Theraclion

Investor Presentation

The first HIFU platform authorized in Europe and the U.S.
to treat varicose veins non-invasively, with Sonovein®

November 2026 | Euronext Growth (ALTHE)

FDA authorization opens the world's largest varicose vein market to Sonovein

FDA DE NOVO AUTHORIZATION

4 Nov. 2026

first and only HIFU platform authorized in Europe and the United States to offer a non-invasive treatment option for patients with varicose veins

1st

A new device classification

The De Novo pathway covers novel devices with no legally marketed predicate. Sonovein, using High Intensity Focused Ultrasound (HIFU), defines a new category

96.8%

Clinical Efficacy - VEINRESET pivotal study

Occlusion at 12 months of target veins (GSV) on 70 patients in 4 U.S. and European centers, with no serious adverse event.

1099T

A U.S. CPT code Cat III is issued

Category III CPT code obtained in June 2026 and effective 1 Oct. 2026, a first step towards coverage and payment.

~1,000

A launch ready to execute

Sonovein Inc. is incorporated. Reference centers come first, ahead of ~1,000 addressable U.S. sites.

Sources: Theraclion press releases, 16 Sept. and 5 Nov. 2026; VEINRESET (ClinicalTrials.gov NCT05926830)

INVESTMENT HIGHLIGHTS

Theraclion combines a large market, a validated technology and recurring revenue

Theraclion applies robotic, non-invasive HIFU to varicose veins.

1

A **large market** that is growing and under-penetrated

$13B market
6.5% annual growth

2

A **validated technology**, now authorized by the FDA

96.8% efficacy
0 serious adverse events

3

A **commercial ramp-up** under way in Europe and the U.S.

FDA authorized Nov. 2026
U.S. CPT code from Oct. 2026

4

A **pay-per-use model** built for recurring revenue

~85% recurring revenue
objective at maturity

5

A **platform** that extends to adjacent indications, after success in veins

Thyroid $3.6B
Breast cancer $20B+

Built on Sonovein®, the only fully robotic, non-invasive HIFU platform: 15 years of R&D, 134 granted patents, FDA De Novo authorization in November 2026.

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November 2026

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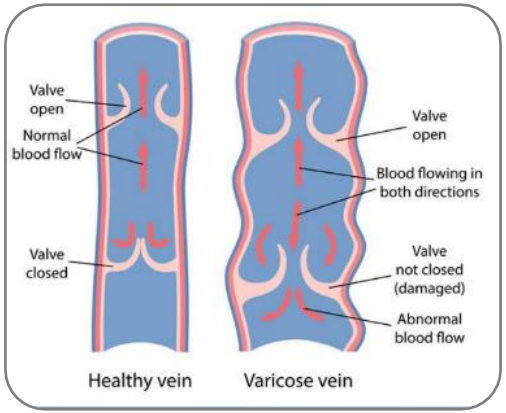
Varicose veins are a widespread and serious condition



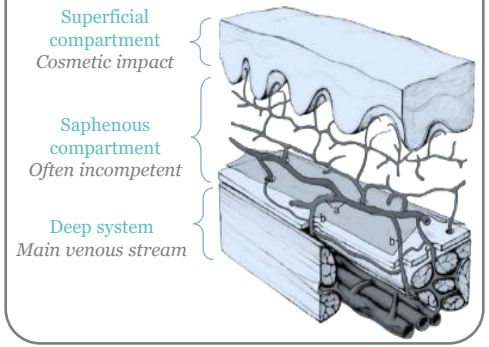
What are varicose veins?

Swollen, twisted subcutaneous veins of the lower leg caused by valve dysfunction leading to blood reflux.

Concrete Symptoms

- **Pain & Heaviness:** Aching, throbbing, or heavy legs.
- **Swelling:** Edema in the lower legs and ankles.
- **Skin Changes:** Discoloration, itching, or hardening.
- **Complications:** Risk of venous ulcers or bleeding.

