



THERACLION CONFIRMS STRONG MID-YEAR ACHIEVEMENTS

Main focus: Access to the U.S. market, R&D and China. Key achievements in H1 2024:

- **FDA pivotal study: treatments completed in June** on schedule
- **Promising R&D progress** in product features
- **Increasing international scientific visibility**
- **Establishment of a dedicated experienced team for the Chinese market** working on manufacture of first prototype

Malakoff, September 6, 2024, 6:30 pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing a robotic platform for non-invasive high-intensity focused ultrasound (HIFU) therapy, provides an update on the key achievements in execution of its strategy for the first half of 2024.

Martin Deterre, CEO of Theraclion, states: *"During the first half of 2024, we achieved significant milestones in Theraclion's strategy towards the full commercial launch of SONOVEIN®. I am confident that SONOVEIN® will revolutionize varicose vein treatments, as evidenced by its growing international scientific recognition. After years of development, I am thrilled to see our product making substantial progress in terms of maturity, bringing us closer to achieving our goals of commercial success and value creation."*

Key milestone in the U.S. FDA approval process for SONOVEIN® completed on schedule

Treatments in the U.S. FDA's pivotal study for SONOVEIN® were concluded in mid-June, as per the scheduled timeline. This marks a significant milestone in the FDA approval process for SONOVEIN®. A total of 70 patients participated in the clinical trial conducted across four leading centers in the U.S. and Europe. With the treatment phase complete, a 12-month follow-up period has now begun. Study results are expected to be available by summer 2025. The market approval application is scheduled to be submitted to the FDA in H2 2025, with approval estimated in early 2026.

Theraclion firmly committed to R&D, the cornerstone of its value proposition

By investing in technological advancements, Theraclion is laying the groundwork for future revenues, ensuring that its long-term prospects are both significant and sustainable. Major progress has been achieved in the past months on specific features of SONOVEIN®, mainly aimed at significantly increasing the treatment speed, which the company prefers to keep confidential, for intellectual property reasons.



SONOVEIN® highlighted in top medical conferences and scientific journal

The latest scientific publication reported that SONOVEIN® had 98.3% efficacy after 12 months. Prof. Paolo Casoni and his team conducted a study to evaluate the effects of High Intensity Focused Ultrasound on great saphenous vein (GSV) incompetence using SONOVEIN®. Out of 188 treated limbs, the treatments showed a 98.3% success rate at the 12-month mark. The findings were published in April in *Phlebology, The Journal of Venous Disease*, a highly regarded peer-reviewed journal in the field of vascular research.

June 2024 also saw the introduction of SONOVEIN® in the *Handbook of Venous and Lymphatic Disorders, Guidelines of the American Venous Forum*, a leading reference book on varicose vein treatments in the U.S., with a dedicated chapter on HIFU treatments written by Dr. Steve Elias.

In addition, 13 Key Opinion Leaders' presentations were made at 9 international conferences in 7 different countries in the first half of 2024.

Clear path to the Chinese market

A series of milestones were achieved in the Chinese market over the past 12 months, starting with selection of top-tier strategic partner Furui. Following establishment of the collaboration in June 2023, the joint venture between the two companies was structured effectively, with the appointment of new management in January and formation of a dedicated and proficient team during the first half of the year. The team has already made significant progress toward producing a first prototype, which will later undergo registration testing — an important step in the development process. Together, these achievements underscore the substantial progress in and commitment to the venture's success in China.

First-half 2024 sales figures

Theraclion is currently focused on assisting SONOVEIN® equipped centers to improve their experience, rather than dedicating resources to prospecting for new customers. Breast and thyroid treatments have been assigned a lower priority. The company is directing its resources towards product and treatment protocol improvements, as well as clinical trials. In H1 2024, the focus was on successful execution of the U.S. clinical study, resulting in steady consumable sales to existing business customers. Sales of new systems are not a priority, which explains their -82% decrease in the first half.

The company will be shifting its focus towards business development in 2025, once the majority of clinical study efforts, including the FDA pivotal study follow-ups, are completed. The company is currently planning its multi-year roadmap towards full commercialization and profitability.



Sales / €K	S1 2024	S1 2023	Variation
System Sales	108	597	-82%
Consumable sales	287	314	-8%
Service sales	46	70	-34%
Theraclion SA Sales	442	981	-55%
Including veins	375	435	-14%
Including breast and thyroid	67	546	-88%

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

Eligible for the PEA-PME scheme

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