

# Investor presentation July 2016



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### Management Team: Track Record of Success in Healthcare



Jean-Yves Burel
Chairman of the Board of Directors

- Former GE executive with 26 years of experience at GE Healthcare
- Vice-President Marketing & Commercial Operations for GE Healthcare International
- Vice-President Sales GE Healthcare EMEA



**David Caumartin** *Chief Executive Officer* 

- 14 years of experience with GE Healthcare
- Experience of sales, marketing and development of new products in the USA and EMEA at GE Healthcare
- Global Head of Mammography at GE Healthcare, VP for M&A Strategy at Alstom



**Anja Kleber** *VP Marketing & Market access* 

- 12 years experience in marketing & market access for Siemens Medical and Accuray
- 4 years as of Head of Marketing / Market Access for Accuray
- IT graduate of the University of Karlsruhe & theses at INSA Lyon



**David Auregan** *Chief Financial Officer* 

- 16 years of experience in Finance with United Technology, GE Healthcare, Arthur Andersen
- 5 years of experience as CFO of listed company EFESO Consulting
- EDHEC Graduate & MBA from Newcastle Upon Tyne Uni



**Sylvain Yon** *Deputy CEO, VP Research & Development* 

- Co-Founder of Echosens in 2001
- Assistant professor at the French Navy Officer School
- Doctorate in physical acoustics from the Paris VII University and a Degree in engineering from ESPCI



Michel Nuta
MD, Chief Medical Officer

- Endovenous thermal ablation by radiofrequency expert
- 13 years in VNUS, a West Coast start-up later acquired by
  Covidien
- MD degree and Medical management & marketing Master in ESCP



# **Company Profile**

#### Non-invasive technology

- Differentiated, non-invasive technology using high-intensity ultrasound (HIFU) for treatment of breast fibroadenomas and thyroid nodules
- CE marked in 2013; 19 systems placed and growing
- Recurring revenues from disposables and service

#### **Operations**

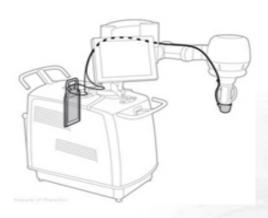
- Based in Malakoff, France
- 34 employees, >50% are dedicated to R&D and clinical trials
- 3 representative offices: Frankfurt, London, Milan
- 1 Branch office opened in Hong Kong (2015)
- Over 100 active patents within 20 patent families (on Echopulse® system and consumable)

#### **Financial summary**

- Listed on Paris Alternext
- ALTHE.PA (ticker) = €7.78 (as of 07/08/2016)
- Market Cap = €37.6 million

#### Our product: the Echopulse®







# Why a capital increase?

#### Build a profitable recurrent business in current markets

- Strengthen German success, first country for Theraclion (9 sites, 1,5 m covered for echotherapy)
- Accelerate conquest of South Korea, (1 EP sold in 2015, authorization to treat expected in H2 2016)
- Expand in CE mark countries (France, Italy, Spain, UK, rest of Europe...)

#### Fund clinical trials to access the biggest countries for current indications

- USA (0,5 m surgeries): FDA submission on Fribroadenoma 3Q'16, Thyroid IDE FDA submission from UVA 2H'16
- China (+/- 2m surgeries): discussion started with Furui, a Chinese HealthCare company and current shareholder of Theraclion (7,8%), to explore possible collaboration to enter Chinese market

#### Expand indications for Echopulse

- Thyroid Cancer: IDE FDA submission from UVA 2H'16: treat & excise protocol for 10 TN & 10 Tca. FUS sponsored study
- Breast Cancer: build on current outcomes in benign nodules for the breast cancer approach, Tübingen University in Germany



# Terms of the rights issue

# Size / Structure

- €9.63 million capital increase with preferential subscription rights (€11.07 million maximum size in case of execution of Extension Clause)
- 1,610,257 new shares issued (which may be increased to a maximum of 1,851,795)
- 1 new share for every 3 existing shares

#### **Pricing**

- Issue price: €5.98 per share
- 18.9% discount to THERACLION' on past 20 days VWAP at July 18, 2016
- 16.8% discount to Theoretical Ex-Right Price (TERP) of €7.19 on same date
- Theoretical value of subscription right: €0.40 per right

#### **Placement**

- France: Public Offer
- EEA (inc UK): Qualified Investors only (which includes regulated entities)

### **Subscription commitments**

• 5 existing shareholders have committed to subscribe for €6.91 million representing around 71,7% of the capital increase of €9.63 million



# **Expected timetable**

22 July

25 July

26 July

**5** August

18 August

22 August

- AMF Visa on the Prospectus
- Press release announcing the terms of the transaction
- Beginning of the subscription period / trading of the preemptive rights
- Closing of the subscription period / end of trading of preemptive rights
- Results of the rights issue
- Settlement / delivery and trading of new shares



Chef de File



# Agenda

- 2015 Highlights and financials
- Theraclion, a specialist in non-invasive tumor treatment
- Commercialization and Geographic Expansion Underway



# **2015 Highlights**

2

x in sales: 1,8M€ vs 800k€ in 2014

3

x more commercial sites: 16 vs 5 in 2014

5

x faster: accelerated treatment with BEAMOTION

6

x more orders signed in 2015: 12 vs 2 in 2014

6

new countries



### Demonstrating accelerated purchase order development



1

Turkey (Penta)



2

Germany (Marienhospital)
Turkey (Penta)







France (AHP)



3

France (AHP and Diaconesses)
Germany (HELIOS)

Full 2014





9

Germany (Paderborn, Bürgerhospital, Bremen, BORAD), Taiwan, Korea, China (University of Hong-Kong), Switzerland (Belinzona), Spain (Madrid), UK (London), Egypt



3

China (University of Hong-Kong), Switzerland (Belinzona), Spain (Madrid), UK (London), Egypt

**Full 2015** 



3

**Germany** (Heilbronn, Coburg) **Italy** (Livorno)



4

**Germany** (Heilbronn, Tübingen, Stephansplatz, Coburg)

**Half 2016** 



Breas



**Thyroid** 

**Strong Half 2016 in terms of number of commercial treatment sites** 



### Strong clinical adoption confirmed



+115% growth in treatment numbers driven by German and Asian thyroid market



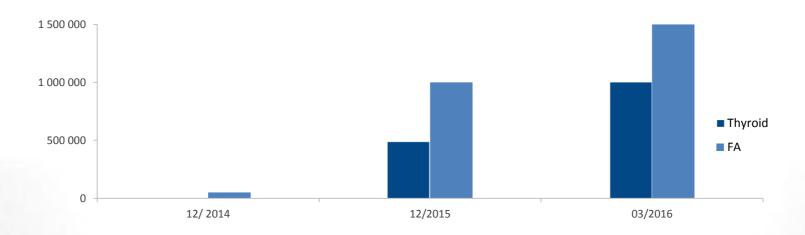
### Establishment of a strong pole of activity in Germany

