

# INVESTORS PRESENTATION

DISRUPTING THE VARICOSE VEINS MARKET WITH **SONOVEIN**®

March 2024

# **EXECUTIVE SUMMARY**

- New Theraclion story: New team, new product, new strategy and new business model
- **Disruptive approach in varicose veins treatment:** SONOVEIN® is totally non invasive
- A huge market: Varicose veins affect 1 in 3 adults
- A proven technology: 95% reflux free\*, zero serious adverse event, 2,300+ veins treated
- Only 24 months away from a blockbuster product: R&D improvements and FDA approval
- **Strategy**: Focus on the US, China and R&D
- Financials: SONOVEIN's enhancement to trigger commercial launch and revenue acceleration

# **VARICOSE VEINS: A WIDESPREAD CONDITION**



# WHAT ARE VARICOSE VEINS?

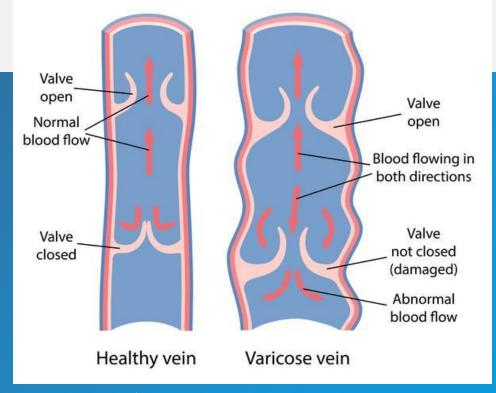
Varicose veins are swollen, twisted subcutaneous veins of the lower leg

Inadequacy of the valves results in reflux of blood in the veins

# **ONE IN THREE ADULTS**



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



Source: Austin Vein Specialists

Source: Maurins et al., 2008

# **VARICOSE VEINS: A MULTIBILLION \$ MARKET POTENTIAL**



# ALIGNED WITH CURRENT MARKET TRENDS



\$13B

Current medical costs for varicose vein treatments worldwide



5M+

Annual addressable procedures



Up to 50%

Sonovein device cost per procedure vs:

• Stripping: 1-2%

Endovenous: 10-15%



SIGNIFICANT GROWTH DRIVERS AND OPPORTUNITIES

- 6,5% annual growth in varicose veins patients driven by
   1 Age 2 Obesity 3 Lifestyle
- 54% of undiagnosed patients in industrialized countries
- Largely unmet medical need in emerging countries + China



- 50% of people afraid of surgery
  - → untapped patient pool for Sonovein

# THERACLION NEW STORY



# A DISRUPTIVE TREATMENT OF VARICOSE VEINS

# TWO MAIN CURRENT METHODS

### **STRIPPING**

INVASIVE ++



Surgery Ripping the vein off

# **ENDOVENOUS**INVASIVE +



Laser, Radiofrequency, Cyanoacrylate glue Burning or gluing from the inside through a catheter

# **STRESSFUL**

Anesthesia Surgery Sterile environment needed

# & RISKY

Potential serious adverse events

# SONOVEIN® VERY LOW RISK

NO SURGERY NEEDED



NO INCISION

# **NON INVASIVE**

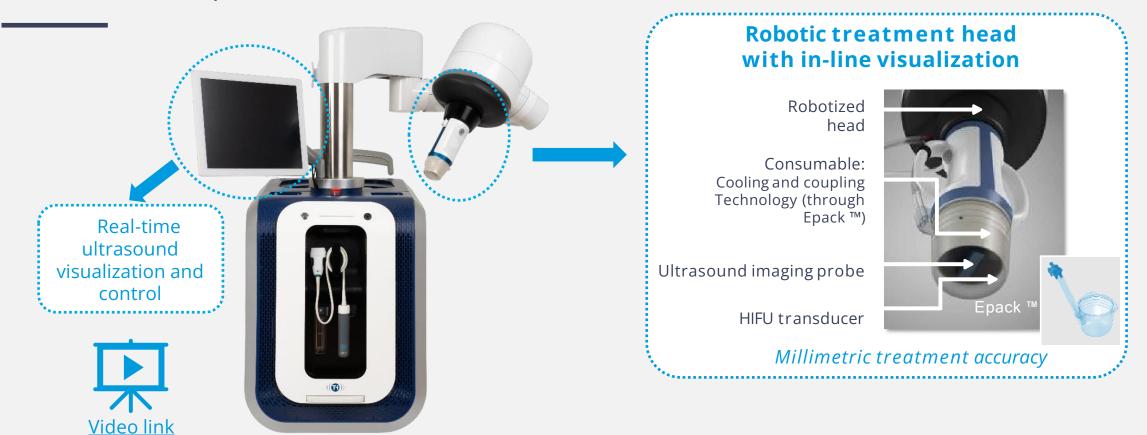
- No serious adverse event to date
- Quick walk-in walk-out procedure
- One operator only
- Data collection-capability & Al automation potential