The Venous System



31% of adults aged 18 to 64 are affected by varicose veins

Source: Maurins et al., 2008

Vein care keeps moving towards less invasiveness

SURGERY

Stripping

Highly invasive · 1920s-2000s



- Surgical vein removal
- Requires anaesthesia
- Long recovery
- Higher risk of complications

Endovenous

Invasive · since 2000s



- Laser, RF Ablation, or glue via catheter
- Still requires sterile field
- Risk of recurrence & side effects

NON-SURGICAL

sonovein®

Non-invasive: the third wave (2020s)



- **The pattern repeats:** each generation is less invasive than the last
- Fully non-invasive and robotic, it treats varicose veins with HIFU (therapeutic ultrasound) from outside the body

Varicose vein treatment is already a $13B market, with a recurring patient base

31% of adults aged 18-64 are affected, one of the most widespread chronic conditions in industrialized countries

10M+ procedures per year worldwide, of which 5 million are directly addressable by Sonovein today

$13B total annual medical expenditure on varicose vein treatments: devices, procedures, hospital stays, and post-operative care combined

€1.5-5K average treatment price, from at least ~€1,500 per treatment in Europe up to $5,700 Medicare HOPD reimbursement for endovenous glue-based procedures in the US

Why it matters

Varicose veins are swollen, twisted veins caused by valve dysfunction. The condition is chronic and widespread, which generates recurring treatment demand.

Theraclion does not need to create demand, only to capture share.

Sources: Maurins et al., 2008; Millennium Studies; Vuylsteke 2015; Abate 2020; Theraclion estimations

The market grows 6.5% a year, with further upside from untapped geographies

1 Organic growth driven by three structural trends

Aging populations

Growing elderly cohorts worldwide increase venous disease prevalence

Rising obesity

Obesity is a major risk factor, and global rates are rising

Sedentary lifestyles

Prolonged sitting and standing increase venous insufficiency

2 Emerging markets offer a large growth reservoir

China alone counts 150 million potential patients, almost entirely untreated today. As non-invasive solutions like Sonovein become available, these markets unlock significant incremental volume.

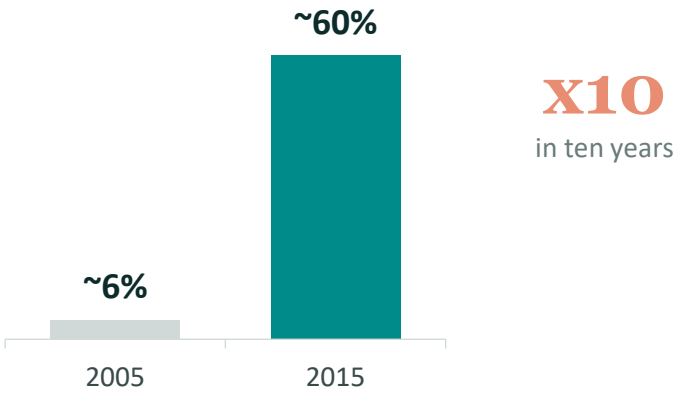
150M

potential patients in China alone

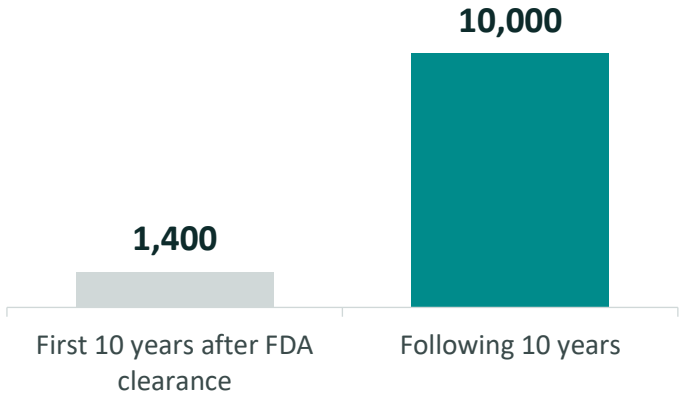
Sources: Millennium Studies; Theraclion estimations

Past shifts in vein care and robotic surgery started slowly, then accelerated sharply

Vein care: share of endovenous procedures in England



Robotic surgery: Intuitive Surgical systems installed



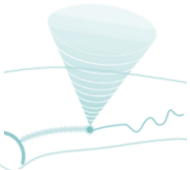
Today's leaders all entered by acquiring pioneers:
Medtronic (VNUS, Sapheon), BD (Venclose), Boston Scientific (BTG)

Sources: Hospital Episode Statistics (NHS England), analysed by Michaels et al., 2022*; Intuitive Surgical*

Sonovein® represents a fundamental breakthrough in varicose vein care

HOW SONOVEIN® WORKS

High Intensity Focused Ultrasound (HIFU)



Focused ultrasound energy delivered **through the skin** ablates the diseased vein — **no incision, catheter or needle**. Real-time imaging and robotised movements ensure millimetric, reproducible precision.

