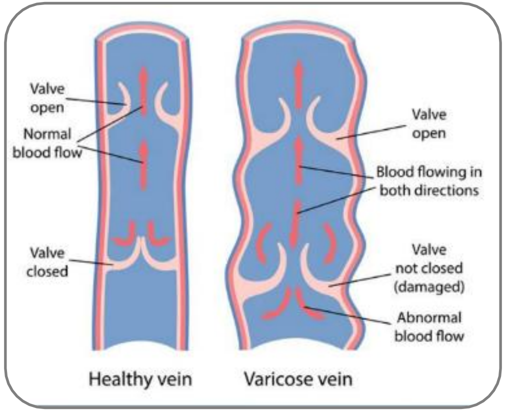
THERACLION

Investor Presentation

The European HIFU platform disrupting the varicose vein market with Sonovein® — poised for global scale

September 2026 | Euronext Growth – ALTHE

Varicose veins are a widespread and serious condition



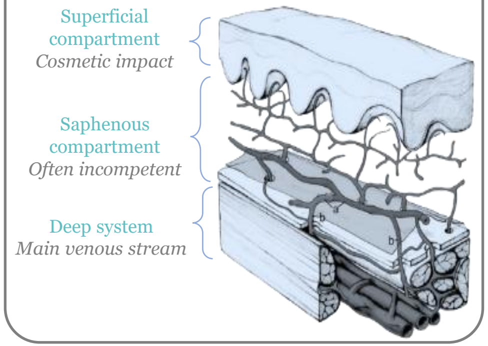
What are varicose veins?

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

Standard of care shifts away from invasiveness

SURGERY

Stripping

Massively invasive · 1920s–2000s

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

→

Endovenous

Invasive · since 2000s

- Laser, RFA, 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

INVESTMENT THESIS – WHY INVEST IN THERACLION?

Theraclion can become a medtech success story

HIFU is revolutionising medicine. **HistoSonics** (liver tumours) was acquired in Aug. 2025 (last valuation $3.75B). Different indications, same platform revolution: our ambition is to **become a European HistoSonics** by conquering the world's largest markets, leveraging our **French technological know-how.**

1

A **massive market** that is both growing and underpenetrated

$13B market
6.5% annual growth

2

A **disruptive technology** that is ready to revolutionize it

96.8% efficacy
0 serious adverse events

3

A company ripe to launch its **commercial conquest**

FDA expected Q3-Q4 2026
US reimbursement CPT code

4

A model built for abundant, **recurring cash flows**

Pay-Per-Use model
and huge competitive moats

5

A platform that extends to **massive adjacent markets**

Thyroid $3.6B
Breast cancer $20B+

Built on Sonovein®—the only fully robotic, non-invasive HIFU platform. 10 years of R&D, 134 patents, validated through a pivotal FDA trial.

Why now: the locks broke — takeoff has begun

2015 – 2024	2023 – 2025	2025 – 2026	H2 2026 →
✓	✓	✓	NOW

Technology
UNLOCKED

Procedure cut from 2h to 45 min — robotics, acoustics and imaging matured into a sellable device.

Clinical proof
UNLOCKED

FDA pivotal VEINRESET: 96.8% occlusion, 0 serious adverse events — parity with the best techniques.

Regulatory
UNLOCKED

CE MDR obtained. US CPT code obtained. FDA clearance expected Q3-Q4 2026.

Commercial takeoff
UNDERWAY

Trajectory of installed base doubling every 18 months, driven by PPU in EU
PPU +30% (FY 24 to FY 25)
First machine in China.
The ramp-up is live.

Invest just after the locks broke — and just before the P&L shows it.

1 | Today, Theraclion addresses the varicose vein market — which is massive

KEY MESSAGES

1. The varicose vein treatment market is already massive
2. Yet, it grows 6.5% annually, with potential for acceleration thanks to untapped geographies
3. Today's treatments somehow fail every stakeholder – there is room for a shift
4. When the varicose market shifts, it does massively and fast

Varicose vein treatment market is already massive

31% of adults aged 18–64 are affected—one of the most widespread chronic conditions in industrialised 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 a high-prevalence, chronic condition that generates recurring treatment demand.

Theraclion does not need to create demand—only to capture share with a superior technology.

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

Yet, it grows 6.5% with potential for acceleration thanks to 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—global rates accelerating

Sedentary lifestyles
Prolonged sitting and standing increase venous insufficiency

2 Emerging markets hold massive growth reservoir

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

150M
potential patients in China alone

Today's treatments somehow fail every stakeholder

Patients refuse the operating room for a non-lethal condition

Pain, sick leave, surgical risks (infections, nosocomial diseases) and 2-3 weeks of compression stockings — ruling out summer treatment. 50% of patients simply forgo care: a massive untreated base.

