

Evgeny Belov

A New Ultrasound Non-Invasive Surgery Platform – SonoFusion



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The Problem



Approximately 40% of people worldwide will face one of these major conditions in their lifetime:

- ▶ **Oncology:** Liver, breast, and prostate cancers.
- ▶ Women's Health: **Uterine fibroids.**
- ▶ 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.



Many of patients with these conditions may not be suitable for surgery:

- ▶ Non-operable tumors
- ▶ Hard-to-Reach Areas
- ▶ Post-Treatment Recovery
- ▶ High surgical costs
- ▶ Unavailable surgical facilities

Our Vision

Our mission is to revolutionize healthcare by replacing invasive surgeries with effective, **non-invasive surgery platform with real time ultrasound imaging feedback**. 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.

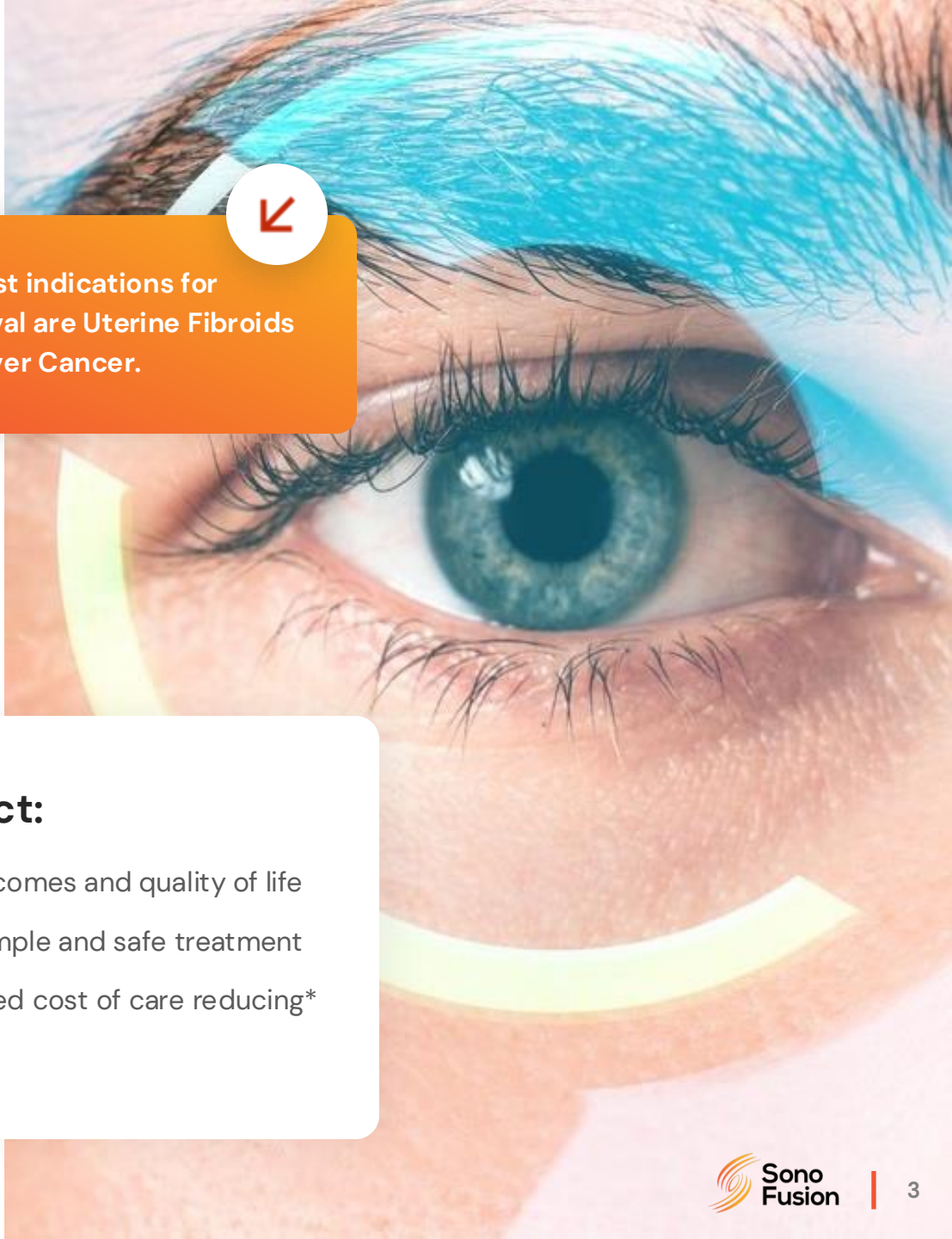
***Over 70% Cost Savings**

Our Advantages:

- Non-invasive treatment procedure.
- Simple and ultra-fast – no complex preparations needed
- More effective and safe.
- Outpatient treatment – no hospitalization required.

