

Translating optoacoustic imaging – the long journey from preclinical research into clinical routine

iThera Medical GmbH

EPIC Meeting on Laser, Optics and Sensors for Medical Devices
Laser World of Photonics, 28th April 2022



iThera Medical: The next major imaging OEM



Developing & commercializing breakthrough imaging technology



Global technology & market leader for optoacoustic imaging (OAI)



Next step: Unleash technology value in routine diagnostic imaging market


iThera Medical – company milestones



First installation of MSOT prototype




Launch of MSOT inVision




Launch of MSOT EIP


Clinical translation




Launch of MSOT Acuity



Launch of RSOM Explorer



CE certification of MSOT Acuity



CE certification of MSOT Acuity Echo




Company incorporation




German Innovation Award



Clinical publication MM SLNs



Clinical publication Crohn's



Clinical publications BC



Clinical publication Duchenne



Clinical evaluation IBD

Strong starting point for growth in the clinics

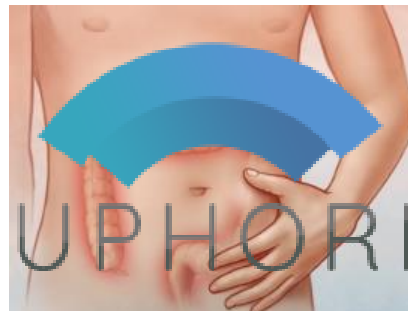


Proven product

First scanner launched in 2012
Used broadly for clinical research
CE mark in 2019 and 2021



* >30 systems for clinical research; the remainder preclinical



Strong data

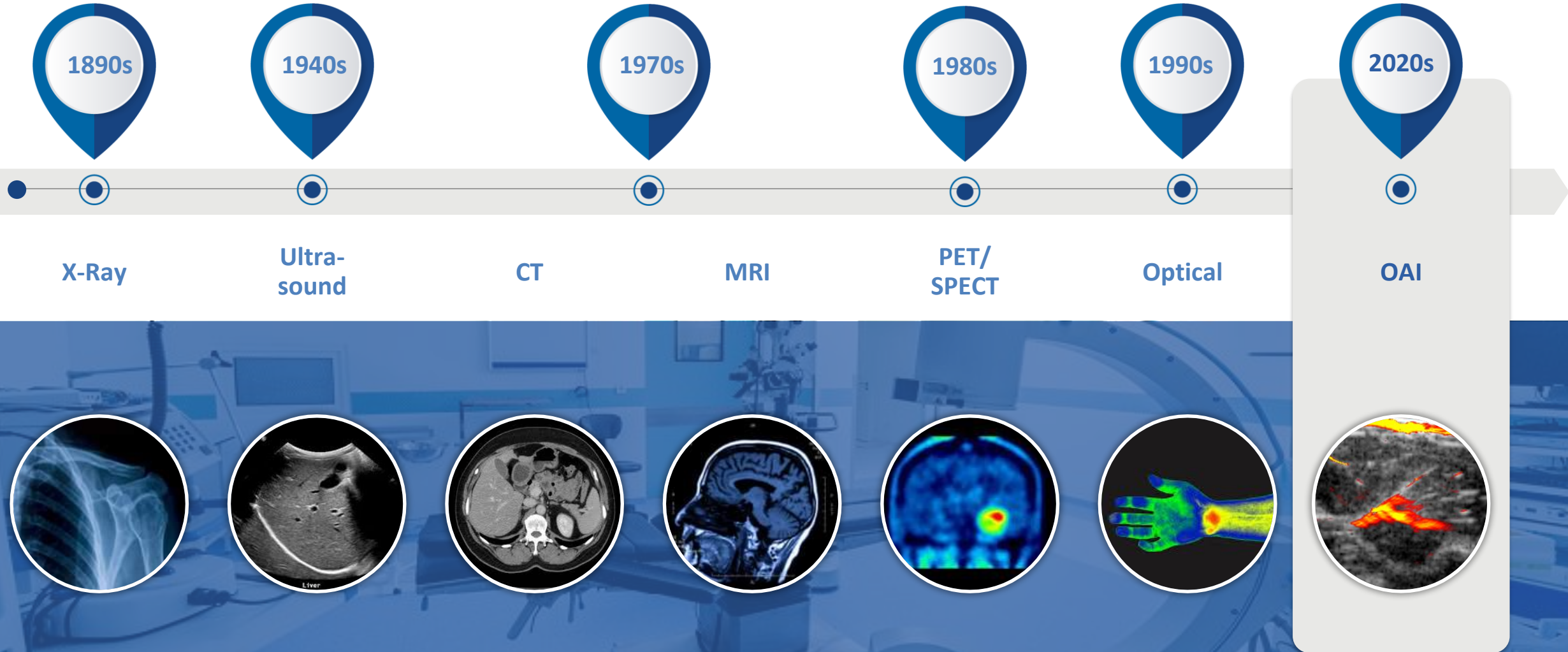
>50 clinical proof-of-concept trials
Multiple high-impact publications
1st regulatory trial ongoing