Physicians are constrained by a fully manual procedure

Manual techniques carry risks of severe errors (e.g. injection into the deep venous system). Practitioners often depend on hospital slots — imposed schedules, no autonomy. Office-based doctors want their own machine.

Care centres lose money and capacity on varicose veins

Costly staff and operating rooms are better monetised on other procedures (e.g. orthopedics). Some centres cannot treat their whole patient base for lack of space or staff — veins dilute overall profitability.

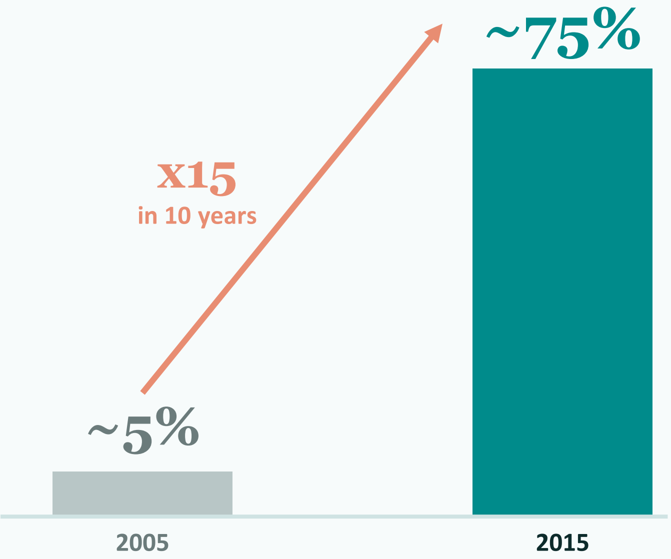
The market is not saturated — it is structurally blocked. Unblocking it is the opportunity.

Sources: Theraclion market research; Vuylsteke 2015

This market shifted before — violently, and fast

When endovenous methods replaced stripping

Share of endovenous procedures



KEY MESSAGES

1 **Being a pioneer pays off - literally**

Every endovenous pioneer was acquired: VNUS, Sapheon, Venclose, BTG were all absorbed by Medtronic, BD and Boston Scientific.

2 **When adoption starts, it does massively and suddenly**

Patients and physicians switch fast when invasiveness drops: stripping was replaced by endovenous within a single decade. The next generation is due.

Less invasive wins — every time. And it wins faster than anyone expects.

Sources: Hospital Episode Statistics (NHS, England) — analysed by Basanquet et al., 2022

2

Theraclion has developed a disruptive technology to revolutionize this market

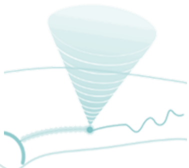
KEY MESSAGES

1. Sonovein® represents a fundamental breakthrough in varicose vein care
2. Sonovein is the next shift, unblocking every stakeholder
3. This breakthrough has been clinically validated
4. Clinical excellence has united an unusually engaged and enthusiastic KOL community
5. The product roadmap will further broaden the addressable market

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 is the next shift, unblocking every stakeholder

PATIENTS

- Walk in, walk out — under one hour
- No incision, no scars, no sedation
- Zero infection or surgical risk
- Treatment possible all year round

→ ***the 50% reluctant to undergo surgery become addressable***

PHYSICIANS

- Robotic precision, real-time imaging
- No manual-gesture risk
- Single operator, standard office
- Full autonomy — no hospital slots

→ ***office-based doctors finally get their own machine***

CARE CENTRES

- No OR, no extra staff, no recovery room
- Frees scarce surgical capacity
- Recurring, profitable revenue line
- New patient flows (aesthetic channel)

→ ***veins turn from a capacity drain into a profit centre***

One device, three unlocked stakeholders — that is how a market shifts.

This breakthrough has been clinically validated

VEINRESET – FDA Pivotal Study (2023–2025)

70 patients | 4 centres (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 – with zero invasiveness

Medtronic ClosureFast (RFA): 95.9% closure at 12mo [1] — equivalent efficacy, but requires incision and catheter insertion surgery.

Medtronic VenaSeal (glue): 96.8% closure at 12mo [1]— equivalent efficacy, but requires incision, catheter insertion and injects permanent glue inside the body.

Sonovein achieves comparable efficacy with zero invasiveness—a fundamentally different risk profile.

