2026 HALF-YEAR RESULTS: THERACLION PREPARES FOR A NEW STAGE IN ITS DEVELOPMENT

Malakoff, 16 September 2026, 6:00 pm (Paris time) - THERACLION (ISIN: FR0010120402; Ticker: ALTHE), an innovative company developing Sonovein®, a robotic platform for non-invasive treatment of varicose veins using High-Intensity Focused Ultrasound (HIFU), today reports its results for the first half ended 30 June 2026, approved by the Board of Directors on 15 September 2026, ahead of the FDA decision on the De Novo submission for Sonovein®, expected between the end of the third quarter and the beginning of the fourth quarter of 2026.

- Category III CPT code issued in the United States, effective 1 January 2027; FDA review of the De Novo submission ongoing.
- Seven new contracts signed since the beginning of the year, four devices made available at the end of the first half; PPU revenue up 9%.
- First clinical implementation of Sonovein® in China, in Hainan.
- Revenue of €663K and operating loss of €3.9 million, in a half-year shaped by regulatory expenses related to the FDA submission and by the commercial and industrial strengthening required to accelerate deployment.
- Cash position of €5.2 million as at 30 June 2026 following an oversubscribed capital increase; cash runway extending into the first or second quarter of 2027.

The first half of 2026 was a period of preparation and commercial launch, along two distinct tracks. On the regulatory track, Theraclion is approaching the FDA decision on Sonovein® fully prepared: the Category III CPT code applicable from January 1, 2027 has been secured, and preparation for a potential U.S. entry is well advanced. On the commercial track, the launch is under way: the commercial teams and production capacity have been strengthened, the installed base has expanded with seven new contracts, primarily on a Pay-Per-Use basis and in Europe, among which four devices were installed at the end of the half, and the first clinical treatments using Sonovein® have been performed in China.

"We are not prejudging the FDA's decision, but our responsibility is to be ready on the day it is issued, and we will be. At the same time, our commercial momentum is becoming more tangible and our pipeline continues to grow. This is a particularly exciting period for Theraclion, with opportunities materialising on several fronts. But nothing is guaranteed: our task now is to sustain this momentum over time, centre by centre, and to build solid, recurring growth, while remaining disciplined in the allocation of our resources. The resources committed in the first half were deployed precisely with this in mind, with a view to markets that could significantly change Theraclion's scale," said Martin Deterre, Chief Executive Officer of Theraclion.

United States: preparing for a new stage for Theraclion

The FDA review of the De Novo submission for Sonovein® is continuing, with a decision expected between the end of the third quarter and the beginning of the fourth quarter of 2026. Ahead of this

decision, Theraclion now holds a Category III CPT code effective 1 January 2027. The Company is actively preparing, both strategically and operationally, for a potential entry into this market.

Commercial momentum taking hold in Europe

Since the beginning of the year, Theraclion has signed seven new contracts covering centres in Germany, Greece, Romania, Hungary, France, Spain and China. Four devices were made available at the end of the first half, with the installations to take place progressively over the coming months, and the first treatments have already been performed. Supported by a growing pipeline of qualified prospects, this momentum points to a doubling of the PPU installed base approximately every 18 months. As the installations occurred mainly at the end of the period, and as each new centre goes through a patient recruitment ramp-up and training period, their contribution to first-half revenue remains marginal, but this opens up prospects for recurring revenue in the coming months.

First clinical implementation of Sonovein® in China

Sonovein® is now used clinically at Boao Super Hospital in Hainan, where treatments are performed on a regular basis. This first implementation provides Theraclion with a local clinical base, while the review of the application filed with the NMPA for mainland China as a whole is progressing.

Enhanced clinical visibility and a platform that continues to advance

Sonovein®'s clinical visibility was strengthened during the half-year, with more than 30 presentations at eight international congresses. In parallel, the first results of the SpeedPulse study, presented in May 2026, reported treatments performed in under 30 minutes with the next-generation prototype. Clinical evaluation, along with industrialisation and regulatory validation work, is continuing.