Key opinion leaders

>110* systems sold and installed
Strong base of KOL users
Equal split across USA, Europe, Asia

OAI: a breakthrough imaging technology



MSOT image formation: 'light in, sound out'

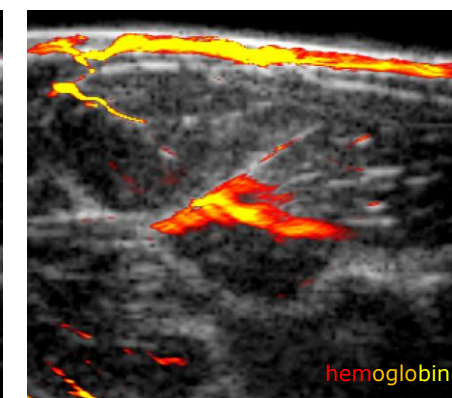
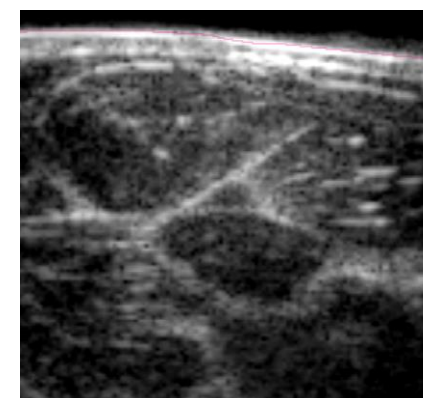
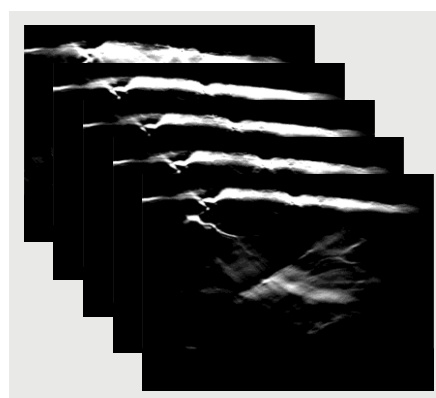
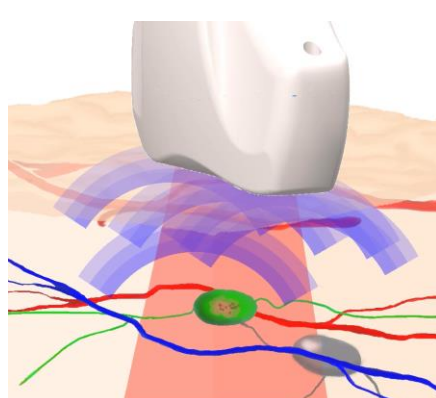
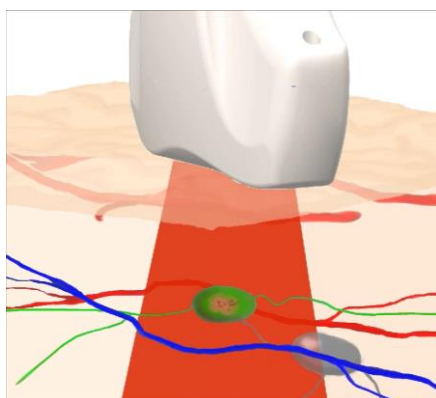
MSOT = Multispectral Optoacoustic Tomography