Source: VEINRESET Study, 2025, VeClose study, [1] Morrison & Gibson, Phlebology, 2019

Clinical excellence has united an unusually engaged and enthusiastic KOL community

13
Peer-reviewed publications

75+
Conference presentations

20
KOLs across 14 countries

4,000+
treatments performed

Selected publications

JOURNAL	KEY RESULT
Theraclion, 2025	FDA pivotal VEINRESET: 96.8% occlusion at 12 months, 70 patients, 4 centres
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 will further broaden the addressable market

Halve treatment time

From 45 min–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

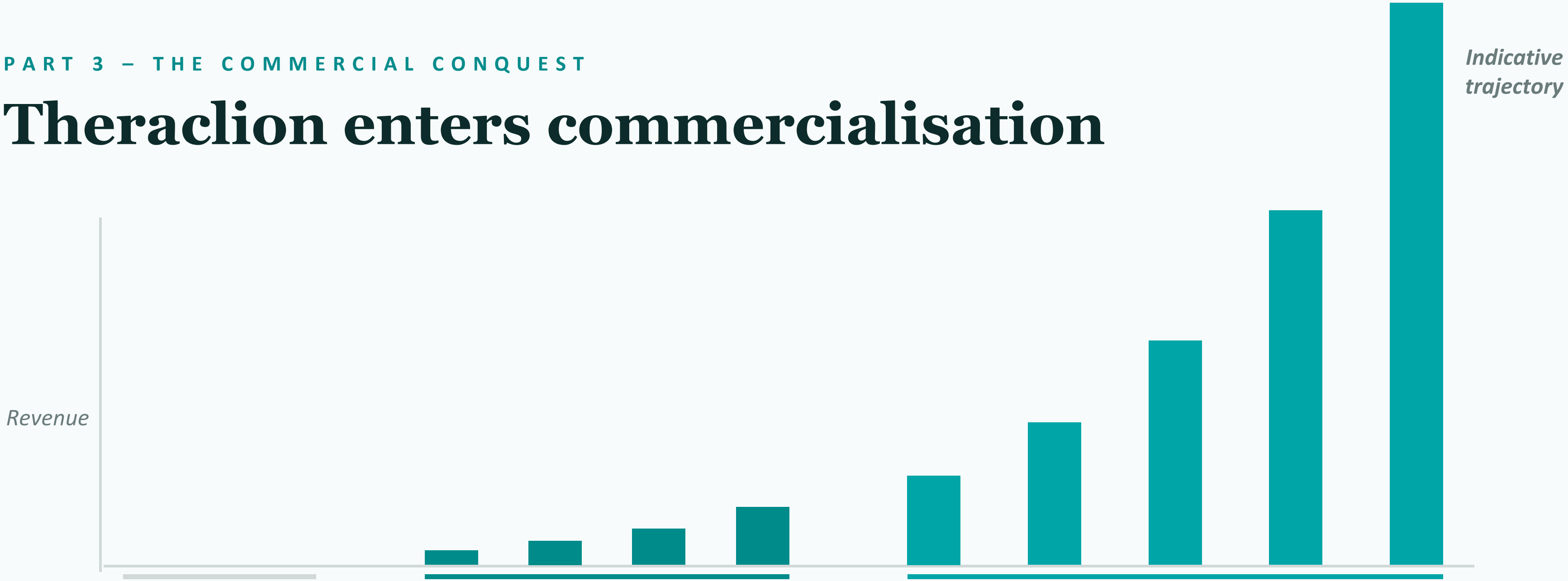
3

Theraclion is now ripe to launch its commercial conquest

KEY MESSAGES

1. Theraclion enters commercialisation
2. Theraclion leverages a dual business model built for adoption
3. Its commercial model is shifting from inbound gathering to outbound hunting
4. A clear focus for Theraclion: prioritising growth in Europe and the U.S.
5. The European ramp-up has started
6. United States market entry is already staged, with a focus on capital efficiency

Theraclion enters commercialisation



R&D — complete

2015–2026

10 years, fully behind us

Phase 1: Commercialisation

2026–2029

Sales ramp-up based on commercial refocus and early adopters' demand

Phase 2: Scaling

2030+

Thanks to market evangelisation and reimbursement milestones, Sonovein becomes the new standard of care

Precedents confirm this trajectory, both in the varicose vein market[1] and in general robotic surgery[2]