### **Echopulse offered in Germany**

- 9 sites
- 1.5m covered
- 3 investors



### Acceleration of the number of patients covered by insurers



Strengthened presence in Germany which will boost the growth



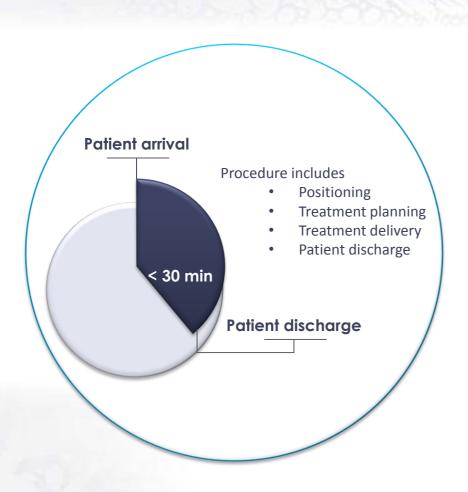
# **Echopulse®** with BEAMOTION Significant reduction of treatment duration



- Optimized energy deposition scheme with moving beam
- With BEAMOTION, treatment requires 7 times less pulses
- With BEAMOTION, treatment is up to 5 times faster



# Echopulse® with BEAMOTION Significant reduction of treatment duration



### **Total procedure duration**

< 30 min

 $[9 - 26 \, min^*]$ 



# **Detailed Group Consolidated Financials**

Profit & Loss			
In K€	31/12/2015	31/12/2014\	/ar. (%)
Revenues	1 531	800	91%
from equipment sales	1 412	774	83%
from equipment rent	75		
from consumables	40	26	54%
from services	4		
Subventions	61	14	337%
Other products	5	6	-10%
Operating income	1 597	820	95%
External charges	-4 815	-2 787	73%
Other operating expenses	-4 023	-2 992	34%
Net operationg income	-7 241	-4 959	46%
Financial income	-178	-183	-3%
Extraordinary income	180	-18	-1098%
Research tax credit	826	526	57%
Net result	-6 412	-4 634	38%
Average number of employees (FTE)	30	22	36%

Balance Sheet			
In MC	21/12/2015	21/12/2014\	(n. 10/)
In K€	31/12/2015	31/12/2014 V	ar. (%)
Net fixed assets	1 894	1 426	33%
Current assets	7 363	6 858	7%
inventories	754	1 298	-42%
cash and cash equivalent	3 753	4 272	-12%
Total assets	9 256	8 284	12%
In K€	31/12/2015	31/12/2014 V	ar. (%)
Equity	756	2 774	-73%
Other equity	5 005	3 955	27%
Other debt	3 495	1 555	125%

Comments					
Extraordinary inc.	includes	227 K€ from	London		

9 256

8 284

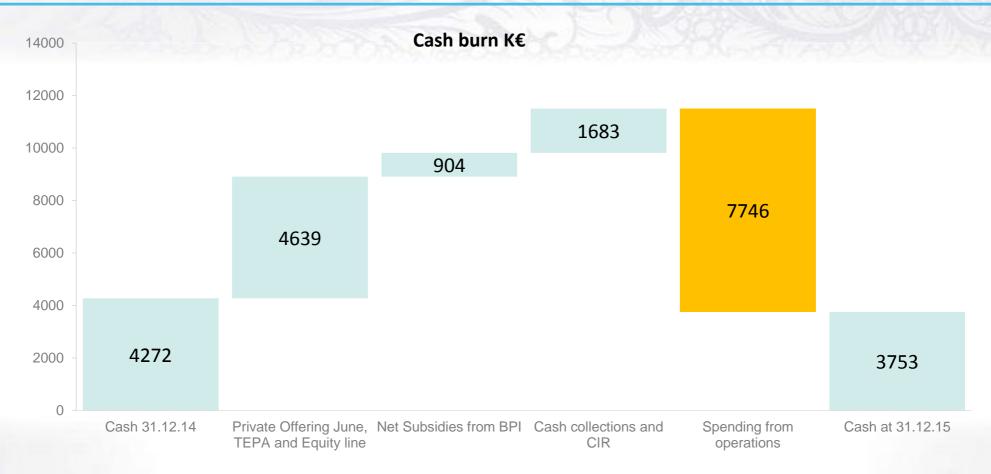
Equity: Private placement in June 2015 raised about €4 M R&D expenses fully absorbed in P&L: € 2,7 M

**Total Liabilities** 



12%

# **Cash Burn Analysis**



• Since March 18, 2015, an equity line financing with Kepler Cheuvreux has been set up. Kepler Cheuvreux has committed to subscribe to successive capital increases, issued by tranches over the next 36 months, within the global limit of 400,000 new Theraclion shares, or 10.6% of the Company's share capital as of March 18, 2015. This could allow Theraclion to receive €4.3 million\* in equity at the stock price as of March 18, 2015. As of June 30, 2016, potential subscription from Kepler Cheuvreux of 255,500 new shares.

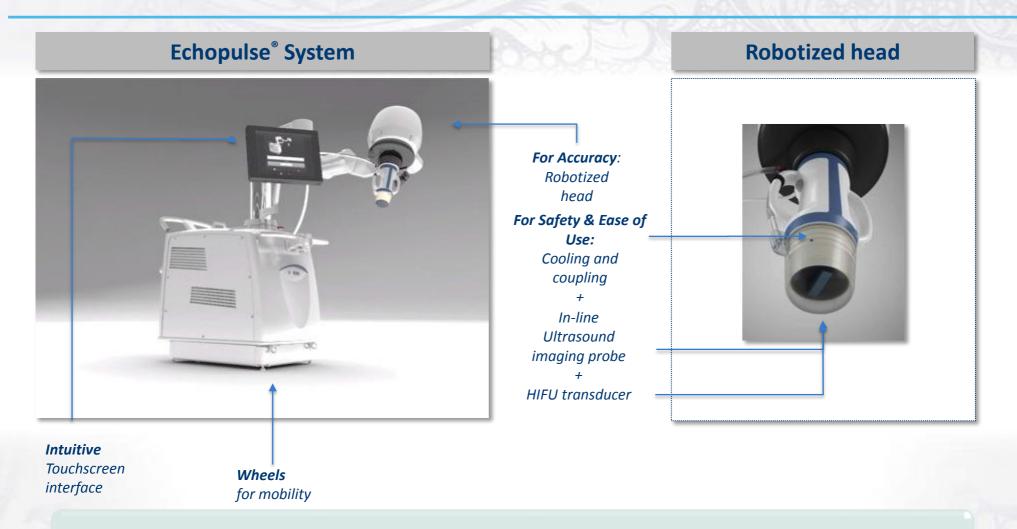


# Agenda

- 2015 Highlights
  - Theraclion, a specialist in non-invasive tumor treatment
- Commercialization and Geographic Expansion Underway



# **Echopulse®: Mobile Robotic Outpatient Tumor Treatment**



**Compact Imaging and Therapy System Provides Ease of Use** 



### Surgery without surgical procedure

- Breast Fibroadenomas and Thyroid Nodules
- Non-Invasive Technology Provides Attractive, Effective
  Alternative to Surgery and Invasive Ablative
  Technologies
- Compact, Mobile and Less Expensive



- Physician Offices
- Patient houses
- Potential additional indications Include Cancer