Our Impact:

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

A close-up photograph of a person's eye. The eye is light blue/green. There are blue and yellow markings on the skin around the eye, possibly from a medical procedure or imaging. An orange callout box with a white arrow points to the eye area.

The first indications for approval are Uterine Fibroids and Liver Cancer.

Our Solution

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

Robot and navigation algorithm



- Compact & cost optimized phased array + robotic arm (3D + angle positioning)
- High flexibility, minimal space
- Fits any geometry with minimal space



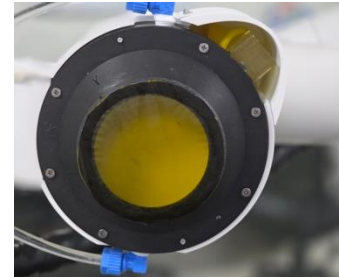
Transducer and electronics



- In-house design
- Cost optimized solution
- Direct skin-coupling
- Continuous and pulse mode (Histotripsy or Thermal ablation or combination)



Ultrasound Imaging feedback



- Real-time imaging feedback
- Full treatment navigation control



SonoFusion





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

Direct acoustical feedback

Histosonics



Thermal

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

Temperature rise destroys targeted tissue

No bleeding or other side effects occur

HIFU



Combined

Ultra-fast, non-invasive treatment

Easy procedure setup

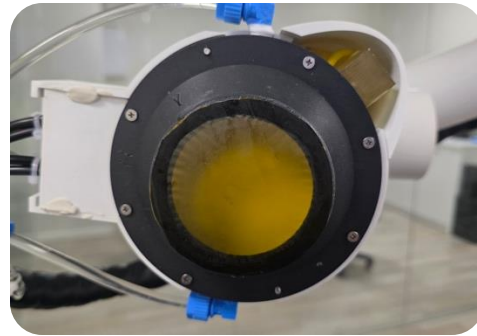
Safe, reduces risks, and ensures faster recovery time.

No MRI required – usable in small clinics

Affordable, reliable, cost optimized design

SonoFusion

Transducer and System View



Experts at in-house development of advanced transducers

Live Performance Showcase



Stability



Line lesion



Point lesion

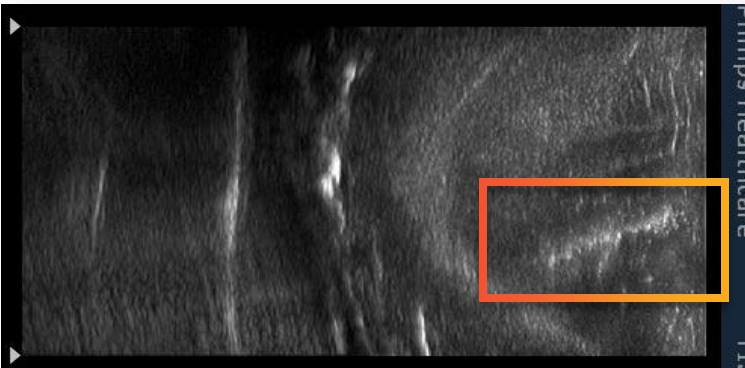
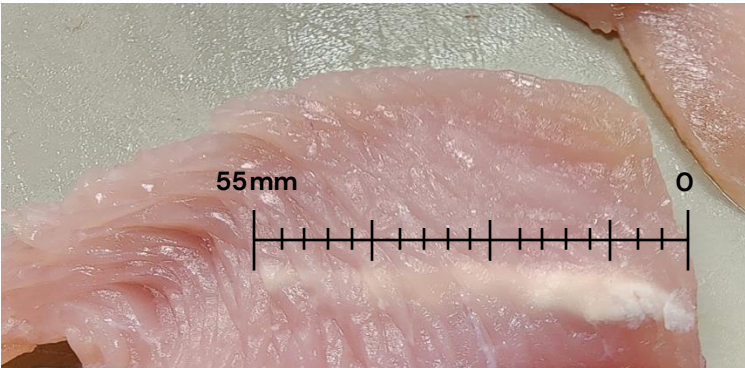


Pattern lesion

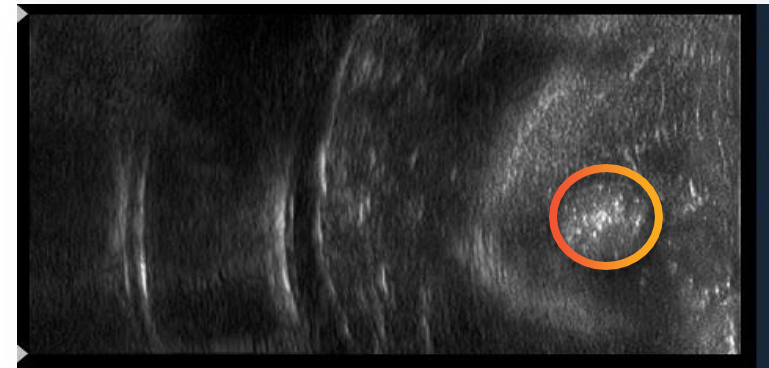
Experts in achieving real outcomes.