1. *Endovenous treatments replaced surgery in ~10 years (~5% to 75% of procedures between 2005 and 2015).*
2. *Intuitive Surgical saw slow initial adoption (1,400 systems in 10 years post-FDA) before becoming the standard of care (10,000 in the following 10 years).*

A dual business model built for adoption

"PPU" TIER-BASED SUBSCRIPTION — "ChatGPT" model

How it works
- No upfront CAPEX
- Monthly subscription with tiered procedure volumes
- Extra procedures billed per use
- All-inclusive: system + EPacks + service

Markets
- Mainly Europe & USA

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

★ PREFERRED MODEL

DIRECT SALES — "Nespresso" model

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

From inbound gathering to outbound hunting

UNTIL NOW

*Inbound "**gathering**" model*

~2%
of FTEs dedicated to sales

TARGET

*Outbound "**hunting**" model*

~25%
of FTEs dedicated to sales

	TODAY	TARGET
Priority	Commercial was not the priority (massive R&D focus)	**Commercial is the #1 strategic priority**
Marketing and communications	No dedicated marketing and communications team and few tools	**Dedicated MedTech marketing expertise, including KOL leveraging tools**
Playbook	*Ad hoc* and maturing commercial approach	**Structured commercial playbook with sales enablement processes**
Sales approach	Mostly reliant on congresses & KOL referrals	**Direct sales & targeted campaigns**
Business intelligence	Little use of BI tools	**Massive use to improve sales methodology – dedicated hiring considered**

Two horizons: aesthetics (out-of-pocket) pays now (1-3 years) — reimbursement pays big (3-5 years)

A clear focus for Theraclion: prioritising growth in Europe and the U.S. China and RoW addressed through partners

Europe — commercial anchor

PRIORITY

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

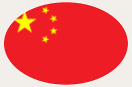
- **Approach: mostly direct + agents**
- **Commercial traction** — Tier-1 sites at 100–150 treatments/year
- **Excellent KOL network**
- **Reimbursement roadmap** in multiple countries
- **315K+ potential treatments** at 35% market share

USA — growth engine

PRIORITY

1,000 addressable sites | FDA clearance expected 2026

- **Clearance expected Q3-Q4 2026 -** commercial start right after
- **$100–150M/y revenue potential** for first 300 centres
- **Reimbursement: CPT Cat III code issued** for 1 Jan. 2027
- **CMS APC & private payers advocacy** underway



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 registration 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 (opportunistic sales – strong inbound demand)
- **Long Term:** Latin America, Rest of Asia

The European ramp-up has started

Driven by PPU in Europe – trajectory: installed base doubling every 18 months

Signed seven new contracts - mostly PPU - with four devices installed by the end of H1 2026. Growth has accelerated every semester since the commercial refocus.

Installed base doubling in 18 months

H1 2026: signings across Europe — and beyond

7 new contracts: Germany, France, China, Spain, Greece, Romania, Hungary

7 new contracts YTD 2026

Recurring PPU revenue keeps compounding

PPU revenue up +30% in 2025 vs. 2024, notably driven by rising utilisation in equipped centres.

+30% PPU revenue 2025 vs. 2024

~60 centres in the active commercial pipeline — the next wave of installations

PRELIMINARY PLAN

United States: a staged, capital-efficient market entry

Two phases, one hard gate: prove the model, then scale.

STAGE 1 — PRE-LAUNCH, STRUCTURE & POC
2026 – 2027

GATE

POC demonstrated with commercial KPIs

STAGE 2 — FULL LAUNCH & GROWTH
as traction confirms

STEP 0
Pre-approval
- US entity + preparation
- CPT Cat III secured; CMS pending
- First commercial system in prep

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

STEP 2
Structure & POC
- 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 capitalised direct US organisation
- Full commercial plan, nationwide expansion
- Capturing commercial traction at scale
- Autonomous US logistics; partnerships and M&A

US Reimbursement roadmap moving forward: CPT Cat III code already obtained: 1099T

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.

4 | Poised for market leadership, Theraclion should generate abundant, predictable cash flows

KEY MESSAGES

1. Recurring revenue model creates structurally increasing margins with volume
2. Theraclion's favourable market position will be highly defensible thanks to its large moats
3. Focus on AI moat: every treatment strengthens the AI data flywheel
4. HIFU competitors acknowledge veins are an excellent market, but are unlikely to attempt entry

Recurring revenue model creates structurally increasing margins with volume

Gross margin grows structurally with the installed base

Once a machine is deployed in PPU, each additional procedure generates revenue at very low marginal cost. Gross margin is projected to progress to above 90% at maturity—a dynamic typical of SaaS/LLM subscription models.