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# **THERACLION NEW STORY**



# SONOVEIN®, A NEW ROBOTIC SOLUTION



# **INTELLECTUAL PROPERTY**

Patents: 164 granted, 211 filed, 30 families in HIFU procedure safety & efficacy, system design and application

# **BASED ON THERMAL ABLATION**



# FROM PRINCIPLE...

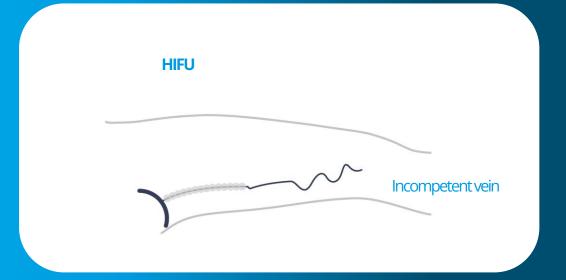
### **ULTRASOUND: FOCUSED ACOUSTIC WAVES**

- A treatment from outside: no incision
- High Intensity Focused Ultrasound (HIFU)

# Spherical transducer Concentrates ultrasound wave to the focal point Focused acoustic wave Produces thermal effect only at the focal point, sparing healthy tissue Localized tissue heating at the focal point

# ... TO APPLICATION

### THERACLION'S SONOVEIN FOR VARICOSE VEINS



- Step by step treatment, **moving along** the vein
- Robot-driven movements
- Real-time ultrasound visualization and control

# FROM ECHOPULSE TO SONOVEIN



### **DEVELOPMENT**

2004 to 2018

**ECHOPULSE**®



Niche markets

······ HIFU for thyroid and ······ fibroadenoma

4,000+ TREATMENTS

### **ACCELERATION**

2019 SONOVEIN® 2020-2021 SONOVEIN® S 2022-2023 SONOVEIN® HD





Large markets



and HD'23 UPG

**ONE PRODUCT UPDATE/YEAR** 

**HIFU** for veins

# **PROOF OF CONCEPT**



# EFFECTIVE AND SAFE TREATMENT OF VARICOSE VEINS



# OVER 2,300 VEIN TREATMENTS TO DATE

- 95% reflux-free\*
- 0 severe adverse event\*\*



# + 18 SITES IN OPERATION IN 12 COUNTRIES

Top centers at more than 100 treatments/year



# + CE MARKING OBTAINED IN 2019

Latest generation of Sonovein in the process to obtain the new MDR CE marking



+ FDA FEASIBILITY STUDY FINALISED FDA Pivotal study started in 2023

The results are as good - if not a little bit better - than some of the results with the more traditional technologies. 95% of patients had a successful healing of the abnormal vein.

All patients felt better.

SONOVEIN really is the next evolution of a completely non-invasive, transcutaneous way of treating vein diseases.

**Dr Steve Elias** - January 2023

(FDA first US trial – principal investigator)

# PROOF OF CONCEPT IN EUROPE THANKS TO STRONG KOL\* PARTNERSHIPS



### **MARKET**

- 22 % of the world vein market
- Heterogeneous access to reimbursement depending on the country

# **EUROPE MARKET PATH**

- Strong and diverse partnerships to refine product and protocol and boost SONOVEIN® awareness
- Reimbursement will be facilitated by US study

# **PROOF OF CONCEPT TODAY**

- Real-life data collection
- Continuous learning
- Market practice representativity
- Commercial relationship and existing recurring revenue
- International awareness through conferences