MSOT

Ultrasound*

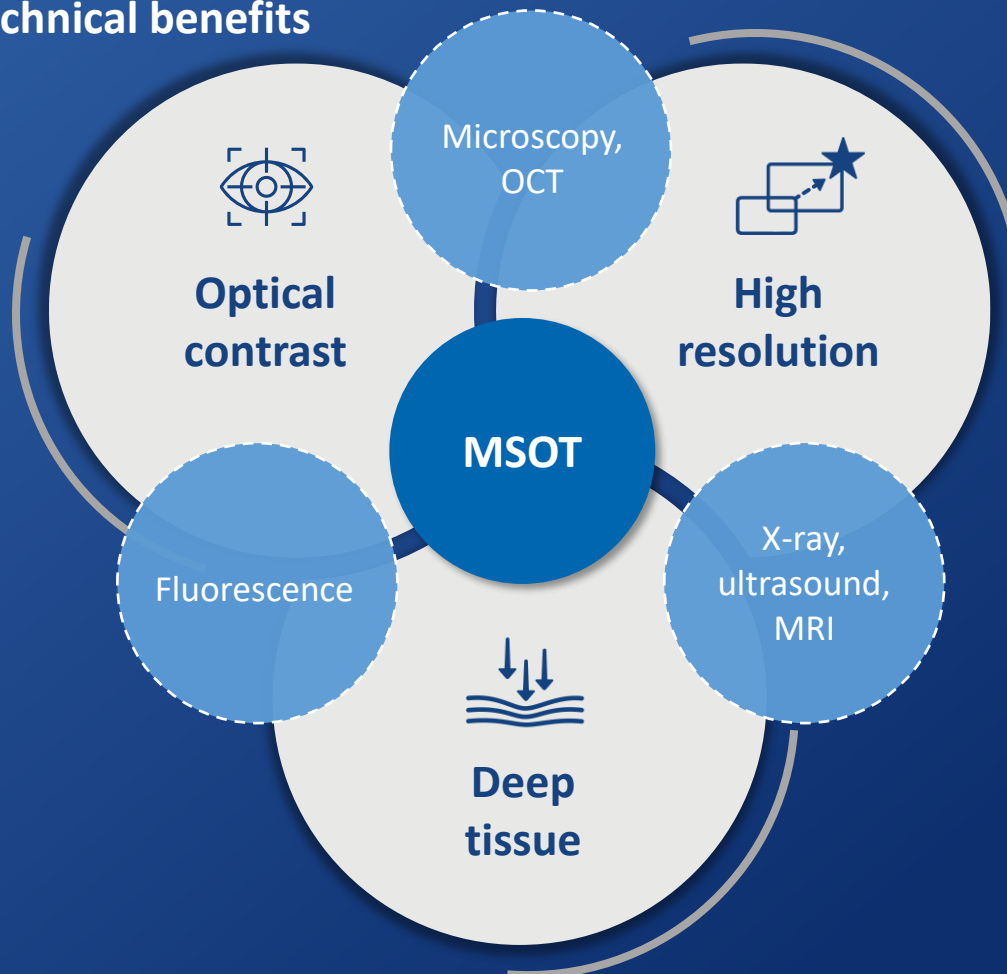
Overlay



* Reflection-mode Ultrasound Computed Tomography (R-UCT) acquired interleaved with MSOT

OAI: The only imaging modality to visualize optical contrast with high resolution in deep tissue

Technical benefits



Clinical benefits



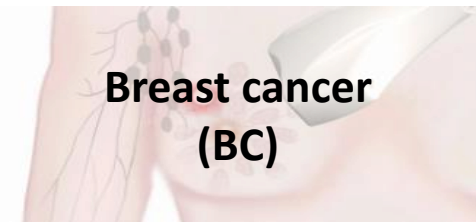
- Visualize and quantify versatile endogenous soft tissue contrast
- Assess disease-related changes in tissue composition
- Enables wide range of applications
 - ✓ Inflammation: HbT* = reddening
 - ✓ Fibrosis: collagen
 - ✓ Cancer: Hb/HbO₂*, lipid/water

* HbT = total hemoglobin; Hb = de-oxygenated hemoglobin; HbO₂ = oxygenated hemoglobin



And radiation-free!