Extracorporeal

No incision, no catheter insertion, no sedation required

Real-time imaging

Embedded ultrasound guides every step of the treatment

Robotic precision

Millimetric accuracy ensures consistent, reproducible outcomes

INTELLECTUAL PROPERTY

134 granted patents | 170 filed | 23 families

WHY IT BEATS SURGERY

The only fully non-invasive device in the world

Where surgery requires **sedation and an operating room**, Sonovein® treats from outside the body — **a single operator, in a standard office**, with the patient out in under an hour.



Treatment benefits

No incision, no scars, no sedation, no infection risk, no recovery room

Simplified procedure

No additional medical staff, immediate return to normal activity

Designed, engineered & manufactured in France

Sonovein removes the barriers current treatments impose on every stakeholder

	Today	With Sonovein
Patients	• Many refuse surgery for a non-lethal condition • Surgical risks, sick leave, 2-3 weeks of compression stockings • 50% of patients forgo care	• Treated awake in a standard office • In and out in under an hour • No incision, scar or sedation • Available all year round
Physicians	• Manual techniques carry risks, e.g. injection into the deep venous system • Dependent on hospital slots	• Robotic precision with real-time imaging • Single operator • Full autonomy in an office setting
Care centres	• Operating rooms and staff earn more on other procedures • Veins dilute profitability or go untreated	• No operating room, extra staff or recovery room • Surgical capacity freed • Recurring revenue line added

Sources: Theraclion market research; Vuylsteke 2015

The FDA pivotal study shows efficacy in line with market leaders, with no serious adverse event

VEINRESET FDA pivotal study (2023-2025)

70 patients | 4 centers (USA + Austria + Czech Republic) | Great saphenous vein (GSV)

"Sonovein is equivalent to traditional treatments, with additional patient benefits."
Dr. Steve Elias, Principal Investigator

96.8%
Occlusion at 12 months

98.5%
Reflux abolition

0
Serious adverse events (SAE)

100%
Pain disappearance

Sonovein is as effective on varicose veins as the market leaders, without invasiveness

Medtronic ClosureFast (RF): 97.0% closure at 12mo (1): equivalent efficacy, but requires incision and catheter insertion surgery.

Medtronic VenaSeal (glue): 97.2% closure at 12mo (1): equivalent efficacy, but requires incision, catheter insertion and injects permanent glue inside the body.

Sonovein achieves comparable efficacy without invasiveness, a fundamentally different risk profile.

Source: VEINRESET Study, 2025, VeClose study, (1) Morrison & Gibson, Phlebology, 2019

Clinical evidence rests on 13 peer-reviewed publications and over 4,000 treatments

13
Peer-reviewed publications

75+
Conference presentations

20
KOLs across 14 countries

4,000+
treatments performed

Selected publications

JOURNAL	KEY RESULT
J. Vascular Surgery, 2026	FDA pivotal VEINRESET: 96.8% occlusion at 12 months, 70 patients, 4 centers
J. Vascular Surgery, 2025	European retrospective: 94.3% at 12M / 95.5% at 24M on 204 veins in 183 patients
Phlebology, 2025	100% efficacy on small saphenous vein (SSV), 15 veins
Phlebology, 2025	100% efficacy on perforator veins, 25 veins
Phlebology, 2025	94% to 97% efficacy at twelve months on 164 veins
Phlebology, 2024	188 limbs: 97.6% at 6 months / 98.3% at 12 months

The product roadmap aims to increase the $/hour for the physician and the center

Halve treatment time

From 45 min to 1h today to 20-30 min within 18-24 months

A new Sonovein prototype has demonstrated treatments below 30 min in SpeedPulse clinical trial in Prague.

Make Sonovein usable by non-specialists

From ultrasound-trained doctor to AI-guided intuitive device with rapid training

AI enables simpler, faster treatments, reducing the learning curve and opening the market for aesthetics clinics.