Breast fibroadenoma



Benign thyroid nodules





### **Echopulse® System Benefits All Three Major Stakeholders**

#### **PATIENTS**

- ✓ One simple outpatient procedure
- NO general anesthesia
- ✓ NO radiation
- √ NO recovery time
- √ NO scarring
- ✓ Eliminates:
  - Post-surgical risks of infection
  - Difficulty with breast-feeding
  - Life-long levothyroxine
- Patient portal; 12k visits/month



http://www.echotherapie.com

#### **PROVIDERS**

- ✓ Attracts new patients
- ✓ Outpatient day procedure
- √ Simple-to-use
- ✓ Reduced treatment time versus traditional surgery
- ✓ Highly mobile device allows organizational efficiency
- ✓ Least expensive HIFU System



#### **PAYORS**

- √ No hospitalization costs
- √ No general anesthesia
- ✓ Avoids post-surgical infections and complications
- ✓ Avoids costly hormone replacement medication
- ✓ Attractive to employers and patients: minimal time off work





# **Echopulse offers substantial benefits versus alternative therapies**

	Echopulse	Traditional Surgery	Min. invasive surgery	
Metric		3-7 cm	1.3 – 2.5 cm	
Incision Length	NONE	0 cm   1 cm 2 cm 3 cm 4 cm 5 cm   6 cm 7 cm	0 cm   1 cm 2 cm 3 cm 4 cm 5 cm   6 cm 7 cm	
Pain after Treatment	NONE	Moderate to significant	Moderate	
Anesthesia	Local or no anesthesia	General anesthesia	Local or general anesthesia	
Duration	30-45 minutes	1 – 2 hours	30 – 45 minutes (breast)	
of procedure			2h (thyroid)	
Length of hospital stay	NONE	1 – 3 days	1 day (-24-)	
Recovery time	IMMEDIATE	5 –10 hours	2 – 3 hours	
Scarring	NONE	xx	X	



### Clinical Results in Peer-Reviewed Journals

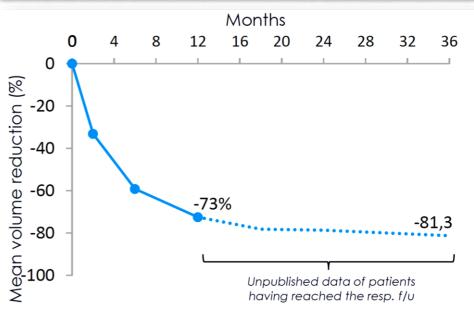
# Multi-center, international 42-patient study

- Significant Breast Fibroadenoma volume reduction at 12 months (unpublished 36 month data, continues trend)
- No ultrasound evidence of regrowth
- Pain / discomfort completely resolved at end of followup
- High patient satisfaction with excellent cosmetic results
- Well tolerated procedure with no serious adverse events

#### Further clinical trials:

- Underway: UVA, Tübingen University, King's College London
- Finalization stage of other trials in US, France, Germany
- Complete destruction of nodules in 90% of patients demonstrated by first "treat and biopsy" study results\*
- Eight publications in leading journals

#### Journal of Therapeutic Ultrasound 'Article of the month'



Ultrasound-guided High-Intensity-Focused-Ultrasound treatment of breast FA - a multicenter experience R. Kovatcheva, et al. Journal of Therapeutic Ultrasound. 2015 Jan 22;3(1):1









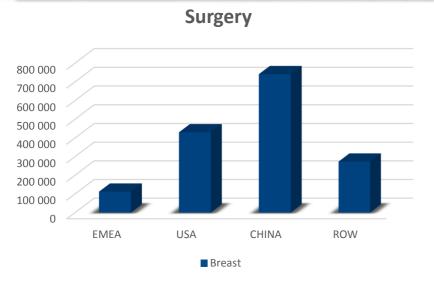




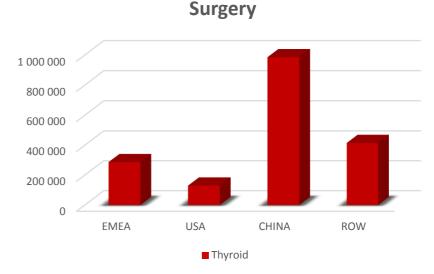


### Theraclion is Focused on Two Large Indications

### Commercialization efforts will focus on three large markets







Sources: (1) Cooper et al, Thyroid 2009, National Cancer Institute, Globocan, bases de données sanitaires France et Allemagne

#### **Rational (conservative)**

- 40-50% of surgery will be replaced by Non- or Minimally-Invasive procedures by year 10 (less in China)
- One system will treat in average 120 patients per year

Conservative 20% Penetration would mean over 1,000 Systems Sales in 10 years Goal: 60 system placements by end 2017



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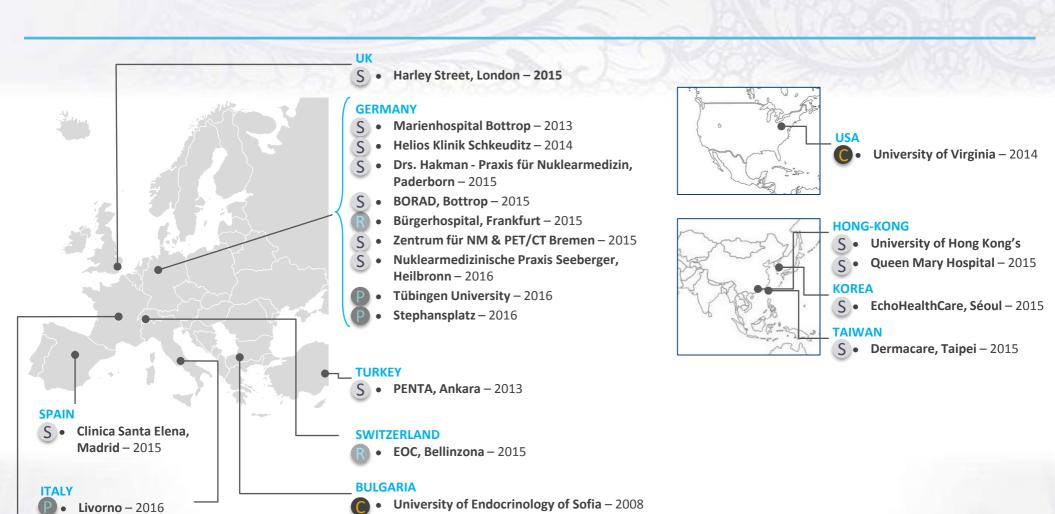


# **Commercialization Process is Well Underway**

- **Established Direct Sales in 4 Largest Markets in EMEA: Germany, France, UK, Italy**
- Some Reimbursement in Germany & Italy; French Authorities Studying
- New French Initiative ("Forfait Innovation") funds medical innovation; Theraclion submission in January 2016 highlighted by French Health Minister
- Opened Asia Office in Hong Kong with VP, Asia: 3 Asian sales in 2015
- Focusing on Prestigious Academic & Private Centers to Drive Market Penetration
- Clinical Study in U.S. to begin shortly



### **Echotherapy Centers Worldwide as of June 2016**





S • American Hospital of Paris - 2014

• Groupe Hospitalier DCSS – 2014











### Theraclion Goal: Establish Echotherapy as a Standard of Care

- Engage Key Opinion Leaders and medical societies in order to get specific codes for echotherapy
- Initiate transitory reimbursement solutions on country by country basis

