et al.*, in *Phlebology*

Revenue Breakdown

Sales / €K	2025	2024	Variation %
Sales of Sonovein® systems	0	379	
Credit Note for Echopulse		(680)	
Merchandise Sales (China)	348	449	(22%)
Sales of PPU & consumables	626	482	+30%
Sales of services	218	199	+10%
Theraclion SA turnover	**1,192**	**830**	**+44%**

Cash Position and Outlook

At December 31, 2025, Theraclion's available cash stood at €3.4 million, supplemented by €0.9 million received in January 2026 from the French tax authorities as reimbursement of the 2024 Research Tax Credit.

Considering these figures and the increased resources mobilized to capitalize on the current commercial momentum, the Company's financial horizon currently extends to the end of May 2026. Supported by its long-standing shareholders, the Company has already actively undertaken steps to secure the cash required to carry out its ambitious business plan and extend its runway.

Next Financial Release

Publication of FY 2025 financial results: April 16, 2026**.**

About Theraclion

Theraclion is a French MedTech company 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 allows patients to resume normal activities immediately. HIFU concentrates therapeutic ultrasound on an internal focal point from outside the body.

Theraclion is developing Sonovein®, a robotic HIFU platform for varicose vein treatment, CE marked under the MDR (EU 2017/745), with the potential to replace millions of surgical procedures each year. To date, Sonovein® has been adopted by more than a dozen centers worldwide and used in over 3,500 procedures. In the U.S., Sonovein® is not available for sale.

Based in Malakoff (Paris), Theraclion's team comprises around 30 people, primarily focused on technology 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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