Enlarge addressable patient population

From most common veins to more types of veins, larger and deeper

Broader patient base = larger market per site

KEY ENABLERS: AI: treatment assistance | ACOUSTICS: faster pulse | ROBOTICS: faster positioning

Patents, know-how, data and regulatory approvals make Sonovein hard to replicate

1

134 granted patents protect critical IP

- 134 granted (170 filed, 23 families).
- Design, application and method patents protect the most critical aspects of the device.

2

15 years of compounded know-how that is difficult to replicate

- Acoustics + robotics + real-time imaging cannot be replicated quickly.
- Thousands of iterations across multiple clinical studies
- 4,000+ treatments since 2018.

3

Data flywheel feeding AI advantage

- Every procedure enriches a proprietary database of imaging and technical logs that trains the AI programme.
- This advantage compounds and a new entrant cannot replicate.

4

Clinical & regulatory moats which take years to build

- FDA De Novo authorization obtained (Nov. 2026).
- CE MDR obtained.
- Each step represents years of work that competitors must repeat from scratch, with no guarantee of success.

Pay-per-use is Theraclion's preferred model

PAY-PER-USE (PPU) SUBSCRIPTION

How it works
- No upfront CAPEX
- All-inclusive: system + EPacks + service
- Minimum monthly fee. Monthly subscription with tiered procedure volumes.
- Standard terms with minimum commitment and upfront payment

Markets
- Mainly Europe & USA

Key advantages
- Lower barrier to adoption and higher lifetime value per centre

★ PREFERRED MODEL

DIRECT SALES: SYSTEM + CONSUMABLES

How it works
- Machine sold at a competitive price
- Single-use consumable generates recurring revenue at higher margin

Markets
- China, Middle East, RoW

Benchmark
- Intuitive Surgical: 85% recurring revenue from consumables & services

Source: InvestInsights

The U.S. and Europe are the priority markets, while China and other regions go through partners



USA: growth engine

PRIORITY

1,000 addressable sites | FDA De Novo since Nov. 2026

- **FDA De Novo granted 4 Nov. 2026**, launch underway via Sonovein Inc.
- **$100-150M/y revenue potential** for first 300 centres
- **Reimbursement: CPT Cat. III code 1099T effective 1 Oct. 2026**
- **CMS APC & private payers advocacy** underway



Europe: commercial anchor

PRIORITY

1,500 addressable sites | CE MDR since Sept. 2025

- **Approach: mostly direct + agents**
- **Commercial traction: Tier-1 sites at 100-150 treatments/year**
- **Excellent KOL network**
- **Reimbursement roadmap** in multiple countries
- **315K+ potential treatments** at 35% market share



China: JV with Furui

OPPORTUNITY

150M patients | JV established in Shenzhen

- **Largest varicose vein market in Asia, underserved**
- **Joint-venture for** domestic dev. & market access
- **Certification done, NMPA review underway**
- **Potential clinical trial start** (lasting 1-2 years)
- **First machine deployed** in Hainan under geographical exemption



Rest of World: distributors

OPPORTUNITY

Aiming at c.100 machines in 5 years | Focus on inbound

- **Short Term:** Middle East, with Saudi SFDA authorization (Oct. 2026) and systems already installed in the region
- **Long Term:** Latin America, Rest of Asia

The European ramp-up has started, with seven new contracts signed in 2026

The PPU installed base is on track to double roughly every 18 months

Seven new contracts signed in 2026, mostly PPU, with four devices made available at the end of H1 2026. Their revenue contribution starts in H2 2026.

Installed base doubling in 18 months

Signings span 7+ countries, in Europe and beyond

Last public update Sept. 2026 : 7 new contracts YTD in Germany, France, China, Spain, Greece, Romania, Hungary

7 new contracts Q1 to Q3 2026

PPU revenue keeps growing as utilisation rises

PPU revenue rose 29% in 2025 and 9% in H1 2026, driven by rising utilisation in equipped centres.