Three target disease areas with established lead applications

| | Lead application | Diagnostic objective | MSOT benefit |
|--|---|--|--|
| Disease area Inflammation |  | <p>Assess grade of inflammation in colon wall</p> | <ul style="list-style-type: none"> • Non-invasive (vs. gold standard colonoscopy) • More accurate than other non-invasive procedures |
| Fibrosis |  | <p>Assess status of muscle tissue degeneration</p> | <ul style="list-style-type: none"> • Objective assessment (vs. subj. physiological tests) • Only quantitative method to assess fibrotic tissue changes |
| Cancer |  | <p>Differentiate malignant from benign lesions</p> | <ul style="list-style-type: none"> • Better sensitivity (vs. x-ray) • Better specificity (vs. US & MRI) |



Status of clinical OAI applications



Preparation



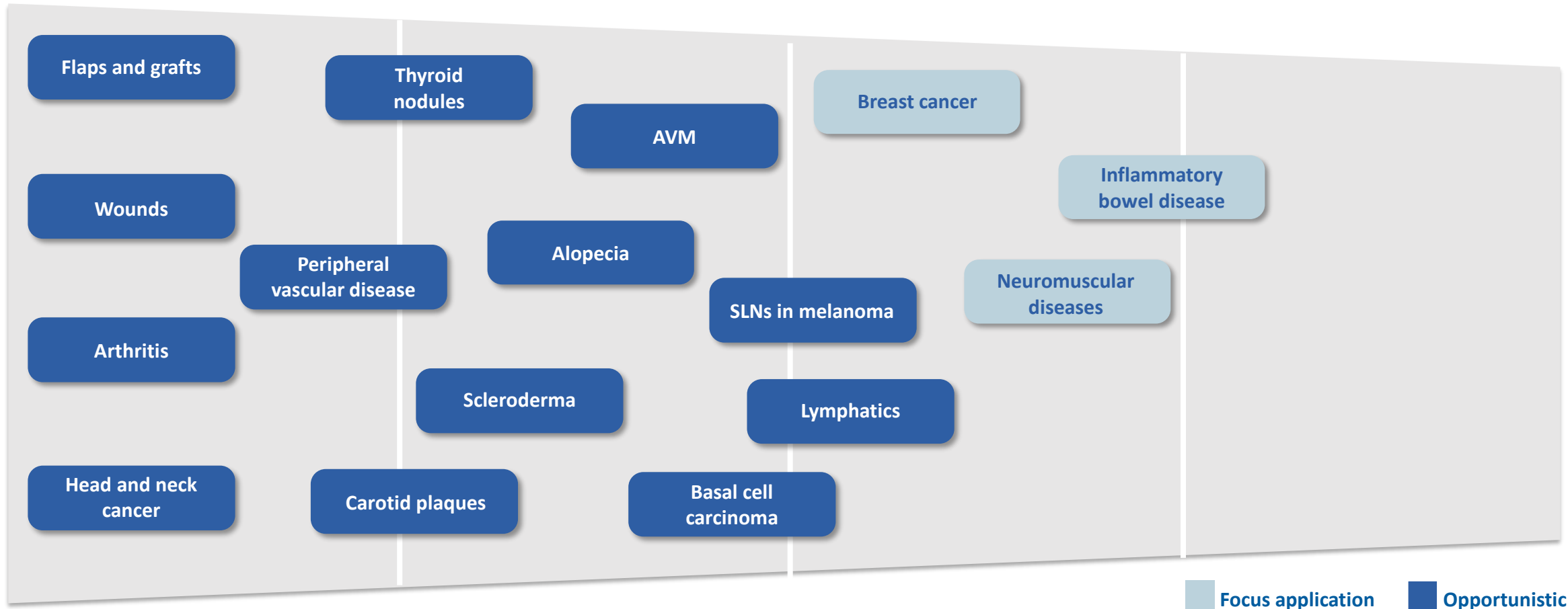
Feasibility



Dissemination & Extension



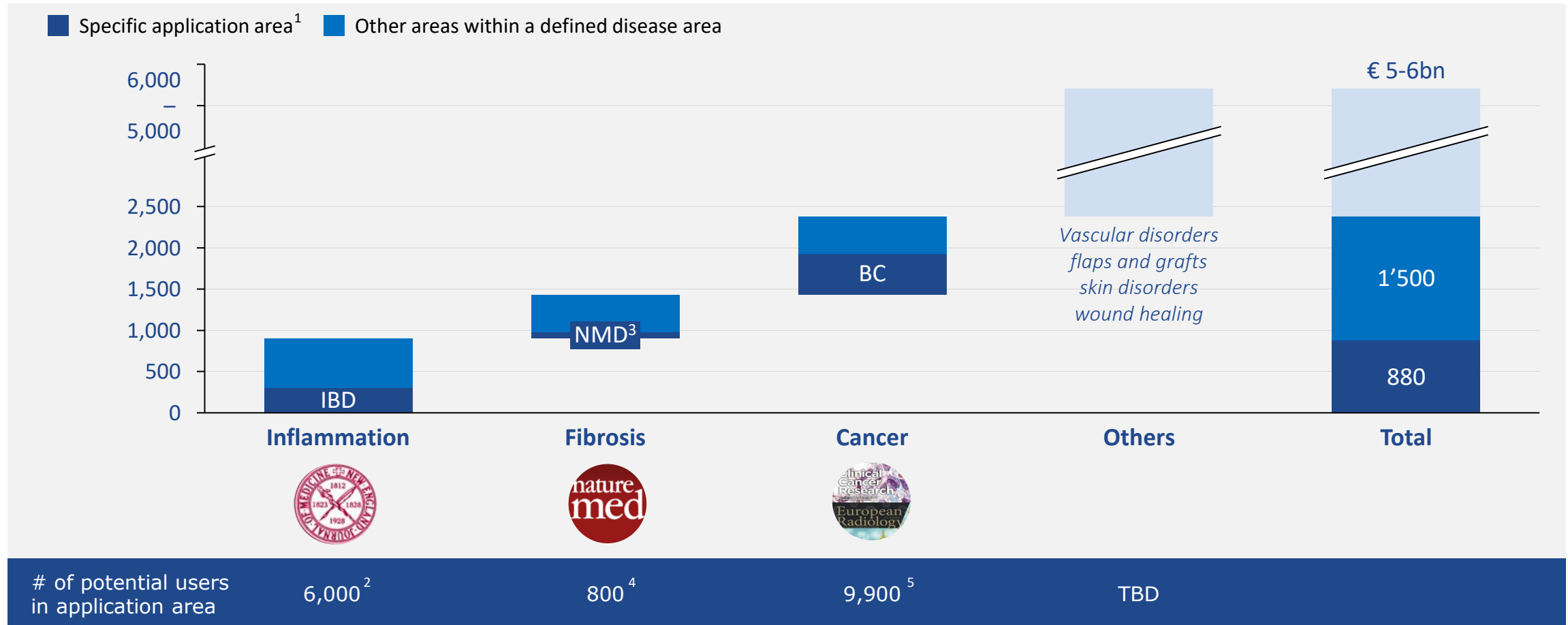
Preparation of commercialization



Focus application Opportunistic

Several €bn market addressable with OAI

€ mn p.a.



1 Selected applications already validated in clinical proof-of-concept studies; market estimate for each application area is based on the system market taking into account the site count and assuming a system price of €250k per MSOT unit with lifetime of 5 years