90% gross margin target

Breakeven is reached with a modest installed base

EBITDA breakeven is projected at ~100 machines deployed globally. Beyond that, nearly all revenue growth converts to cash—massive operating leverage.

~100 machines to breakeven

Revenue recurrence is structural, not commercial

Each PPU centre generates continuous revenue as long as it treats patients—no new purchase decision required. A practitioner who integrates Sonovein has no reason to remove it.

~85% recurring at maturity

Comparable: Intuitive Surgical — 85% recurring revenue, $160B+ market cap, built on the same razor-and-blade logic

Source: Theraclion projections

Theraclion's favourable market position will be highly defensible thanks to its large moats

1

134 patents locking down critical IP

- 134 granted (170 filed, 23 families).
- Design, application, and method patents create a legal fortress around 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.
- That is a compounding advantage no new entrant can replicate.

4

Clinical & regulatory moats which take years to build

- FDA pivotal completed.
- CE MDR obtained.
- Each step represents years of work that competitors must repeat from scratch—no guarantee of success.

Focus on AI moat: every treatment strengthens the AI data flywheel — a compounding moat

Live imaging + robotics + AI = road to automated treatment

Sonovein continuously collects ultrasound imaging and technical data. An integrated AI engine analyses and proposes treatment actions:

- Locate the vein / target
- Move to target position
- Choose adapted treatment parameters
- Deliver the therapy
- Monitor energy delivery
- Move to next relevant location

A new entrant would need years of clinical data to train comparable AI—data that only accumulates through actual patient treatments.

Data Flywheel

Every treatment feeds a proprietary dataset that trains the AI—a compounding competitive advantage no new entrant can replicate.

4,000+

treatments since 2018

Though HIFU competitors acknowledge veins are an excellent market, they are unlikely to attempt entry

HIFU competitors acknowledge the varicose veins market is an opportunity

> *"Sonovein had a brilliant idea to enter the varicose veins market. Its product is magic and the market is fantastic.*
>
> — Top executive, competitor

...yet they are very unlikely to attempt entry

- **Veins are a particularly complex market** to penetrate[1]
- **Large players generally prefer acquiring** smaller players[2] once they have passed the clinical, regulatory, and technological barriers and demonstrated product-market fit
- **Sonovein has tremendous moats** (see above)

1. *Notably due to the unique anatomical complexity of veins, absence of an FDA predicate, and singularly complex and demanding KOL ecosystem.*
2. *Virtually all of the large American players' assets on veins were acquired: VNUS, Sapheon, (Medtronic) and BTG (now Varithena by Boston Scientific), Venclose (Becton Dickinson), Acotec (Boston Scientific - distribution).*

5 | When Theraclion proves its delivery on varicose veins, it can deploy across massive adjacent markets

The HIFU platform is generic—varicose veins are only the first use case

Sonovein is not a single-indication product but a non-invasive soft-tissue therapy platform. Robotic HIFU guided by real-time imaging can target and treat any tissue accessible to ultrasound. Each euro invested in vein R&D strengthens the platform for all future indications.

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

Structured for Success

An experienced team, committed shareholders, clear roadmap

KEY MESSAGES

1. Decades of medtech, regulatory, and R&D experience in the management team
2. The board brings deep medtech experience, including US market entry and exit success stories
3. Historical cornerstone shareholders provide long-term stability

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

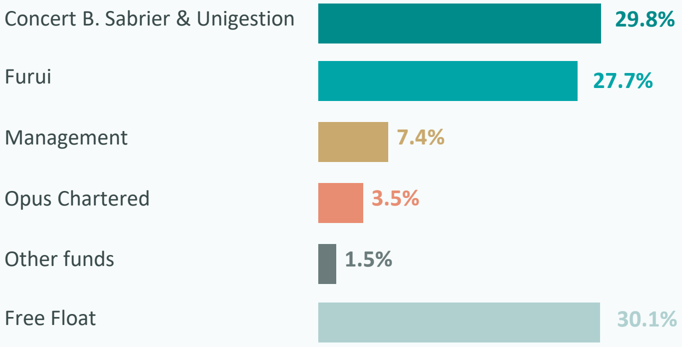
Board Member

CBML / Augusta
Real Estate & Capital Investment
THC since 2022

STRUCTURED FOR SUCCESS

Historical cornerstone shareholders provide long-term stability

SHAREHOLDERS (as of May 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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THERACLION

Appendix

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

Moat #1 – Sonovein combines five technological innovations protected by 134 patents

- **Robotised treatment head**
  Millimetric accuracy via robotic positioning
- **Embedded ultrasound imaging**
  Real-time visualisation of target vein
- **HIFU transducer**
  Focused energy delivered through the skin
- **Cooling system**
  Ensures patient comfort during procedure
- **Single-use EPack™**
  Proprietary consumable

Treatment process

High-energy ultrasound waves propagate through the skin to the target tissue, generating controlled heating. The process is repeated stepwise with robotic-driven movements. Tissue reaction is monitored in real-time via embedded imaging.