**Clinical Proof** 

CE Marked
350 Treatments

- Generate initial sales with private "Early Adopters"
- Use Echopulse® as marketing weapon

**Business Proof** 

Achieve 60 system placements with early adopters

4,500 Treatments

- Build-out the commercial network
- Enter the US and China markets

**Echotherapy as a standard of care** 

1,000 WW installations for Breast Fibroadenomas & Thyroid Nodules

Over 500,000 Treatments in 10 years

**New Indications** 

Scientific concept
HIFU

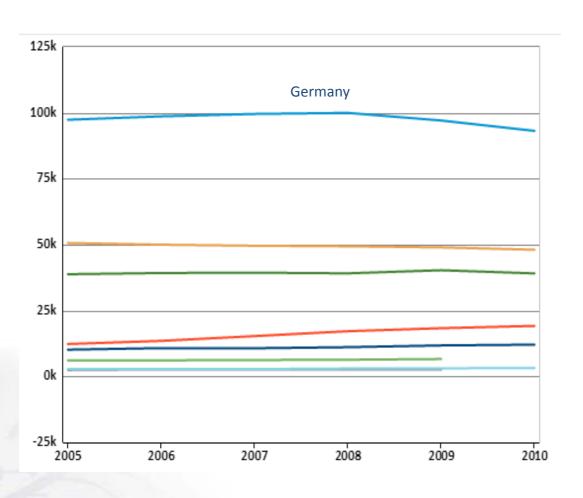


19 early adoptors to date\*

### Germany: The biggest thyroid market in Europe



### **Annual # of thyroidectomies per country**



#### + 50 000 treatments with radioactive iodine

- · Treatment of hot nodules
- Treatment in inpatient settings

- Italie Thyroidectomy In-patients (total number)
- Allemagne Thyroidectomy In-patients (total number)
- Espagne Thyroidectomy In-patients (total number)
- France Thyroidectomy In-patients (total number)
- Royaume-Uni de Grande-Bretagne et d'Irlande du Nord -Thyroidectomy - In-patients (total number)
- Pays-Bas Thyroidectomy In-patients (total number)
- Belgique Thyroidectomy In-patients (total number)
- Suisse Thyroidectomy In-patients (total number)



### **Germany: A strong year for sales in 2015**



### All 2015 sites treat thyroid, 4/5 are nuclear medicine



Jose Abellan-Martinez

VP, Germany & Central Europe

- More than 30 years experience in healthcare BD
- GE Healthcare Sale & Marketing Leader
- Experienced in Vascular, Cardiology & Radiology
- Integration leader and manager of Image Diagnose



Marienhospital, Bottrop – 2013

Helios Klinik, Schkeuditz – 2014

**Drs. Hakman NKM, Paderborn** – 2015

**BORAD, Bottrop** – *2015* 

**Bürgerhospital, Francfort** – 2015

**Zentrum für NM & PET/CT, Bremen** – 2015

Nuklearmedizinische Praxis Seeberger, Heilbronn – 2016

**Tübingen University** – 2016

Stephansplatz, Hamburg – 2016



# **Germany: Reimbursement is key**



### Very successful start via integrated care contracts

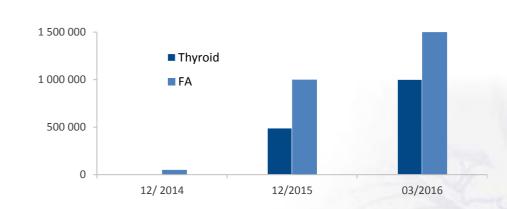
#### **Integrated care contracts**

- Offer insurers possibility to differentiate from competition
- Offer
  - « Innovation »
  - « Patient's choice »
  - « Cost-efficiency »

#### Agreements with Insurance companies



#### **Covered German population**

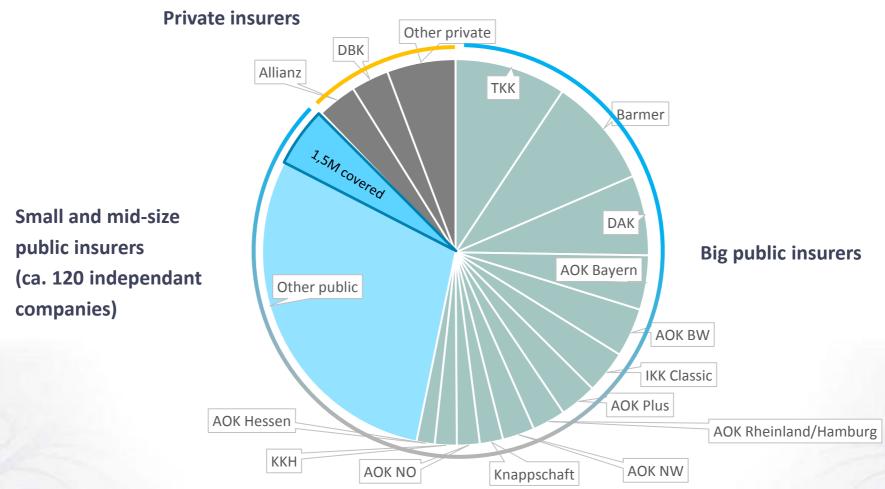




### Germany: Next Step with global approach to Insurer Market

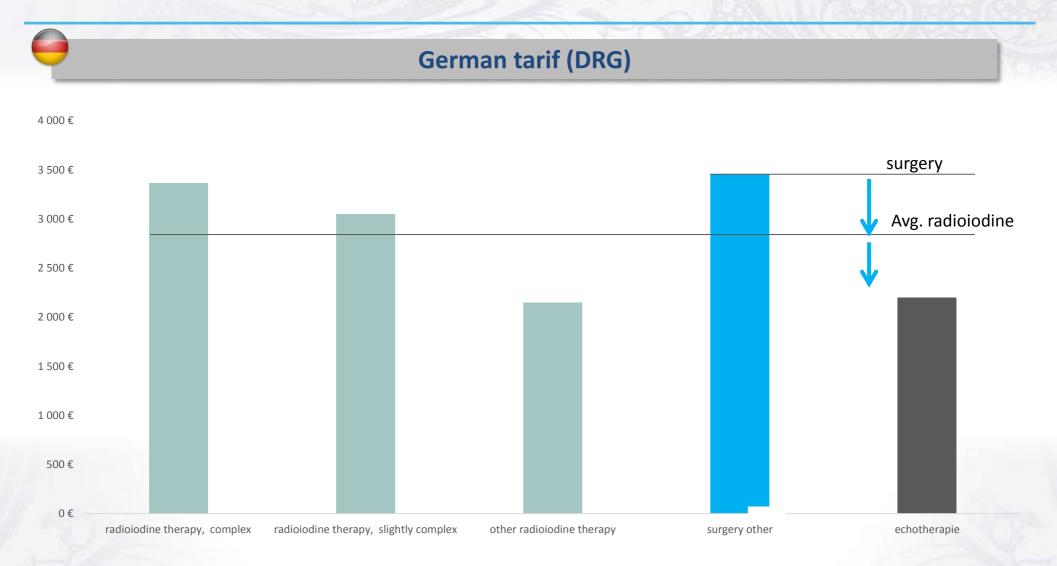


### Approach with different types of insurers





# **Germany: A cost effective solution in echotherapy**





# Germany: Strong key opinion leader support





Prof. Hahn, Tübingen University

Certified Breast Center



Dr. Kolberg, Marienkrankenhaus Bottrop

- Certified Breast Center
- Innovation track record (Intrabeam, MR HIFU...)