# ONLY 2 YEARS AWAY FROM FULL THROTTLE COMMERCIALIZATION



# **SONOVEIN TO THE MARKET: A RIGOROUS PATH**

**'23** 

**'24** 

**'25** 

**'26** 

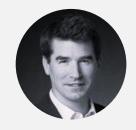
**'27** onwards

| US access (FDA)  | Pivotal Study<br>starts     | Final<br>treatments<br>(Mid 2024)            | Final Results<br>(Mid 2025)                     | FDA Clearance  |                                      |
|------------------|-----------------------------|--|---|--|--------------------------------------|
| China (Furui JV) | Partnership<br>construction | Successful<br>prototyping                    | Manufacturing<br>capability<br>Trial initiation | Global manufacturing<br>platform<br>Clinical trial             | NMPA clearance                       |
| Europe           |                             | refine product and լ<br>ess (Key Opinion Lea | orotocol; 2/ to boost<br>aders partnerships)    |  |                                      |
| Technology       | Al bricks                   | Al + Robotics+<br>acoustics<br>new bricks    | New robotic + Al<br>product on human            | New industrialized<br>platform w/ robotics +<br>Al + acoustics | Full automated<br>Al guided device   |
| Reimbursement    |                             |  |   | Process start in the<br>US                                     | Europe:<br>facilitated by US<br>data |

# THERACLION NEW STORY: A NEW MANAGEMENT TEAM



# A SKILLED NEW MANAGEMENT TEAM (2022-2024)...



Martin Deterre, PhD
CEO (May 2023)
15y. exp
Pixium Vision, Livanova
M.I.T., Polytechnique
Theraclion since Dec. 2020



Laurence Géricot

Chief Financial Officer
(Jan. 2024)
35y exp.
Theradiag, HP,
Europlasma



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Executive Chairman
McKinsey 20y.
Private Equity 13y.
Theraclion since Jan. 2022

Yann Duchesne

# ... SUPPORTED BY A STABLE AND EXPERIENCED TEAM



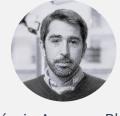
Michel Nuta, MD

VP Veins & Chief

Medical Officer

30+y. exp.

THC since Jan. 2013



Jérémie Anquez, PhD
VP Research & Chief
Scientific Officer
15+y. exp
Telecom ParisTech
THC since June 2010



Vivien Jourdannaud VP QARA 10y. exp Mauna KEA THC since Oct. 2015



Gaylord Tallec, PhD
VP Operations
15y. exp
CEA, lifesearch
THC since Sept. 2016



Marketing Director
10y. exp
Dior, Figaret, EM Lyon
THC since Oct. 2021



29 employees based in Paris, France23 engineers, 6 PhD, 1 PharmD, 1 MD

# THERACLION NEW STORY: NEW STRATEGY FOCUSED ON



# THE US, CHINA AND R&D (1)

### **MARKET**

- Largest varicose vein market in the world: 45%
- High price market
- Homogenous access to reimbursement



- Feasibility study completed
- Pivotal study started
- FDA clearance expected early 2026

### **US TARGETS**

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- Reach 300 high volume medical centers (200 treatments/year) at \$1,200, i.e. \$72m annual revenue
- Reach \$400m-500m annual revenue at maturity



### **MARKET**

- Largest potential varicose vein market in Asia
- Underserved market that could move directly to Sonovein's non-invasive solution to reach so far untreated patients

# CHINESE MARKET PATH & PARTNERSHIP WITH FURUI

- Domestic product development and market access via Furui
- Global manufacturing
- Furui's products sold only in China

# **FURUI PARTNERSHIP MILESTONES**

- Joint-Venture with Furui
- Prototyping
- Registration
- Clinical trial start (1.5-3 years)

# **THERACLION NEW STORY:** NEW STRATEGY FOCUSED ON THE US, CHINA AND R&D (2)



# Finalizing BLOCKBUSTER PRODUCT in 2 years



**ACCELERATE** TREATMENT TIME

**IMPROVE** 

**EASE OF USE** 

From:

1h to 1.5h

**Down to:** 45min or **30min** 

From:

a device for an ultrasound

trained medical doctor

**Down to:** an Al-guided, intuitive

device for a non-specialist



**INCREASE ADDRESSABLE** PATIENT POPULATION

From:

mostly great saphenous\* vein

Up to:

more types of veins, larger, deeper

**KEY ENABLERS** 

AI

**ACOUSTICS** 

ROBOTICS

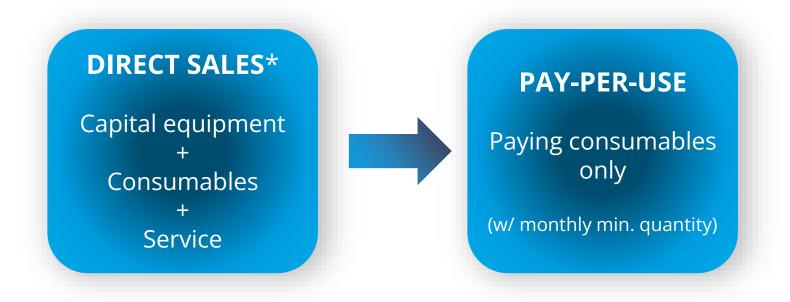
**CLINICAL PRACTICE** 

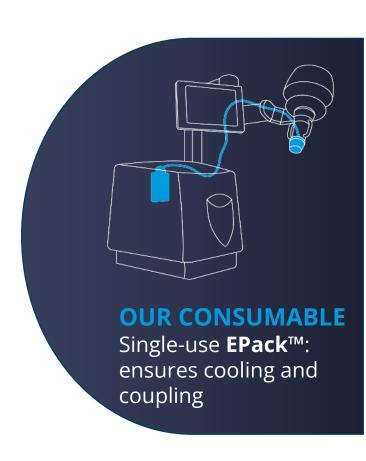
No pro-active commercial expansion before Sonovein's improvements implementation - despite strong incoming demand

# THERACLION NEW STORY NEW BUSINESS MODEL, PAY-PER-USE



# RECURRING REVENUES YEAR ON YEAR VERSUS 1-OFF REVENUES





\* To medical centers, hospitals, clinics

# P&L: NET LOSS OF €3,7 M, DOWN €1,3 M LOW SEASONALITY LEVEL OF R&D SPEND



| En €K                                | 31/12/2022 | 31/12/2023 | Var. % |
|--------------------------------------|------------|------------|--------|
| Turnover                             | 1 235      | 1 822      | 48%    |
| Other Products                       | 132        | 2 095      | 1490%  |
| Total Revenues                       | 1 367      | 3 917      | 187%   |
| 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                     | -6 308     | -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                           | -4 964     | -3 675     | -26%   |

### Decrease of €1,2 M

- Costs decrease and containment in H1 2023: €0,8 M
- R&D seasonality: 0,4 M€ linked with preliminary feasibility study for FDA extra charges in 2022 and pivotal study starting late 2023 with limited costs impact in 2023

 Includes depreciations (€559K)

Depreciation of APAC subsidiary equity and receivables : €1,9 M

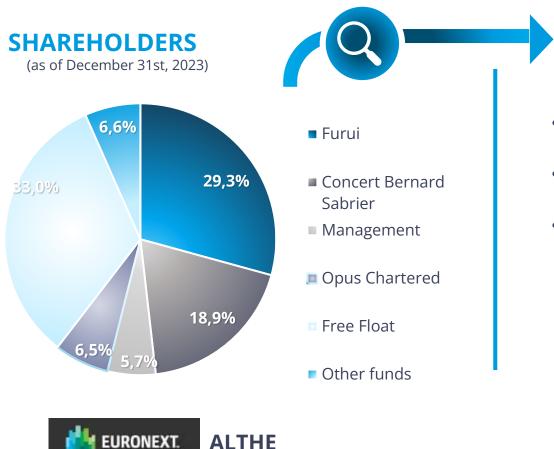
# **BALANCE SHEET 2023**



| K€                                       | 12/31/2022 | 12/31/2023 | Variation |
|--|------------|------------|-----------|
| Non-current assets                       | 4 583      | 2 542      | -2 041    |
| Including intangible assets              | 1 297      | 1 225      | -72       |
| Including tangible assets                | 127        | 106        | -21       |
| Of which non-current financial assets    | 3 159      | 1 211      | -1 948    |
| Current assets                           | 9 360      | 16 122     | 6 762     |
| Inventory                                | 3 055      | 3 055      | 0         |
| Cash and cash equivalent                 | 2 520      | 7 815      | 5 295     |
| Other assets                             | 3 772      | 5 252      | 1 480     |
| Total Asset                              | 13 943     | 18 664     | 4 721     |
| Equity                                   | 545        | 5 647      | 5 102     |
| Non current liabilities                  | 6 537      | 6 290      | -247      |
| Including advances from BPI              | 6 290      | 6 290      | 0         |
| Current liabilities                      | 6 861      | 6 727      | -134      |
| Incl. Accruals for Risk & Curr. Exposure | 25         | 215        | 190       |
| Incl. Loans (PGE)                        | 2 506      | 1 947      | -559      |
| Total Liabilities                        | 13 943     | 18 664     | 4 721     |