2 Management estimate of relevant clinics and gastro specialist offices (Tier 1-3)

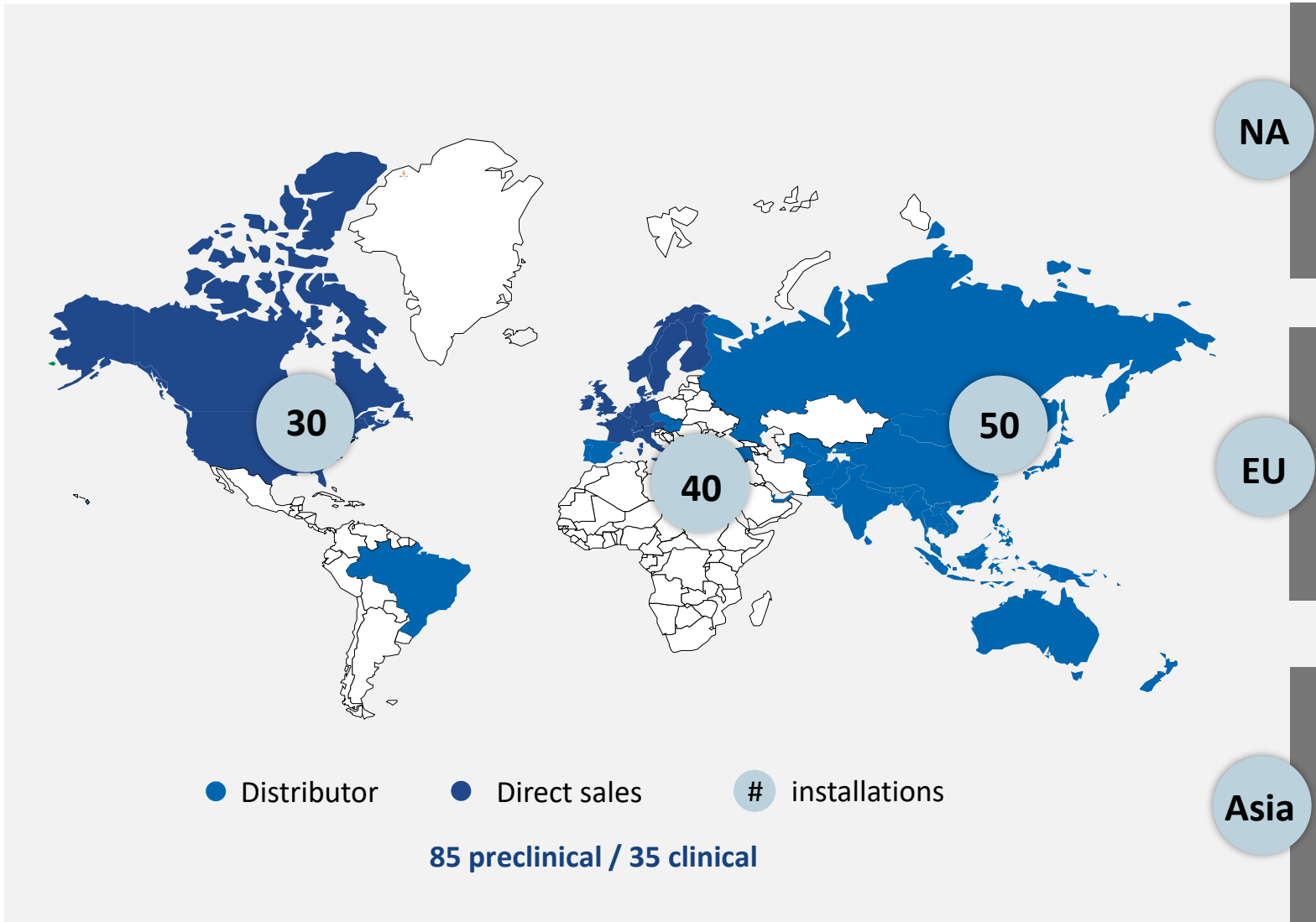
3 Includes all types of NMDs (muscular dystrophies, myopathies, motor neuron diseases, ion channel diseases, mitochondrial diseases, neuromuscular junction diseases, peripheral nerve diseases); assuming 2 systems per site

4 Management estimate of relevant clinics (specialized MDA care centers, Tier 1 only)

5 Management estimate of relevant clinics (Tier 1-3)




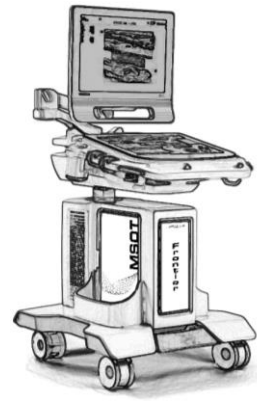
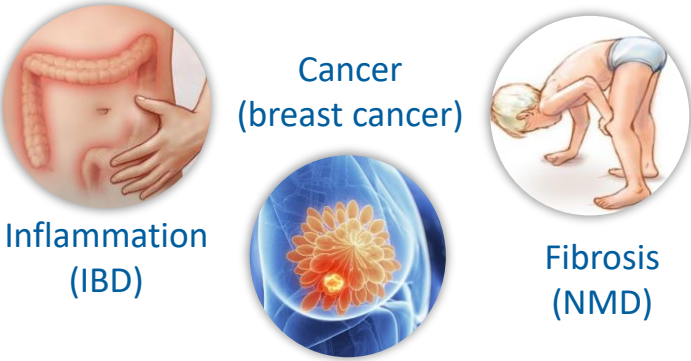

Significant global installed base, broad KOL uptake

Status 04/2022: 120 installations



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The next step: Entering the field of routine diagnostics

| | | |
|---|---|--|
| <p>Proven product</p>  <p>CE</p> | <p>Strong data</p>  | <p>Key opinion leaders</p>  |
| <p>Diagnostic device</p>  <p>CE + FDA</p> <p>Half the price & size Commercially viable For routine use</p> | <p>Expand evidence</p>  <p>Inflammation (IBD) Cancer (breast cancer) Fibrosis (NMD)</p> | <p>Geographic expansion</p>  <p>Europe, North America, China Starting with Tier 1 providers</p> |

PARTICIPATE IN AN IMAGING REVOLUTION.
Optoacoustics, the next generation in biomedical imaging.