### Nuclear Medicine



**Prof. Luster, Marburg University** 

- Head of thyroid section endocrine society, Head of thyroid section Nuclear medicine
- Co-leader of clinical study



Prof. Grünwald, Frankfurt University

- Several publications by Uni Frankfurt
- President of German NucMed professional community





Dr. Vorländer, Bürgerhospital Frankfurt

 Certified center of excellence for thyroid surgery, 1400 surgeries/per year



### **Germany: Intense media activity**

### 22 Articles in 6months – reaching 20 Mio online and 20 Mio printed press readers



Franen entwickelt sich im Laufe des Lebens ein Tumor, der gutartig

Moderne Behandlung mit Ultraschall:

te Gewebe als Fremdkörper wahr und baut es in der Heilungsphaist. Auch wenn ein Fi-broadenom das Leben mit Echopulse werden pie können wir gutarti-

der Echo-Theranie ist: Sie wird mit Hilfe überwacht. Ein spezielles Kühlsys tem sorgt zudem Haut bei dem einmaligen



Deutschland können somit vom nicht-invasiven Verfahren als schonende Alternative zur Operation, dass ganz ohne Schnitt auskommt und keine Narben hinterlässt profitieren. Wenn Frauen einen ist der Schock zunächst einmal groß. Auch wenn sich herausstellt dass es sich um einen gutartigen Tumor handelt, sorgt die Frage nach der

erstatten ab sofort ihren Pati-

entinnen im Rahmen eines

Sondervertrages die Kosten

für die Echotherapie bei Fib-

roadenomen, der häufigsten

gutartigen Veränderung der

#### Opera-Nicht invasive Ultraschall-Thera bei Fibroadenomen

adenome nicht invasiv therapiert den. Dabei werden Ultraschallw gebündelt und der entstehende Br punkt gezielt auf das gutartige Tur gewebe gerichtet. Im Brennpunk hitzt sich das Gewebe auf 85°C, wird bei zerstört und in der Zeit nach dei handlung abgebaut, da es vom O nismus als Fremdkörper wahrgen men wird. Es entstehen keine Na

Fünf Betriebskrankenkassen om, das etwa 10 % der Frauen im Lauf des Lebens entwickeln Damit könnte in Deutschland bald Schluss sein, denn immer mehr Krankenkassen übernehmen die Kosten für die Behandlung

mit der Echotherapie.

Echotherapie: Mit Ultraschall gegen gutartige Brusttumore

Bei der Echotherapie werden die Schallwellen gebündelt. ähnlich den Sonnenstrahlen unter einer Lune Werden diese Bündel dann gezielt auf ein Tumorgewebe gerichtet, entsteht ein Brennpunkt. In der Folge erhitzt sich der Knoten auf 85 Grad und schmilzt förmlich unter der Behandlung. Der Organismus nimmt das so zerstörte Gewebe als Fremdkörper wahr und baut es ung. So nach und nach ab. Eine Be-Mittels Echotherapie können Froaden- sonderheit der Echothera-

gnostischer Ultraschallbilder überwacht. Diese Echtzeitüberwachung sorgt für eine Millimetergenaue Behandlung und stellt sicher, dass umliegendes Gewebe optimal geschont wird. Ein effizientes Kühlsystem sorat dafür, dass die Haut bei dem einmaligen Eingriff von 20 unter lokaler Betäubung keinen Schaden nimmt. Einzige bislang bekannte Nebenwirkungen: eine vorrübergehende Schwellung oder Ver-

Stelle, die sich aber in der Rewieder zurückbildet.

Narbenbildung

ambulante Behandlung unter lokaler Betäubung Echtzeitkontrolle mittels Ultraschallbildern

kurze Behandlungsdauer (20 Min. bis 1.5 Std.) und schnelle Erholung

Angeboten wird die Echotherapie aktuell in Deutschland im Marienhospital Bottrop und der HELIOS Klinik Schkeuditz, die beide bereits Patientinnen erfolgreich behandelt haben.

härtung der behandelten stattung der Echotherapie durch

gel nach wenigen Vergrößerte Schilddrüse: Hitze statt Skalpell



teiserkeit – auch gutartige Schilddrüsenknoten verursachen Beschwerde Eine Operation bringt Abhilfe, ist aber mit Risiken verbunden. Neuere /erfahren sind schonender und sicherer: Bei den sogenannten



### Therapien gegen Krebs

Harmlose Knoten

gon, ein Edel-Gas durch die Nadel direkt in den Tumor. Die Spitze wird dabei bis zu Minus 185 Grad kalt. Um die Nadel herum entstehen Temperaturen von bis zu -40 Grad. Nach acht Minuten hat sich mitten im Tumor ein 2 bis 4 cm großes Eiskristall gebildet. Der Tumor ist quasi komplett eingefroren Das Helium taut das Eis wieder hauptsächlich bei Tumoren in der Leber, den Nieren oder in der Prostata angewandt. Doch diese Methode stößt auch an Grenzen. So eignet sie sich nur



E Selektive Interne Radiotherapie Für Patienten mit bösartigen Lebertumoren, die nicht für Tumore mit einer Größe mit lokalen Verfahren - wie z. zwischen 1 und 5 cm – nur in
der Niere kann man auch grö
Ren Corche in in an auch grö
ger Therapie behandelbar sind ßere Geschwulste behandeln. und nicht mehr auf eine Che-

de Option. Dabei werden mehrere Millionen kleiner radioaktiver Kügelchen über einen kleinen Leistenkatheter in den Körper eingebracht. Sie gelangen mit dem Blutstrom direkt in das gut durchblutete Tumorte Strahlung mit maximal 11 Millimeter Reichweite aus. Tumorgewebe wird so von innen lungsquote bei fast 100 Prozent. heraus zerstört oder zumindes verkleinert. Das den Tumor umgebende gesunde Leberge webe erholt sich rasch von dieser Behandlung - im Gegensatz

zur Standart-Strahlentherapi

Körper liegen, an besonder oder herkömmlicher Bestrah-lur Bid 003. jog Typ: JPEG-Bid Ge-Joseisyöße: 336 kB

gewebe. Von dort senden die ist der Nutzen von Ionen etwa adioaktiv beladenen Mikro- für bösartige Speicheldrüsen kügelchen über mehrere Tage und Knochentumore an der hinweg eine lokale hochdosier- Schädelbasis – so genannte Chordome und Chondrosarko me. Bei letzterem liegt die Hei-



#### **GUT ZU WISSEN**

#### Sondervertrag für Echotherapie

Mehrere Betriebskrankenkassen erstatten ihren Patientinnen im Rahmen eines Sondervertrages die Kosten für die Echotherapie bei Fibroadenomen, der häufigsten gutartigen Veränderung der weiblichen Brust. Bei der nicht-invasiven Echotherapie werden Schallwellen gebündelt. Werden diese Bündel gezielt auf ein Tumorgewebe gerichtet, entsteht ein Brennpunkt. In der Folge erhitzt sich der Knoten auf 85 Grad und schmilzt. Der Organismus nimmt das so zerstörte Gewebe als Fremdkörper wahr und baut es nach und nach ab. Die Echotherapie wird mit Hilfe von Ultraschallbildern überwacht. Diese sorgt für eine Millimeter-genaue Behandlung und stellt sicher, dass umliegendes Gewebe geschont wird.