# THERACLION NEW STORY NEW SHAREHOLDING STRUCTURE





# FURUI (300049:CH): GENUINE STRATEGIC PARTNERSHIP

- Theraclion's investor since 2016
- China JV created in 2017
- Replication of Echosens' Success:
  - **Echosens (France):** +/-300 employees, global leader in non-invasive liver diagnostics.
  - Furui lead development in China, supports R&D in France and global commercial deployment.
  - Echosens China is a key contributor to Echosens
     Global P&L.

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# SONOVEIN SUCCESS IN VARICOSE VEINS WILL OPEN THE WAY TO OTHER THERAPIES

# THYROID NODULES

\$3.6B market 1,800,000 annual thyroid nodules surgeries WW

Theraclion's historical market

Latest Vein platform can disrupt the Thyroid market

# **BREAST CANCER**

\$20B market, strong growth

Huge potential for HIFU combined with traditionnal therapies: immunology or chemotherapy

Clinical studies ongoing at University of Virginia with Theraclion's device

# **MORE INDICATIONS**

Hyperthermia - Possibility to heat cancer tissue locally prior to radiotherapy

Research programs ongoing

Other indications

### **VARICOSE VEINS**

**Build platform** 

Succeed 1st commercial breakthrough

# **GLOSSARY**



- **HIFU**: High Intensity Focused Ultrasound is a non-invasive therapeutic technique that uses non-ionizing 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

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# THANK YOU!

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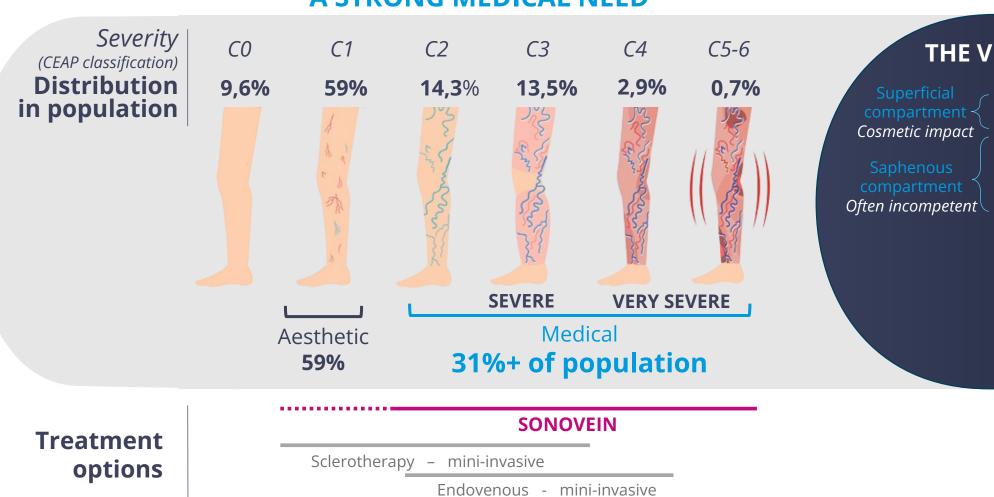


# **APPENDICES**

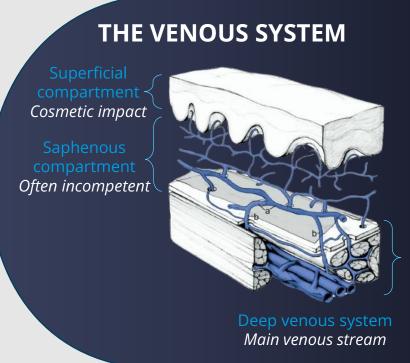
# **VARICOSE VEINS: A WIDESPREAD CONDITION**



# A STRONG MEDICAL NEED



Stripping - invasive



Source: Maurins et al., 2008

# FOCUS ON SHORTENING TREATMENT DURATION



# STANDARD GREAT SAPHENOUS VEIN OVERALL TREATMENT DURATION