First-half 2026 financial results

In K€	30/06/2026*	30/06/2025	Change	% Change
Revenue	**663**	**835**	**(172)**	**(21%)**
Equipment sales	*296*	*285*	*11*	*4%*
PPU and consumables sales	*333*	*305*	*28*	*9%*
Service sales	*34*	*245*	*(211)*	*(86%)*
Grants	4	3	1	33%
Other income	759	61	698	1,144%
Total operating income	**1,425**	**898**	**527**	**59%**
Purchase of goods and inventory changes	1,132	90	1,042	1,158%
External expenses	1,514	1,664	(150)	(9%)
Personnel expenses	2,317	1,786	531	30%
Other operating expenses	378	227	151	67%
Total operating expenses	**5,340**	**3,768**	**1,572**	**42%**
Operating result	**(3,915)**	**(2,870)**	**(1,045)**	**36%**
Financial result	(141)	(143)	2	1%
Non-current result	0	0	0	0%
Research tax credit	450	475	(25)	(5%)
Net result	**(3,606)**	**(2,538)**	**(1,068)**	**42%**

** These financial statements were subject to a limited review by the company's statutory auditors.*

Theraclion's revenue amounted to €663K as of 30 June 2026, compared with €835K in the first half of 2025. This change primarily reflects the decline in sales of services, consumables and merchandise in China, which had benefited from cyclical factors in the first half of 2025.

PPU revenue continued to grow, reaching €333K as of 30 June 2026, up 9% compared with H1 2025 (€305K). It should be noted that, as the new devices contracted in 2026 were installed mainly at the end of the second quarter, they are only marginally reflected in revenue recognised in the first half of 2026 and their contribution will become visible from the second half of 2026 onward. With regard to service revenue (maintenance), the decline is very largely explained by the expiration of legacy multi-year contracts that had not yet been renewed.

The operating result for the first half of 2026 stood at -€3.9 million, compared with -€2.9 million in the first half of 2025. This change notably reflects the expenses incurred to prepare the next stages of Theraclion's development, in particular, the regulatory work related to the U.S. submission, the strengthening of the commercial teams and the ramp-up of production. The latter takes place ahead of commercial deployment in order to anticipate the opening of new centres and support the growth of the installed base.

The change in “Other income” essentially reflects the change in inventories (production placed into/drawn from inventory), to be read together with the symmetrical change recorded in expenses. The balance of expenses corresponds to the cost of goods sold, the depreciation of PPU machines and the shipment of consumables related to these contracts.

Going concern and cash runway

As of 30 June 2026, Theraclion's available cash amounted to €5.2 million, following the oversubscribed capital increase completed in spring 2026 (net proceeds of €5.8 million received in May 2026). For several years, the Company has consistently benefited from the ongoing support of its two long-standing shareholders, Furui and Unigestion, which actively support the financing of its development strategy.

The capital increase was accompanied by the issuance of share subscription warrants (BSAs) that could provide up to €2 million in additional funds if fully exercised. Depending on the exercise of these BSAs and the pace of commercial deployment in the United States, the Company's cash runway extends from the end of the first quarter to the end of the second quarter of 2027.

Theraclion also continues to evaluate various financing solutions to support the next stages of its development, including the financing of the machines in its installed base, the pre-financing of the research tax credit (approximately €0.9 million) and a financing transaction that could be considered in connection with commercial deployment in the United States and obtaining marketing approval from the FDA.

Governance

On 18 June 2026, the Annual General Meeting renewed the Board of Directors, now composed of Lijuan Deng, Claude Lenoir, Cédric Bellanger, Mehdi El Glaoui and Vincent Gardès. On 8 July 2026, the Board of Directors appointed Vincent Gardès as its Chairman, replacing Claude Lenoir, interim Chairman, who remains a director. This appointment strengthens Theraclion's governance at a key moment in its

development. Vincent Gardès's experience in commercial acceleration, international development and supporting MedTech companies through scale-up phases is an asset to support the Company in its next stages, in particular the deployment of Sonovein® in Europe and the preparation of its entry into the U.S. market.

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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) requires neither incisions nor an operating room, leaves no scars and allows patients to immediately resume their daily activities. The HIFU method concentrates therapeutic ultrasound towards an internal focal point from outside the body.
Theraclion is developing Sonovein®, a HIFU robotic platform for the treatment of varicose veins, CE-marked under the MDR (EU 2017/745), with the potential to replace millions of surgical procedures each year. To date, Sonovein® has been adopted by more than a dozen centres worldwide and has been used in more than 4,000 procedures. In the United States, Sonovein® is not yet available for sale.

Based in Malakoff (Paris), the Theraclion team consists of approximately 40 people.

For more information, please visit **www.theraclion.com** and follow us on **LinkedIn**.

Theraclion is listed on Euronext Growth Paris
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