

Evgeny Belov

# A New Ultrasound Treatment Platform – SonoFusion



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# The Problem



**Approximately 30%–40% of the global population is likely to experience at least one of the following medical conditions during their lifetime:**

- ▶ Cancer: Liver, breast, prostate, kidney, and pancreatic cancers.
- ▶ Bone Metastases: Pain and complications associated with advanced cancer.
- ▶ Heart Issues: Arrhythmias requiring cardiac tissue ablation.
- ▶ Urological Problems: Benign prostatic hyperplasia (BPH) and prostate cancer.
- ▶ Gynecological Disorders: Endometriosis and adenomyosis.
- ▶ Neurological Diseases: Parkinson's disease and essential tremor.
- ▶ Women's Health: Uterine fibroids.



**Approximately 50%–60% of patients with these conditions may not be suitable for surgery:**

- ▶ Inoperable Conditions
- ▶ Hard-to-Reach Areas
- ▶ Post-Treatment Recovery
- ▶ High surgery operation cost



# Our Vision

Our mission is to revolutionize healthcare by replacing invasive surgeries with effective, non-invasive solution. We aim to deliver treatments that are accessible to more patients, enable faster recovery, and are affordable for everyone. By providing a low-cost system for every physician's clinic, we strive to make advanced care universally available.

## Our Advantages:

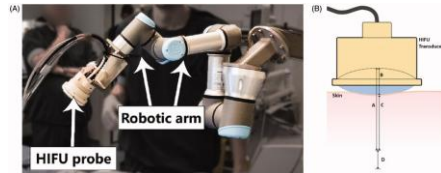
- Non-invasive treatment procedure.
- Simple and Ultra-fast – no need in complexity preparations.
- More effective and safe.
- Ambulatory treatment – no needs in hospitalization.

## Our Impact:

- PATIENTS – Outcomes and quality of life
- PROVIDERS – Simple and safe treatment
- PAYERS – majored cost of care reducing

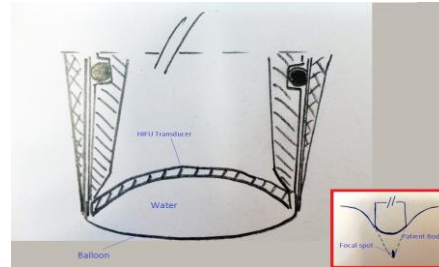
# Our Solution

Is an innovative ultrasound treatment platform that combines histotripsy and thermal ablation to deliver precise, non-invasive ultrasound procedure.



Small and low-cost phase array with z-axis steering  
Robotic arm for XY and angle positioning

- High flexibility in mechanical setup
- Fits any geometry with minimal space



HIFU require a large N.A. probe.

Competitors use clumsy, costly probes with complex setups that increase the treatment distance.

We provide a small affordable probe, pressed against soft tissue. It ensures both effective coupling and large N.A.



First transducer version

Final version will be integrated with real time Imaging Ultra Sound.

## PLATFORM BOM:

Transducer \$2K

Positioner \$8K

Imaging System \$1K

Electronic parts \$2K

Water System \$1K

Chassi and mechanical parts \$1K

Plastic covers \$1K

**TOTAL: \$16K**



# Our Solution

A non-invasive and effective surgical platform that combines **Histotripsy and Thermal Ablation Ultrasound**. It allows us to focus at depths of 0-10 cm with an 8kW peak and 1kW continuously(acoustic).

## Histotripsy

Ultra-high amplitude, microsecond-duration sound pulses are directed at the targeted tissue.

The rapid expansion and collapse of microbubbles cause destruction of the tissue at a sub-cellular level

Capable of sub-millimeter precision

**Histosonics**



## Thermal

High-amplitude, continuous sound energy is directed at the targeted tissue

Fast temperature rise destroys targeted tissue

No bleeding or other side effects occur

**HIFU**



## Combined

Ultra-Fast treatment.