+29% PPU revenue in 2025

~60 centres in the active commercial pipeline

The U.S. launch proceeds in two capital-efficient stages, scaling as soon as early sites prove the model

STAGE 1: PRE-LAUNCH, STRUCTURE & FOUNDATION
2026-2027

GATE

STAGE 2: FULL LAUNCH & GROWTH
with partner / distributor

Gate = Commercial KPIs
Scale once gate is met, allowing early acceleration if traction confirms

STEP 0 · DONE
Pre-authorization
- Sonovein Inc. incorporated
- CPT 1099T obtained (effective Oct. 2026); CMS pending
- FDA De Novo granted Nov. 2026

STEP 1 · NOW
Pre-launch
- First pilot systems
- Limited geography
- Operations from France
- Scalable organisation
- Optimised budget
- Direct approach to fine-tune customer-product fit

STEP 2
Foundation
- Small local team
- Limited geography
- Congress-driven inbound sales
- Level-1 service localised
- Direct approach to fine-tune customer-product fit

STAGE 2
Full launch with partner / distributor
- Distributors or strategic partnerships (target)
- Less likely: fully capitalized direct US organization
- Full commercial plan, nationwide expansion
- Capturing commercial traction at scale
- Autonomous US logistics; partnerships and M&A

U.S. reimbursement roadmap: CPT Category III code 1099T effective 1 Oct 2026

Go-to-market priorities:
big vein centres (2000+ treatments per year), then smaller vein clinics and chains, then physicians' offices. In parallel, an opportunity exists with aesthetics centres.

Revenue grew 43% in 2025, and PPU revenue kept growing in H1 2026 despite one-off effects

FY 2025: €1.19M, up 43%

Equipment sales more than doubled, and PPU and consumables rose 29% to €626K.

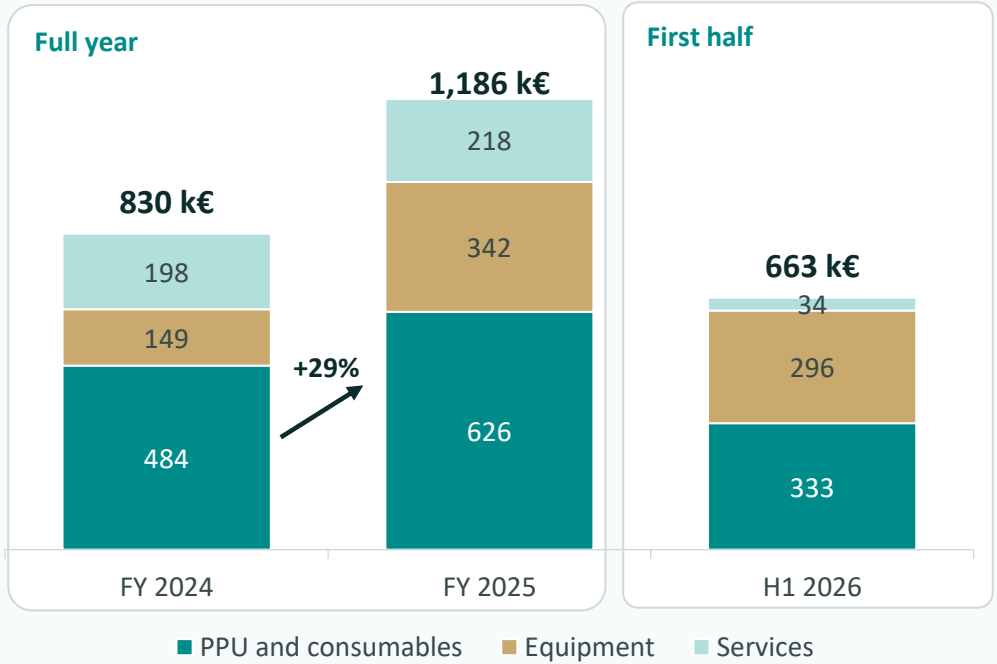
H1 2026: €663K

H1 2025 included one-off parts sales in China, and legacy maintenance contracts expired / still under negotiation

PPU up 9% in H1 2026

Four devices installed at end-June contribute from H2 2026.

Revenue lags signings: new contracts turn into installations within months, then into PPU revenue over the coming half-years.



Sources: annual accounts 2025 (approved 15 April 2026); H1 2026 accounts (limited review). Revenue in K€

Theraclion has cleared its key regulatory milestones and now turns to execution

ACHIEVED

2019
CE mark
First European approval

2023-2025
VEINRESET
FDA pivotal study, 96.8% occlusion

Sept. 2025
CE MDR
Certified under the new EU regulation

June 2026
CPT code
Category III code 1099T obtained Active 1st Oct.

