



THERACLION DELIVERS ITS 2023 STRATEGIC OBJECTIVES

Malakoff, December 14, 2023, 06:30pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing a scalable robotic platform for non-invasive ultrasound therapy, is now taking stock of its achievements over 2023.

Martin Deterre is appointed Managing Director to accelerate the deployment of the 3-pronged strategy:

- Access to the US market;
- Access to the Chinese market and development of industrial capacity in China;
- Continued product development (artificial intelligence, robotics, improved treatment protocols).

"I am delighted with the major advances achieved in 2023. The start of the pivotal vein study in the United States, the partnership established with the Chinese group Furui, the acceleration in the number of treatments and the achievement of major technological developments all contribute to securing Theraclion's commercial success," said Martin Deterre.

Launch of pivotal study: the United States in sight

The process of gaining access to the colossal US market is proceeding according to plan. The first treatments in the pivotal study took place in the United States in October. Since then, new cases have been treated in Europe. Treatment will continue in the first half of 2024, and results will be known after 12 months' follow-up, in accordance with the protocol approved by the FDA (Food and Drug Administration). Market authorization in the US is envisaged after the FDA's statutory review period, by early 2026.

Partnership with Furui: a new start for the Chinese market

Furui has already invested €6 million in Theraclion by June 2023. Further investments of €4 million are planned: €1 million via exercise of ABSAs and €3 million via licensing rights. A first ABSA exercise for 0.5 M€ was recorded following the launch of the pivotal study in the United States. Theraclion and Furui have also made significant progress over the last 3 months in structuring their joint venture, which will enable access to the high-potential Chinese market and extend production capacity in China.

Innovations in Artificial Intelligence (AI) and robotics

Significant new hardware and software enhancements to the system are deployed in the field as



part of the ongoing clinical study and have received excellent feedback from the investigating physicians. Advances made in integrating the latest-generation robotics and AI will facilitate the adoption of the system and improve patient care. These developments will enhance the product's competitiveness and commercial potential, contributing to a considerable appreciation in the company's value.

A new milestone: 2,000 veins treated with SONOVEIN®.

Following on from the 1,000 veins treated in 2022, this year Theraclion has treated 2,000 veins with its SONOVEIN® robotic platform. No severe adverse events have been reported, confirming the technology's excellent safety profile. Such acceleration demonstrates the method's capacity for adoption by centers and its relevance for patients and doctors alike.

Exploring potential in breast cancer treatment

In the first half of the year, the Cancer Center at the University of Virginia in the United States acquired the latest generation SONOVEIN® HD for the launch of a new clinical trial, approved by the FDA. The aim is to assess the combined effects of High Intensity Focused Ultrasound (HIFU) and chemotherapy in patients with early-stage breast cancer. This study could pave the way to a new market with considerable global potential.

Funding secured for 2024

The company has stepped up its efforts to ensure sound financial management, in particular by controlling its expenditure. As budget forecasts currently stand, 2024 should be fully covered financially.

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 nor an operating room, leaves no scars, and allows patients an immediate return to their daily activities. Echotherapy, as the HIFU treatment method is called, concentrates therapeutic ultrasounds to an internal focal point from outside of the body.

Theraclion has developed two CE-marked robotic platforms delivering echotherapy: SONOVEIN® for varicose veins and ECHOPULSE® for breast fibroadenoma and thyroid nodules. Each representing the potential to replace millions of surgical procedures every year.



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

For more information, please visit www.theraclion.com or www.echotherapy.com and follow the account on [LinkedIn](#).

Theraclion is listed on Euronext Growth Paris

Eligible for the PEA-PME scheme

Mnemonic: ALTHE - ISIN code: FR0010120402

LEI: 9695007X7HA7A1GCYD29

Theraclion contact

Martin Deterre

Chief Executive Officer

contact@theraclion.com