



## THERACLION REVIEWS ITS 2024 ACHIEVEMENTS

Malakoff, January 6, 2025, 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 its 2024 activities.

- **On-track progress of the pivotal FDA clinical trial**
- **Sharp increase in the number of scientific presentations and publications**
- **Over 3,000 SONOVEIN® treatments performed to date**
- **Product maturity reached and commercialization accelerated**

Martin Deterre, Theraclion's Chief Executive Officer, states, *"In 2024, Theraclion achieved key milestones in its strategy focused on accessing the U.S. and Chinese markets and advancing a market-ready SONOVEIN® product. In addition to the continued progress of our FDA (Food&Drug Administration) clinical study, SONOVEIN reached a new level of maturity, in particular in terms of clinical efficacy and treatment speed<sup>1</sup>. Our product and our business model are now proven, with an increasing number of presentations and publications from KOLs. Looking ahead to 2025, we are ready to shift gears towards commercialization and revenue generation"*.

### **Progress of the FDA-approved clinical study on schedule**

In the United States, the FDA-approved pivotal study for SONOVEIN® reached a key milestone in mid-June, as treatments were completed on schedule. The trial was conducted at four leading centers across the United States and Europe and included 70 patients.

The 6-month follow-up period concluded in December 2024, marking another important milestone in the study.

The 12-month follow-up is currently underway, with final results expected by summer 2025. We plan to submit the marketing authorization application to the FDA in the second half of 2025, with approval estimated in the first half of 2026, subject to the FDA's schedule. These developments mark a critical step toward entering the world's largest market and unlocking strategic partnership opportunities.

### **Progress in product maturity and scientific presentations**

Strong indications of growing market adoption have emerged this year, with Sonovein vein treatments exceeding the milestone of 3,000 procedures performed.

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<sup>1</sup> See published clinical results: [https://www.theraclion.com/wp-content/uploads/2024/12/Exhaustive-Publications-and-Presentations\\_18\\_12\\_24.pdf](https://www.theraclion.com/wp-content/uploads/2024/12/Exhaustive-Publications-and-Presentations_18_12_24.pdf)



2024 saw a new record reached, with 29 presentations on SONOVEIN® delivered at 25 events across 11 countries. A total of 15 key opinion leaders shared their experiences with non-invasive treatment of varicose veins using focused ultrasound. They highlighted the adoption of SONOVEIN® in their daily practice.

In addition, three scientific papers on SONOVEIN® were published in the high-impact factor *Phlebology* journal, and a chapter of the 5<sup>th</sup> edition of the *Handbook of Venous and Lymphatic Disorders – Guidelines of the American Venous Forum* was dedicated to the technology.

Furthermore, the completion of 400 procedures performed by a treatment center that opened just two and a half years ago is also one of the strongest indicators of the product's maturity in 2025.

### **Focus on strategic realignment on the vein market**

Theraclion continues its strategic refocus on the varicose vein market and confirms its decision to cease commercialization of its Echopulse devices for thyroid treatment in the near future. At the beginning of 2024, Theraclion announced its decision not to renew CE marking for Echopulse in accordance with the new European MDR regulations, which consequently affected various regulatory approvals in Asia. In this context, while the Theraclion China joint-venture focuses its efforts on commercial development of SONOVEIN, Theraclion has decided to reclaim older-generation Echopulse machines initially intended for the Chinese market. These systems have become challenging to market due to the updated strategy. In order to mitigate the impact on the joint venture, Theraclion will issue a €680K credit note. Based on the latest financial statements as of June 30, this transaction will result in a reduction in trade receivables on the balance sheet, causing a decrease in revenue and hence in net income of the same amount. The reclaimed machines will be recorded as inventory at their original value and will be fully depreciated. These accounting operations, which pertain to prior fiscal years, will enable Theraclion to finalize the impacts of discontinuing Echopulse commercialization.

### **2024 turnover**

The revenue for the year 2024, excluding an adjustment related to the issuance of a credit note for the Echopulse activity amounting to €680K, stands at €1,485K. This sustained activity compared to the first half of 2024 is driven by the sale of a Sonovein system in the Middle East and growth in recurring revenue.

Sales of consumables and services increased by 9% compared to 2023, reflecting the growth in recurring revenue.

The sale of only one system in 2024 explains the -33% variation compared to 2023.

Theraclion has so far focused on supporting centers equipped with SONOVEIN® to enhance their experience rather than prospecting for new clients. In 2024, the company allocated its resources



to improving products and treatment protocols, as well as clinical trials to ensure the success of the U.S. clinical study.

Starting in 2025, given the progress made in clinical studies and R&D, the company will focus on commercial development, with a priority on Europe and the Middle East. With this initial commercial rollout, Theraclion aims to achieve €2.5M in revenue in 2025 and €5M in 2026. Beyond 2026, once FDA approval is obtained, the company anticipates an acceleration in sales driven by the deployment of its commercial strategy in the U.S.

<b>Sales / K€</b>	<b>2024 Before adjustment (*)</b>	<b>2024 After adjustment</b>	<b>2023</b>	<b>Variation %</b>
Sales of Sonovein systems	808	808	1 201	-33%
Credit Note to be issued for Echopulse	-	(680)		
Sales of consumables	478	478	504	-5%
Sales of services	199	199	117	70%
<b>Turnover Theraclion SA</b>	<b>1 485</b>	<b>805</b>	<b>1 822</b>	<b>-56%</b>
Including veins	1 442		1 200	
Including breast and thyroid	43	(637)	622	
Other operating revenue	141	141	2	
Licenses			2 000	
<b>Operating revenue total</b>	<b>1 626</b>	<b>946</b>	<b>3 825</b>	<b>-75%</b>

(\*) Credit note to be issued to the Theraclion China joint venture for the return of Echopulse machines

### **Evolution of cash flow and going concern**

As of December 31, 2024, Theraclion had a cash balance of €4.1 million, down from €5.9 million at end June 2024. This cash position will cover Theraclion's needs until the beginning of the second quarter of 2025.

The Company has already taken steps to secure the financing it needs in order to pursue its strategy and begin its commercial expansion. In the event that the Company is unable to obtain such funding, its long-term viability could be at risk.

### **Next financial publication**

Publication of the 2024 financial results on April 29, 2025.



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## **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<sup>®</sup>, which has the potential to replace millions of surgical procedures every year. In the United States, SONOVEIN<sup>®</sup> 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](http://www.theraclion.com) and follow the [LinkedIn account](#).**

Theraclion is listed on Euronext Growth Paris

Eligible for the PEA-PME scheme

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