Oct. 2026
Saudi Arabia
SFDA authorization

Nov. 2026
FDA De Novo
U.S. marketing authorization

AHEAD

2026-early 2027
U.S. launch
First commercial treatment in the U.S.

2027
US Reimbursement
CMS payment level for U.S. procedures

2027
U.S. stage 1
Pilot systems and foundation with achieved commercial KPIs

2027
Europe
Commercial momentum keeps growing and reflected in top line

Under review
China
NMPA registration for mainland China

Within 18-24 months
Next generation
Treatment time cut to 20-30 minutes

Sources: Theraclion press releases (16 Sept. and 5 Nov. 2026); company information

Varicose veins are the first indication of a broader HIFU platform

Sonovein is a platform: robotic, image-guided HIFU can treat any tissue ultrasound can reach. We will extend to new indications only once veins have proven successful.

Varicose Veins — NOW

$13B total healthcare spend

- Current focus: build platform & proof
- Generate cash flows to fund extensions
- 5M+ addressable procedures/year

Thyroid Nodules — NEXT

$3.6B | 1.8M procedures/yr

- Theraclion's historical market (10 years)
- Latest Sonovein re-enters with superior tech
- Most natural adjacency

Breast Cancer — HORIZON

$20B+ | millions treated/yr

- Clinical studies ongoing at University of Virginia
- HIFU + immunotherapy combination
- Strategic medium-term option

Sources: Millenium studies, other market studies & Theraclion assumptions

The management team brings decades of medtech, regulatory, and R&D experience



Martin Deterre, PhD
CEO
15+y. exp, Livanova, Pixium
M.I.T., Polytechnique
THC since 2020, CEO since 2023



Julie Veisseire
CFO
15+y. exp, ESCP, PwC, Dassault Systèmes, Canon, Carmat
THC since 2025



Michel Nuta, MD
CMO
30+y. exp, ex-VNUS
THC since 2013



Jérémie Anquez, PhD
CSO
15+y. exp, Telecom ParisTech
THC since 2010



Alexandra Rocher
COO
25y. exp, Safran, Mauna Kea, Pixium/Science, THC since 2026



Thibault Le Normand
CBO, Sales & Marketing
10y. exp, Sophysa
THC since 2025



Vivien Jourdannaud
VP QARA
10y. exp, Mauna Kea
THC since 2015

~40 employees | Malakoff, France | 26 engineers, 5 PhD, 1 PharmD, 1 MD | Devices manufactured in France

The board brings deep medtech experience, including US market entry and exit success stories



Vincent Gardès
Chairman of the Board
MedTech entrepreneur, international expansion specialist (notably in the USA)
ex-Vexim (acq. Stryker), Germitec CEO, Amber Implants
THC since 2026



Lijuan Deng
Board Member
17+y. in healthtech
Board of Echosens, Furui
THC since 2023



Mehdi El Glaoui
Board Member
Ex-CEO Lab. Cassenne, Wyeth
Founder Lab. Marjorelle
THC since 2021



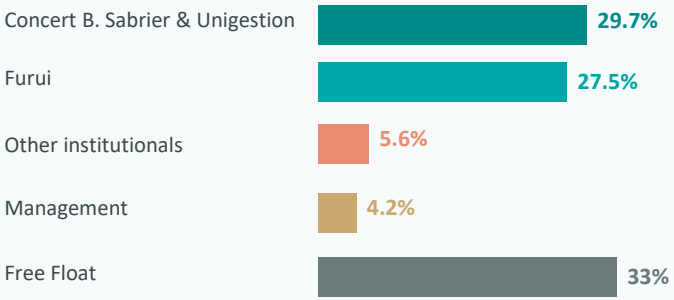
Claude Lenoir
Board Member
Former CEO Echosens &
Air Liquide Medical Systems
THC since 2023



Cédric Bellanger
Board Member
CBML / Augusta
Real Estate & Capital Investment
THC since 2022

Two cornerstone shareholders hold 57% of the capital

SHAREHOLDERS (as of July 31, 2026)



EURONEXT GROWTH | ALTHE

Support from historical cornerstone shareholders

Furui: genuine partnership

- Theraclion's supporting investor since 2016.
- China JV created in 2017, strong support in China.