User-friendly patient interface

Non-invasive: Safe, reduces risks, and ensures faster recovery time.

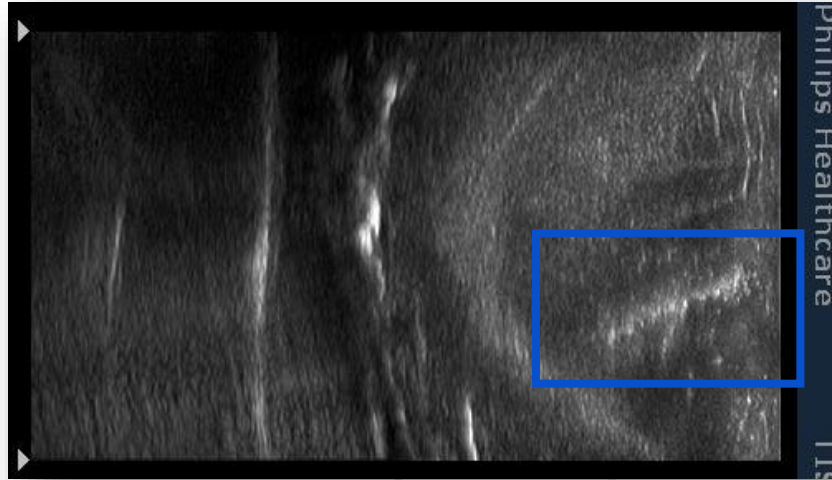
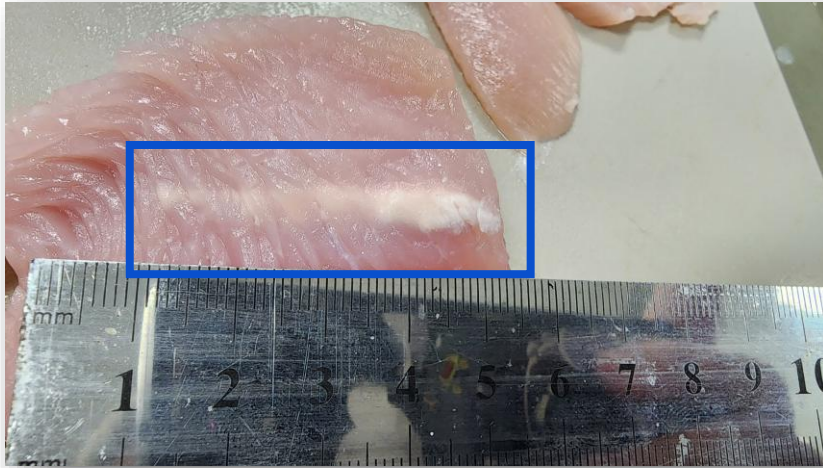
No MRI required: Affordable and accessible for small clinics.

Cost-effective: Reliable, low-cost design.

