



## THERACLION REACHES MAJOR MILESTONES IN 2022, PAVING THE WAY FOR THE COMMERCIAL DEPLOYMENT OF SONOVEIN®

**Malakoff, January 16<sup>th</sup>, 2023, at 6:30pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing a scalable robotic platform for non-invasive ultrasound therapy, shares its 2022 annual report, marked by accelerated technological development and activity of the reference centers, and:**

- **1,264 SONOVEIN® treatments** performed as of December 31<sup>st</sup>, 2022;
- **Preliminary results similar to the standards of invasive treatments** (95% reflux free after one week in the **first clinical study in the US**);
- **A clinical study on early-stage breast cancer** at the University of Virginia: a possible opening to a new market.

### **The driving force of value creation: R&D**

In accordance with the strategy established by Yann Duchesne, Executive President of Theraclion since January 2022, the focus is on improving technological performance and clinical benefits to access the US vein market.

The launch of the latest robotic platform for the treatment of varicose veins in May marked a real turning point for the ultrasound technology. Integrating a very high performance imager, this model makes it easier to identify the vein to be treated, resulting in a faster and more effective treatment, and paving the way for automated treatment support through the integration of algorithms.

### **SONOVEIN® successfully implemented and adopted in the US and in Europe**

The particularly enthusiastic reception from the medical profession quickly led to the deployment of this new generation in the main reference centers. The presence of SONOVEIN®, all models combined, extends in Europe to 9 centers in 7 different countries. The threshold of 1,000 treatments of varicose veins with SONOVEIN® was crossed in April. In the United States, the University of Virginia Cancer Center, which has partnered with Theraclion on breast cancer research since 2017, wanted to acquire this new version to open up new research opportunities. The success of this study could open up the breast cancer treatment market for Theraclion.



### **Promising preliminary results for the first clinical trial on varicose veins in the US**

A feasibility trial was conducted at the Venous Disease Center at Englewood Hospital, New Jersey, by vascular surgeons Dr. Steven Elias, Dr. Antonios Gasparis and Prof. Nicos Labropoulos between May and October. While awaiting definitive results, Dr Steven Elias has already presented encouraging preliminary results at the American Vein & Lymphatic Society (AVLS) annual meeting in October: 95% of treated cases (19/20) showed no reflux after a week. This first clinical trial in veins is a major step in the process leading to FDA (Food and Drug Administration) approval and thus gaining access to the US varicose vein treatment market, the biggest in the world, which is Theraclion's development priority.

### **KOL (Key Opinion Leader) treatment protocols formalization and intensification of the reference centers' activity**

In Europe, the focus has been on formalising treatment protocols with the help of KOL (Key Opinion Leaders) to ensure the success of the future multi-centre trial required to obtain FDA marketing authorization in the US. Theraclion plans to file its trial application with the FDA in the second semester of 2023.

The clarification and precision of the treatment protocols has led to an increase in the number of doctors trained in the technology in the various reference centers in Europe and Asia. This productivity of the partner centers has enabled doubling consumables sales for varicose veins treatments.

### **Strategic partnership under negotiation**

Negotiations with a potential strategic partner being well underway at the end of the year, their successful conclusion's announcement is to be expected in the coming months. This new financial contribution will extend the financial visibility to the whole year 2023. At 31 December 2022, the available cash amounted to €2,490k, in line with 31 December 2021. Taking into account the expected sales receipts and expenses, Theraclion should be able to meet its cash needs until the end of May 2023.

### **2022 turnover**

Theraclion SA achieved a turnover of €1,235K in 2022, a decrease of 17% compared to 2021.

System sales, at €764k, were down 28%. Theraclion sold one refurbished Echopulse® and one SONOVEIN® in 2022, in the Persian Gulf, compared to 4 refurbished Echopulse® and one SONOVEIN® in 2021. The sale of the latest generation device ordered by the University of Virginia will be recorded in 2023.



Sales of consumables increased by 80%, driven by a doubling of sales in the varicose vein indication. Theraclion has chosen to make SONOVEIN® available to 8 reference centres in Europe to develop treatment protocols. These centres have the possibility to use SONOVEIN® in their commercial practice as well, which is a revenue generator for Theraclion.

<i>Turnover /K€</i>	<b>2022</b>	<b>2021</b>	<b>Variation</b>
Systems sales	764	1,059	-28%
Consumables sales	360	200	+80%
Services sales	112	222	-50%
<b>Theraclion SA sales</b>	<b>1,235</b>	<b>1,481</b>	<b>-17%</b>
Including breast & thyroid	295	937	-69%
Including veins	940	530	+77%

### **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), Theraclion's team of 30 people is mostly made up of engineers and researchers. Designing and manufacturing the products, they also support a limited number of reference centers, where treatment protocols are defined, paving the way for the clinical trial required to obtain US market access.

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

Theraclion is listed on Euronext Growth Paris

Eligible for the PEA-PME scheme

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