### **Market Access – European Markets**



#### **France**



### **United Kingdom**



### Italy

### "Forfait Innovation": new innovation financing decree published in 2015

- MoH launched tool to facilitate market access
  - Financing of a study to prove missing evidence
- Therclion was first company to submit
  - Show clinical non-inferiority and economical superiority





Michael Leach
VP, UK & Northern Europe

- More than 20 years experience in healthcare BD
- NHS Lead radiographer
- GE & Nuffield Business developer
- Entrepreneur in Managed Equipment Service in UK

• First sales in prestegious Harley Street Clinic



**Giuliano Laghi** *VP, Italy & Southern Europe* 

- Strong experience in sales, marketing and development of radiofrequency (RF) and ultrasound products in the field of surgical technology
- 12 years experience at Johnson & Johnson
- From 2010 to 2014, Sales and Marketing Director of the Italian diagnostic ultrasound division of Toshiba

Reimbursement by FASI insurance for HIFU treatments (2K€ for breast treatment)

Addtl. Italy opportunity for regional KOLinitiated reimbursement



### Market Access – Asian Markets

#### Asia



**Dennis Guo**VP Asia

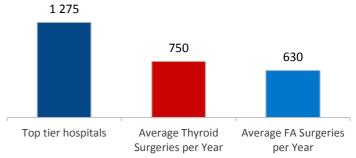
- Based out of the new Asia office in Hong Kong since March '15
- 15 years of healthcare business development experience in Asia

#### **Business Development**

- Distributors
  - Korea
  - Singapore
  - Taiwan
  - ... More to come
- Installations /sales to date
  - Hong Kong
  - Korea
  - Taiwan
- Strong regional momentum
  - Non-invasiveness
  - Out-of-Pocket payment



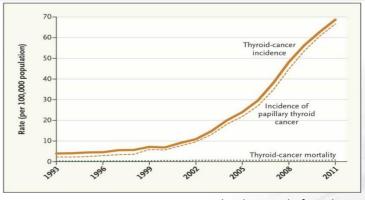
#### **Surgeries of Thyroid and FA in China**



China Hospital Data Base 2012



#### **Thyroid incidence in Korea**



New England Journal of Medicine



# Preparing the ground for successful U.S. market entry

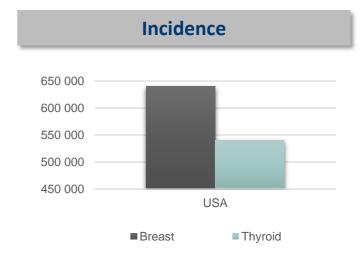


#### **USA**

- Investigational Device Exemption Granted Feb. 2014
  - U. of Virginia (UVA) clinical trial for Safety & Efficacy data (on-going)
- Specific-Patient Population
  - Hispanic and Afro-American women: specific risks for Fibroadenoma

#### **Market Entry Strategy**

- Clinical Trial for FDA 513(k) Submission
  - Multi-center, prospective single-arm clinical trial planned: UVA, Columbia, Bellevue/NYU
  - Endpoints likely to include Patient-Reported Outcomes
  - Patient follow-up may be 12 months
- First indication: Breast Fibroadenomas; Thyroid to follow
- Work with both surgical and radiology communities to validate Echopulse and to reflect value of procedure in new CPT code
- Deploy instruments before market-approval to support science and eventual rollout
- Initial site selection to be based on key criteria such as financial incentives, academic centers
- Intense after-sales and reimbursement support to make initial sites a success