Intellectual Property

134

patents granted (170 filed, 23 families)

Design, application, and method patents create a legal fortress.

Moat #2 — 15 years of compounded know-how create an expertise that is difficult to replicate

~ Acoustics
HIFU energy delivery

- Focused ultrasound wave propagation
- Precise energy dosimetry
- Tissue-specific absorption models
- Cooling interface engineering

+ Robotics
Automated positioning

- Sub-millimetric treatment head control
- Real-time trajectory correction
- Patient anatomy adaptation
- Reproducible procedure execution

Real-time imaging
Live ultrasound guidance

- Vein detection & tracking
- Treatment monitoring feedback
- Safety zone enforcement
- AI-assisted image analysis

15 years of R&D

26 engineers

4,000+ treatments

This expertise was built through thousands of iterations across multiple clinical programmes. A new entrant would need to rebuild this knowledge base from scratch—a process that took Theraclion 15 years and can hardly be compressed.

Moat #4 — Clinical and regulatory achievements represent years of work that is difficult to replicate

2019
CE Mark
First European approval for Sonovein

2023–25
FDA Pivotal Study
Successful pivotal trial with top US KOLs

2025
CE MDR
New EU regulation compliance achieved

2026
FDA De Novo
US market clearance expected Q3-Q4 2026

13 peer-reviewed publications	**75+** conference presentations	**20** KOLs across 14 countries	**4,000+** treatments since 2018

Each clinical and regulatory milestone represents years of work. A competitor entering today would face 5–10 years of clinical development, regulatory submissions across multiple geographies, and the need to build a KOL network from scratch—with no guarantee of success.

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2025 Financial Results

Profit & Loss statement 2025

In K€	31/12/2025	31/12/2024	Change	% Change
Revenue	1,186	830	356	43%
Equipment sales	342	149	193	129%
PPU and consumables sales	626	484	142	29%
Service sales	218	198	20	10%
Grants	0	141	(141)	(100%)
Other income	1,133	1,191	(58)	(5%)
Total operating income	2,319	2,162	157	7%
Purchase of goods and inventory changes	81	1,428	(1,347)	(94%)
External expenses	3,642	3,228	414	13%
Personnel expenses	3,672	3,357	315	9%
Other operating expenses	1,298	968	330	34%
Total operating expenses	8,693	8,981	(288)	(3%)
Operating result	(6,374)	(6,819)	445	(7%)
Financial result	(154)	49	(203)	(417%)
Non-current result	1	30	(28)	(96%)
Research tax credit	837	984	(147)	(15%)
Net result	**(5,690)**	**(5,757)**	**67**	**(1%)**

The annual accounts were approved by the Board of Directors on April 15, 2026.

Balance Sheet 2025

K €	31/12/25	31/12/24
Intangible assets	1,132	1,133
Tangible assets	878	858
Financial Fixed Assets	1,198	1,202
Total Fixed Assets	**3,208**	**3,193**
Stock	3,298	2,838
Stock Depreciation	-726	-726
Trade debtors	451	708
Trade provision	-156	-541
Other debtors and prepayments	3,057	1,823
Total Current Assets	**5,924**	**4,102**
Cash	**3,379**	**4,171**
TOTAL ASSETS	**12,511**	**11,466**

K €	31/12/25	31/12/24
Ordinary share capital	2,991	2,317
Share premium account	2,428	3,440
Reserves N-1	-2,317	0
Profit and loss reserves	-5,690	-5,757
Total Equity	**-2,588**	**0**
Provision for risk	19	119
Total Provision	**19**	**119**
Convertible bonds	4,341	
Other loans	6,438	6,294
Bank loans	600	1,292
Total Loans	**11,379**	**7,586**
Trade Creditors	1,394	1,473
Tax & Social creditors	879	338
Other creditors and accruals	1,427	1,950
Total Trade & other Creditors	**3,700**	**3,761**
TOTAL LIABILITIES	**12,511**	**11,466**

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THERACLION

Thank you

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