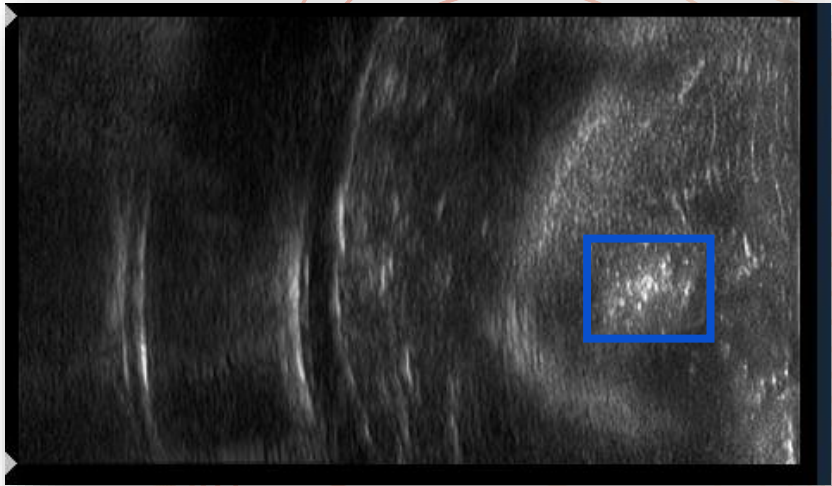
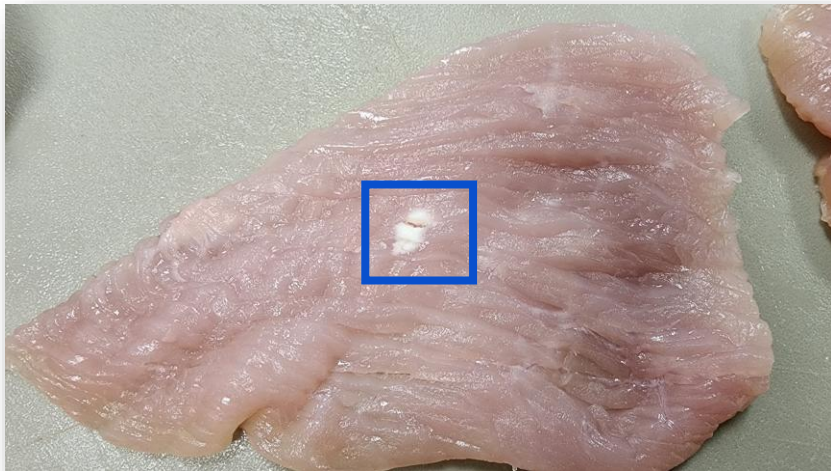
**SonoFusion**

# Ultrasound Feedback

Electronically steered ablation



Precise focal ablation



# Market Opportunity



## Oncology:

Market Size: \$1.67 billion (2023)

Growth: CAGR 13.5% (2024–2030)

Key Focus: Non-invasive tumor ablation for liver, breast, prostate, kidney, and pancreatic cancers.



## Gynecology (Endometriosis and Adenomyosis):

Market Size: \$1.5 billion (2022)

Growth: CAGR 14.3% (2024–2032)

Key Focus: Non-invasive treatment for endometriosis and adenomyosis.



## Bone Metastasis:

Market Size: \$19.7 billion (2022)

Growth: CAGR 8.1% (2023–2031)

Key Focus: Pain relief for cancer patients.



## Neurology (Essential Tremor and Parkinson's Disease):

Market Size: \$4.28 billion (2021)

Growth: CAGR 12.1% (2022–2030)

Key Focus: Non-invasive care for Parkinson's disease and essential tremors.



## Cardiology:

Market Size: \$3.5 billion (2022)

Growth: CAGR 13.5% (2023–2032)

Key Focus: Cardiac tissue ablation for arrhythmias.



## Women's Health (Uterine Fibroids):

Market Size: \$4.87 billion (2023)

Growth: CAGR 9.3% (2024–2032)

Key Focus: Non-surgical treatment for uterine fibroids.



## Urology (Benign Prostatic Hyperplasia):

Market Size: \$11.6 billion (2023)

Growth: CAGR 5.6% (2024–2030)

Key Focus: Minimally invasive treatments for BPH.