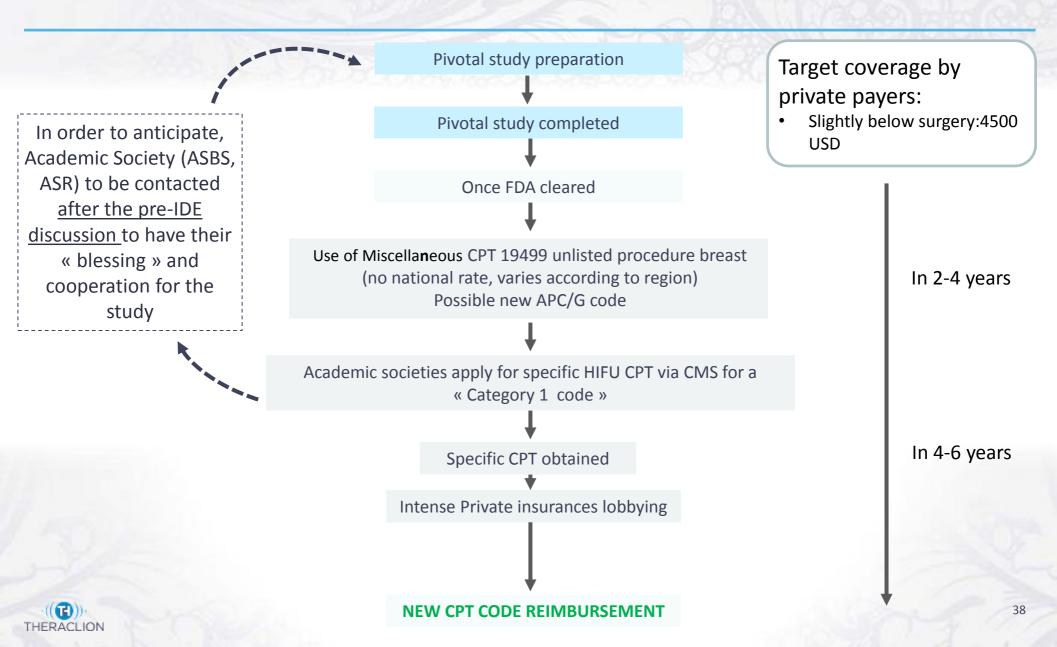
Dr. David Brenin UVa/Charlottesville



Dr. Sheldon Feldman NYPH/Columbia

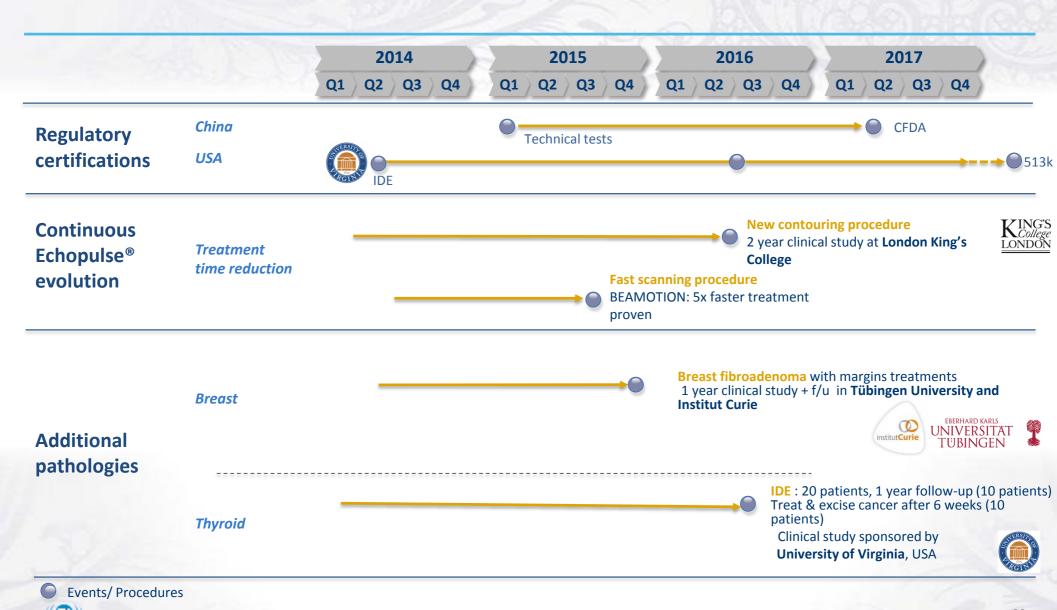


# Roadmap through FDA clearance to new CPT Code



# Business Strategy: Key milestones and roadmap

THERACLION



### **Investment Thesis**

- Large Existing Market and Demand for Non-Invasive Ablation
- Patented Mobile Technology Greatly Increases Ease of Use
- Excellent Clinical Results with First Two Indications; Many Potential Applications
- Approved in Europe; Focusing Now on Asia and US Regulatory Processes
- Commercialization and Geographic Expansion Underway
- 2015: doubling sales, tripling commercial sites... to be continued in 2016





# **BACK-UP SLIDES**

# Shareholding structure and share information

#### Stock information (July 8th, 2016)

Alternext Paris

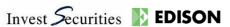
Ticker: ALTHE

ISIN code: FR0010120402

• Stock price: 7.78 €

• Market Cap.: 37.6 M€

• Sell side coverage:

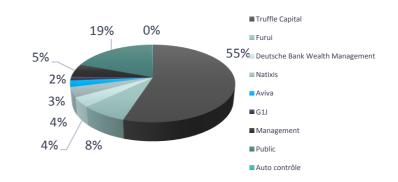






**ALTHE** 

#### Shareholder structure (as of July 8th, 2016)



### **Stock price**



#### **Contacts**

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Directeur Financier

Tel.: +33 (0)1 55 48 90 70 David.auregan@theraclion.com

**NewCap:** Communication financière

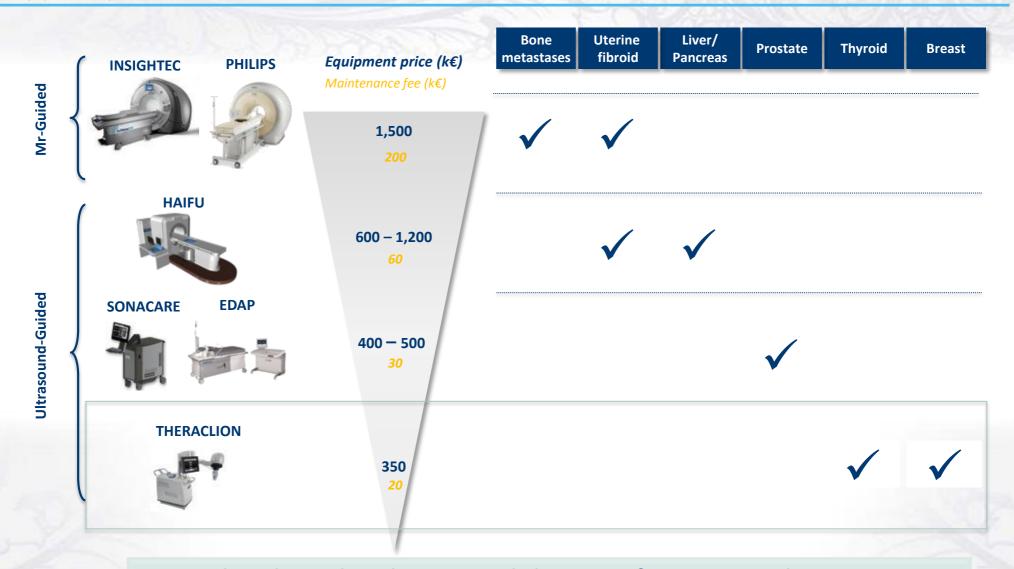
et Relations investisseurs

Emmanuel Huynh / Valentine Brouchot

Tel.: +33 (0)1 44 71 94 96 theraclion@newcap.eu



# Theraclion is the only player in both thyroid and breast treatment





# Theraclion, the only HIFU\* player for thyroid and breast



RF\*\*/ Laser/ Cryoablation



- Novian Health
- AngioDynamics
- Icecure
- Galil Medical
- Sanarus

**Vacuum Biopsie** 



- Bard
- Hologic
- Mamotome

Surgery





### Publications in leading scientific journals (1/5)





#### Journal of Therapeutic Ultrasound – Thyroid nodules

Dr Korkusuz (Frankfurt)

Early assessment of HIFU\* treatment of benign thyroid nodules by scintigraphic





Dr Korkusuz (Frankfurt)

Local thyroid tissue ablation by HIFU\*: Effects on thyroid function and first human feasibility study with hot and cold thyroid nodules



#### **Expert Review of Medical Devices** – Breast fibroadenoma

Dr Cavallo Marincola (Roma)

HIFU\* in breast pathology: non-invasive treatment of benign and malignant lesions



#### Journal of Therapeutic Ultrasound – Breast fibroadenoma

Dr Kovatcheva (Sofia)

Ultrasound-guided HIFU\* treatment of breast fibroadenoma – a multicenter experience



#### Journal of Therapeutic Ultrasound – Thyroid nodules

Dr Korkusuz (Frankfurt)

Volume reduction of benign thyroid nodules three months after a single treatment with HIFU\*



#### Radiology - Thyroid nodules

Dr Kovatcheva (Sofia)

Ultrasound-quided HIFU\* Ablation of Benian Solid Thyroid Nodules: Initial Clinical Outcomes



#### **Röfo** – Thyroid nodules

Dr Korkusuz (Frankfurt)

Localized thyroid tissue ablation by High Intensity Focused Ultrasound: Volume reduction, effects on thyroid function and immune response





Markus Hahn (Tübingen)

Thermosurgical Ablation of Breast Fibroadenoma. First experiences with a HIFU system



Note: (\*) HIFU: High-Intensity Focused Ultrasound.