Replication of Echosens' Success:

- Echosens (France): 2 orders of magnitude higher revenues and valuation, ~300 employees, global leader in non-invasive liver diagnostics.
- Furui leads development in China, supports R&D in France and global commercial deployment.
- Echosens China is a key contributor to Echosens' Global P&L.

Bernard Sabrier & Unigestion

- Theraclion's supporting investor since 2018.

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GLOSSARY

- **HIFU:** High Intensity Focused Ultrasound is a non-invasive therapeutic technique that uses non-ionising ultrasonic waves to heat or ablate tissue.
- **Venous reflux or Chronic Venous Insufficiency (CVI):** occurs when veins no longer circulate blood properly. It often affects the leg veins, causing blood to pool and leading to swelling and discomfort.
- **Serious Adverse Events (SAE):** an adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a birth defect.
- **CEAP classification:** the CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classification is an internationally accepted standard for describing patients with chronic venous disorders
- **FDA:** Food and Drug Administration
- **MDR:** Medical Device Regulation (EU) 2017/745, applicable regulation for medical device CE approval in Europe
- **KOL:** Key Opinion Leader
- **rVCSS:** Venous Clinical Severity Score, scoring the severity of the venous pathology
- **NMPA:** National Medical Products Administration, Chinese competent Authority
- **CMS:** Centres for Medicare & Medicaid Services
- **CPT:** Current Procedural Terminology – US reimbursement

THERACLION

H1 2026 Financial Results

Income statement H1 2026

In €000s	30/06/2026	30/06/2025	Var	Var %
Revenue	**663**	**835**	**(173)**	**(21%)**
From equipment sales	*296*	*285*	*11*	*4%*
From PPU and consumables sales	*333*	*305*	*28*	*9%*
From services sales	*34*	*245*	*(211)*	*(86%)*
Grants	4	3	1	39%
Other income	759	61	698	1,144%
Total operating income	**1,425**	**898**	**527**	**59%**
Purchases of goods and change in inventories	1,132	90	1,042	1,158%
External charges	1,514	1,664	(150)	(9%)
Personnel expenses	2,317	1,786	531	30%
Other operating expenses	378	227	151	66%
Total operating expenses	**5,340**	**3,768**	**1,572**	**42%**
Operating profit/(loss)	**(3,915)**	**(2,870)**	**(1,045)**	**36%**
Net financial income/(expense)	(141)	(143)	2	(1%)
Non-recurring profit/(loss)	0	0	0	0%
Research tax credit	450	475	(25)	(5%)
Net profit/(loss)	**(3,606)**	**(2,538)**	**(1,069)**	**42%**

Balance Sheet as of 30 June 2026

Assets, in €000s	30/06/2026	31/12/2025
Intangible assets	1,190	1,132
Property, plant and equipment	1,173	879
Financial assets	1,180	1,189
Total non-current assets	**3,543**	**3,199**
Inventories and work in progress	2,788	2,574
Advances and payments on account on orders	576	453
Trade receivables and related accounts	256	294
Other receivables	2,375	2,489
Prepaid expenses	26	114
Treasury shares	17	9
Cash instruments	4,200	1,500
Cash at bank and in hand	1,019	1,879
Total current assets	**11,257**	**9,312**
Total assets	**14,800**	**12,511**

Liabilities and equity, in €000s	30/06/2026	31/12/2025
Share capital	3,656	2,991
Share, merger and contribution premiums	5,152	2,428
Retained earnings	(5,580)	(2,317)
Profit/(loss) for the period	(3,606)	(5,690)
Total equity	**(378)**	**(2,588)**
Conditional advances	6,290	6,290
Provisions for risks	34	19
Convertible bonds	4,341	4,341
Borrowings from credit institutions	280	600
Miscellaneous borrowings and financial debts	326	148
Trade payables and related accounts	1,491	1,394
Tax and social security liabilities	1,072	879
Payables on non-current assets	390	390
Other payables and deferred income	954	1,037
Total liabilities and equity	**14,800**	**12,511**

Net amounts. Condensed from the half-year financial statements; totals may not add due to rounding.

Theraclion

Thank you

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