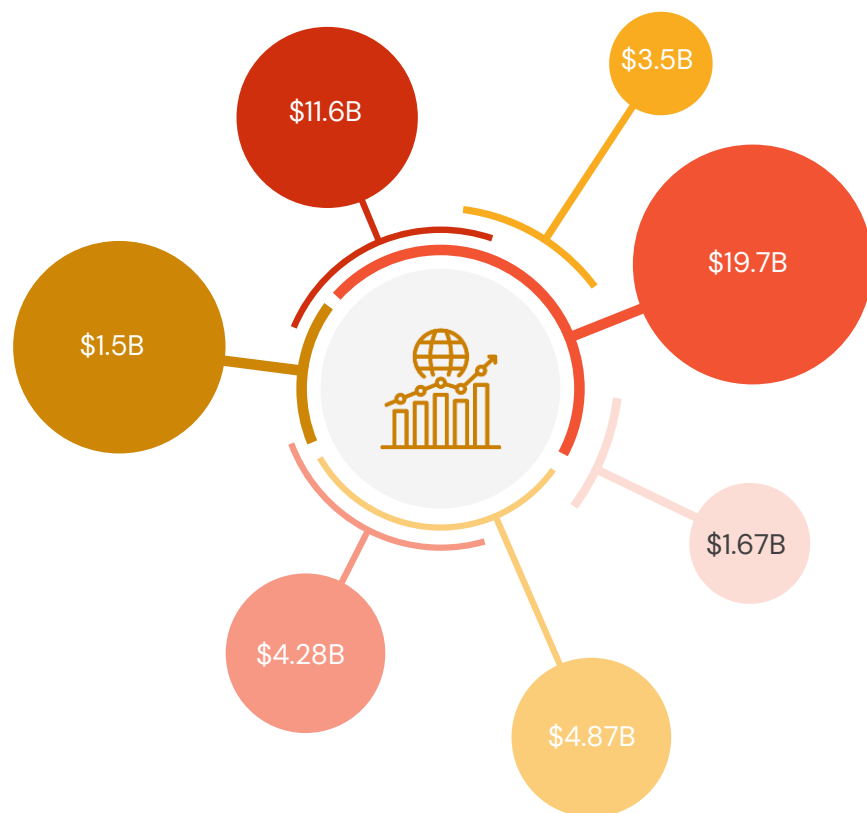
## SUM: Market Opportunity

Total Market Size: \$47.12 billion

Average CAGR: 10.9%



# Market Opportunity



## Global Market

- Oncology
- Bone Metastasis
- Cardiology
- Urology
- Gynecology
- Neurology
- Women's Health

## Roadmap

### Initial:

- ▶ Liver cancer
- ▶ Breast cancer
- ▶ Kidney cancer
- ▶ Pancreatic cancer
- ▶ Thyroid cancer
- ▶ Uterine fibroids
- ▶ Endometriosis and adenomyosis
- ▶ Pain relief for cancer patients

### Mid-term:

- ▶ Minimally invasive treatments for BPH
- ▶ Prostate cancer

### Long-term:

- ▶ Cardiac tissue ablation for arrhythmias.
- ▶ Parkinson's disease and essential tremors.



# Regulatory Strategy – FDA 510(k)

## Predicate Devices:

Insightec – MRgFUS – FDA approved

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Philips – MR-HIFU – FDA approved

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Profound Medical – Sonalleve – FDA approved

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HistoSonics – RAST FDA approved

## Competitors

Insightec – MRgFUS

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Philips – MR-HIFU

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Haifu – JC200

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Alpinion – Alpius 900

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Profound Medical – Sonalleve Theraclion – Sonovion

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HistoSonics – RAST FDA approved

# Business Model Opportunity

Total U.S potential market size:\$32.75B

Total U.S. Potential: 2,300 installations.

## Company Objectives

2-year milestones:

- ▶ Series A to found
- ▶ Full Integration
- ▶ Animal clinical trials
- ▶ Regulatory strategy preparation – FDA/MDR
- ▶ Patents submission
- ▶ Human trials preparation



# 2-year Milestones Plan



# The Team



## Evgeny Belov, B.Sc.

- 16 years of medical device industry experience and commercial leadership.
- Sofwave, Syneron-Candela, Illuminage, Neuronix, Chronisense, Arineta, Horizon 2020



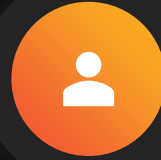
## Oleg Prus, PhD.

- 20 years of experience in high-power focused ultrasound (HIFU) transducer technology, ultrasound technology development, algorithmics, simulations.
- Insightec

The team successfully founded previous products



# Contact Detail



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