



THERACLION ANNOUNCES 2023 FINANCIAL RESULTS AND CONTINUES ITS ROADMAP

- Continuation of the strategy focused on access to the US and Chinese markets for SONOVEIN[®], and its improvement through R&D;
- Rapid start-up of the pivotal study in the United States: two-thirds of treatments have already been completed to date;
- A capital increase of €8.4 M subscribed by the main reference shareholders in May 2023;
- Opening up to the Chinese market through our joint venture with the Furui Group, a long-standing shareholder in Theraclion;
- Continued R&D efforts by Theraclion to further improve SONOVEIN[®] notably through AI and robotics, with major concrete milestones expected in the next two years;
- More than 2,000 veins treated, and sales efforts for SONOVEIN[®] not yet really underway.

Malakoff, March 27, 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, presents its 2023 financial results and reviews the execution of its strategy.

U.S. pivotal study underway

An initial feasibility study in 2022 showed 100% feasibility and 95% absence of venous reflux. A larger pivotal study began in October 2023. A larger pivotal study, designed to accelerate entry into the world's leading varicose vein treatment market, began in October 2023. Treatment has begun at the four study centers in Europe and the United States, and over two-thirds of patients have been treated to date. Study results will be available after a 12-month follow-up period, in accordance with the protocol approved by the Food & Drug Administration (FDA). U.S. marketing authorization is expected following review by early 2026.

The foundations of value creation: R&D and AI

Significant progress has been made in developing new technological building blocks, notably in artificial intelligence, robotics and acoustics. By combining the system's real-time imaging capabilities with robotics, AI algorithms will be implemented in order to automate certain tasks, speed up procedures and considerably simplify interactions between physicians and SONOVEIN[®]. At the same time, partnerships with a dozen reference centers in Europe are continuing (some of them already account for 100 to 150 treatments a year), improving treatment protocols and

contributing to the rapid advancement of the technology. Concrete milestones in transformative improvements to SONOVEIN® are expected over the next two years.

A successful capital increase

A capital increase of €8.4 M was carried out at the end of May, mainly thanks to the historical shareholders, including notably Furui, a Theraclion SA shareholder since 2016. In addition to an initial investment of €6 M, Furui has committed to further funding of €1 M, subject to Theraclion meeting specific operational targets. An initial payment was made following the launch of the pivotal study in the United States.

A new partner to accelerate access to the Chinese market

Close collaboration has been established between Furui and Theraclion in order to conquer the Chinese market. Theraclion has licensed its technologies and brands to Theraclion China, the pre-existing joint venture between the two companies, in return for €3 M fee. Theraclion China was consolidated and restructured in 2023 in order to actively launch its execution plan in early 2024. These advances enabled €2 M in license royalties to be invoiced to Theraclion China for Echopulse® and SONOVEIN® at the end of 2023.

Results 2023

In K€	31/12/2022	31/12/2023	Var. %
Turnover	1 235	1 822	48%
Grants	7	2	-71%
Other products	125	2 093	1576%
Total Revenues	1 360	3 917	188%
COGS (purchase and stocks variation)	466	331	-29%
External charges	3 820	2 573	-33%
Personnel charges	3 102	3 153	2%
Other operational Charges	287	1 014	253%
Total operating expenses	7 675	7 070	-8%
Operating result	-6 314	-3 153	-50%
Financial result	-8	-1 955	23179%
Non recurring result	350	384	10%
R&D tax credit	-1 002	-1 049	5%
Net result	-4 971	-3 675	-26%

Accounts approved by the Board of Directors on March 26, 2023.

On the business front, Theraclion focuses on supporting and assisting centers currently using its products in the treatment of their patients and does not devote resources to prospecting for new



customers. In this context, the company is not currently focusing on generating significant sales but is instead directing its resources primarily towards product and treatment protocol improvements, as well as clinical trials.

Theraclion SA reported sales of €1,822 K in 2023, up 48%

Instrument sales are up 58% and include the sale of a limited number of systems. Sales of consumables, recurrent in most cases, amounted to €506 K, up 41%, driven by a significant increase in the varicose vein indication, up 61%. In line with its strategy, Theraclion is making SONOVEIN® available to reference centers involved in the development of treatment protocols, while also integrating it into their business practices. Hence, Theraclion's performance on this revenue item in 2023 reflects these treatment centers' favorable adoption of Theraclion's solutions.

Operating revenues amounted to €3,917 K, including €2,000 K in royalties from licenses granted to the Theraclion China joint venture.

Operating expenses came to €7,070 K, down by €605 K. External expenses came to €2,573 K, compared with €3,820 K in 2022. This decrease is due to a reduction in spending, particularly in the first half of 2023, and to lower R&D spending in 2023.

Personnel costs remain at a level comparable with 2022 (+€50 K).

Total expenditures on R&D and development of new products amounted to €3.9 M (compared with €4.3 M in 2022). This amount includes people-related expenses and costs incurred for the development and prototyping, the establishment of treatment protocols, and clinical trial in the United States. They are €402 K lower than in 2022, the year in which the FDA feasibility study was carried out and finalized. In addition, the pivotal U.S. study began in the fourth quarter of 2023, with a limited impact on 2023 expenses (€175 K). R&D investments are expected to intensify in 2025 and 2026 until FDA approval is obtained.

Theraclion's Hong Kong subsidiary was set up in 2015 in order to address the Asian market with Echopulse®, targeting treatment of fibroadenoma of the breast and thyroid. Given the refocusing on the vein treatment market and on improving the product's design and functionalities, it was decided to restrict the subsidiary's expenditure and short-term commercial ambitions, while continuing to support existing customers and maintain the installed base. The subsidiary's shares and related receivable have been written down by 1,879K€. Taking into account exchange losses, financial interest and charges on marketable securities, net financial income came to a loss of 1,955K€.

The research tax credit amounted to €1,049 K at the end of December 2023, compared with €1,001 K in 2022. The company received €998 K in respect of the 2022 research tax credit in December 2023.



Net loss came to €3,675 K, down €1.3 M on 2022.

Net cash position

In K€	31/12/2022	31/12/2023	Var
Treasury	2 489	7 815	5 326
Medium-term cash position	31		-31
Total cash and cash equivalents	2 520	7 815	5 295
Bank loans	-2 506	-1 947	559
Net cash position	14	5 868	5 854

Theraclion's net cash position is €5.9 M on December 31, 2023. Expected short-term cash inflows include license royalty payments of €2 M.

About Theraclion

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

The HIFU (high-intensity focused ultrasound) treatment method concentrates therapeutic ultrasound on an internal focal point from outside the body. It requires no incisions or operating room, leaves no scars and allows patients to return immediately to their daily activities.

Theraclion is developing SONOVEIN®, a CE-marked robotic platform for HIFU treatment of varicose veins, with the potential to replace millions of surgical procedures every year.

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

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

Theraclion is listed on Euronext Growth Paris

Eligible for the PEA-PME scheme

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