# Publications in leading scientific journals (2/5)

### Senologie\* – Breast fibroadenoma



#### Deutsche Gesellschaft für Senologie

#### **Advantages of HIFU**

Complete ablation or significant volume reduction in all patients, compared with baseline values

Disappearance or significant reduction of symptoms

**No recurrences or incidences of regrowth** observed for up to 12 months post-treatment

Very well tolerated by patients

**Scar-free process:** 

- good cosmetic outcomes
- avoiding complications associated with surgical incisions

Painless procedure should local analgesia be correctly administered

High patient satisfaction

#### **Material & Methods**

- 27 cases
- Maximum size 25 mm
- Outpatient setting under local analgesia
- Overall duration: 30 45 min

#### **Limitations of HIFU**

- Results not noticeable immediately
- Honest doctor-patient communication needed to avoid overly optimistic expectations
- Not every FA can be treated (ex.: excessively large FA)
- Occasional transient indurations caused by small thermo-induced inflammations of tissue

#### **Conclusion**

"Histology performed 12 months after treatment was able to show absence of vital tissue in 90% of cases. The technique which is very easy to use could be envisioned for breast cancer treatment in the short-term future."



Pr. Markus Hahn, senior author within the Tubingen

### Publications in leading scientific journals (3/5)

Radiology:
A major medical and international publication

### **Radiology\*** – Thyroid nodules

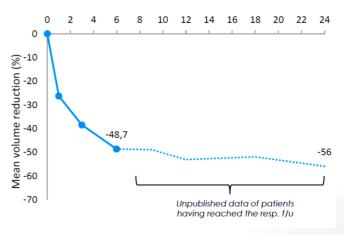
# Radiology

- Ablation effectiveness
- 1 treatment only
- Favorable cosmetic and safety outcomes
- Procedure preserving skin integrity and thyroid function

#### **Material & Methods**

- 20 patients: 24 65y
- Volume reduction assessed after 3- to 6-month follow-up

#### **Volume reduction**



Mean volume reduction over time (% vs. months)

Echopulse® postoperative results confirmed at mid-term by the nodule volume assessments



# Publications in leading scientific journals (4/5)

Elected article of the month

### Journal of Therapeutic Ultrasound\* - Breast fibroadenoma

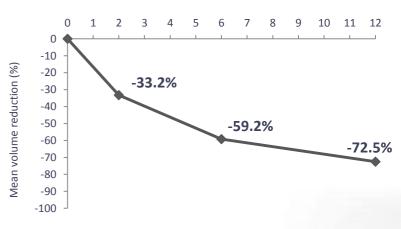


- Ablation effectiveness proven by significant breast fibroadenoma volume reduction at 6 and 12-month follow-up
- Persistent decrease in fibroadenoma volume for all cases
- No ultrasound evidence of regrowth
- Symptoms reduction with pain and discomfort related to fibroadenoma completely resolved at the end of the follow-up
- High patients' satisfaction with excellent cosmetic results
- Well tolerated procedure with no serious adverse events

#### **Material & Methods**

- 42 patients: 16 52y
- Follow-up: 2, 6 and 12 months
- Multicenter and international study

#### **Volume reduction**



Mean volume reduction over time (% vs. months)

Results showing long-term effectiveness and safety of Echopulse®



# Publications in leading scientific journals (5/5)

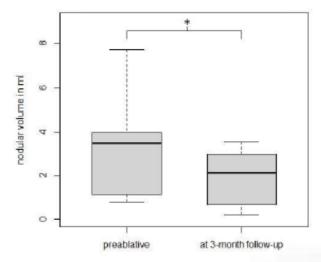
### Journal of Therapeutic Ultrasound\* – Thyroid nodules



- Median volume reduction of about 50% 3 months after treatment
- Nodule volume reduction in all patients
- Treatment well tolerated by all patients
- No serious adverse event

#### **Material & Methods**

- 9 patients: 36-80 year
- Treatment on an outpatient basis with local or no anesthesia



Median nodular reduction within 3 months after HIFU treatment: 0.7 ml [0.4 - 4.7ml]



### **Forfait Innovation**

### **Upcoming Submission**

#### New tool for the reimbursement of innovation for:

- Medical innovation: a key factor in the improvement of the health of French people
- French MedTech: a source for innovation and jobs creation

### **Open to submission since August 2015**

- No eligible file submitted
- Theraclion ready to submit



Marisol Touraine French Health Minister

#### Tumor ablation with ultrasound-guided ultrasound: 10% cheaper than surgery

- Less post-operative pain
- Improved quality of life
- Potentially the only option for patients with multiple fibroadenomas



# KOLs See Echopulse® as an Exciting Innovation



"In my opinion, it is a very good method. **Patients are interested because it allows them to avoid a surgical intervention** for this benign pathology."

> Roussanka Kovatcheva - Professor of endocrinology University Hospital of Endocrinology of Sofia – Bulgaria





"In the HIFU treatment of breast fibroadenoma, first results are encouraging for an outpatient technique **very well tolerated** with significant fibroadenoma's volume reductions."

> Marc Abehsera - Radiologist Americain Hospital of Paris-France





"We are pleased now, based on our experience with this new brand, to offer women with benign mass in the chest a new high quality and non surgical method. The successful clinical trials testify for the high therapeutic value of Echopulse."

> Hans-Christian Kolberg – Chief of the Department of Obtetrics and Gynecology Marienhospital Bottrop - Germany





"To date, the Echopulse device has performed well on the patients we have treated in the fibroadenoma study. It is my hope, given good results in the current study, that in the future we will be able to test the efficacy of focused ultrasound ablation to treat malianant tumors of the breast in the US."

University of Virginia





"After traditional surgery and mini-invasive surgery, echotherapy now pioneers non-invasive surgery"

David Breninn, MD - Breast surgeon

Richard Villet - Breast surgeon Hôpital des Diaconesses - France





"Providing the possibility for non-invasive treatment avoids unnecessary costs to the healthcare system in general as costly surgical interventions will be avoided. "





### **Board of Directors**



Jean-Yves Burel
Chairman of the Board of Directors

- Former GE executive with 26 years of experience at GE Healthcare
- Vice-President Marketing & Commercial Operations for GE Healthcare International
- Vice-President Sales GE Healthcare EMEA



PhD. François Lacoste *Administrator* 

- Co-Founder of Theraclion
- 25 years experience as an engineer in R&D for projects in the field of HIFU/non-invasive therapies
- Director R&D at EDAP TMS for 15 years



**Samuel Levy** *Administrator* 

- Co-founder and President of Allurion Technologies in 2009
- Graduate from Yale and Harvard Medical School



Wolfram Eichner
Administrator

- 25 years experience in the pharmaceutical field (Beiersdorf AG and Fresenius Kabi)
- Since 2011, Manager and Analyst at Apus Capital, a German investment fund



**Dr. Philippe Pouletty** *Permanent representative of Truffle Capital* 

- Co-Founder and General Partner of Truffle Capital
- Founder of 3 biotechnology companies in Europe and the US
- Member of the Board of 14 biotechnology companies and medical device in Europe and North America
- Doctor of Medicine (University Paris VI) and postdoctoral researcher at Stanford University



Vincent Gardès

Administrator

- 21 years experience in the spine sector (Stryker Spine, Medtronic Group)
- General Director of Vexim since December 2011



Bernd Von Polheim

Administrator

- 20 years experience at GE Ultrasounden and GE Healthcare
- Currently General Manager at GN ReSound, responsible for the distribution of hearing products in the Danish society in Germany