Ultrasound Feedback

Electronically steered ablation



Precise focal ablation



Main Competitors

Feature	SonoFusion	HistoSonics	Haifu
Technology	Histotripsy + Thermal	Histotripsy	Thermal
Navigation	Imaging US	Imaging US	Imaging US
Feedback	Ultrasound real time	Ultrasound real time	Ultrasound Post treatment
Accuracy	1mm	1mm	1mm
Volume	0-200cc (no bleeding)	0-1.6cc	0-200cc (no bleeding)
Setup	Direct skin-coupling	Water bath setup	Water bath setup
Transducer design	In-house	Outsourced	In-house
Application	Liver, breast, BPH, prostate, uterine fibroids ...	Liver (FDA approved)	Liver, kidney, pancreas, breast, uterine fibroids-no FDA aproval
Treatment mode	Continuous and pulse mode	Pulse mode	Continuous mode
Treatment time	Fast	Slow	Slow
Depth	~100mm(can be adapter to 200mm)	~100mm	~100mm

SonoFusion Estimated Procedure Cost & Time

Indication	Setting	Time of Procedure	SonoFusion Estimated Cost	Midpoint
Liver Cancer	Inpatient	90–120 min	\$3,200–4,200	\$3,700
Uterine Fibroids	Outpatient	45–60 min	\$1,300–1,800	\$1,550
Breast Cancer	Outpatient	45–60 min	\$1,800–2,300	\$2,050
Prostate Cancer	Outpatient	60–90 min	\$1,800–2,300	\$2,050
Bone Metastases	Outpatient	45–60 min	\$1,800–2,300	\$2,050
Arrhythmias	Inpatient	120–150 min	\$3,200–4,200	\$3,700
BPH	Outpatient	30–45 min	\$1,300–1,800	\$1,550
Adenomyosis	Outpatient	45–60 min	\$1,800–2,300	\$2,050

Procedure Price Estimation calculation example

Liver Cancer Staff: \$2,000

- Disposables: \$300
- Facility: \$2,000
- Amortization: \$80

**\$4,380 → rounded
\$3,200–4,200**

Standard Procedures cost vs SonoFusion

Indication	Standard Procedure Avg Cost	SonoFusion Avg Cost	Δ Savings (USD)	SonoFusion Cost 20% uplift (USD)	Savings %	Savings (USD)
Liver Cancer	\$31,989	\$3,700	\$28,289	\$9,358	70.7%	\$22,631
Uterine Fibroids	\$15,155	\$1,550	\$13,605	\$4,471	70.5%	\$10,684
Breast Cancer	\$40,225	\$2,050	\$38,175	\$9,685	75.9%	\$30,540
Prostate Cancer	\$22,625	\$2,050	\$20,575	\$6,165	72.8%	\$16,460
Bone Metastases	\$15,650	\$2,050	\$13,600	\$4,770	69.5%	\$10,880
Arrhythmias	\$27,650	\$3,700	\$23,950	\$8,490	69.3%	\$19,160
BPH	\$8,070	\$1,550	\$6,520	\$2,854	64.6%	\$5,216
Adenomyosis	\$17,035	\$2,050	\$14,985	\$5,047	70.4%	\$11,988

Market Opportunity



Liver Cancer:

Market Size: **\$3.8 billion**

Growth: CAGR 11.5% (2025–2034)

Key Focus: Non-invasive tumor ablation for liver.



Women's Health (Uterine Fibroids):

Market Size: **\$5.3 billion**

Growth: CAGR 9% (2024–2032)

Key Focus: Non-surgical treatment for uterine fibroids.



Cardiology:

Market Size: **\$2.8 billion**

Growth: CAGR 9.22% (2025–2034)

Key Focus: Cardiac tissue ablation for arrhythmias.



Oncology:

Market Size: **\$21.8 billion**

Growth: CAGR 11.5% (2025–2034)

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



Urology (Benign Prostatic Hyperplasia):

Market Size: **\$1.6 billion**

Growth: CAGR 5.6% (2024–2030)

Key Focus: Minimally invasive treatments for BPH.



Bone Metastasis:

Market Size: **\$3.1 billion**

Growth: CAGR 8.1% (2023–2031)

Key Focus: Pain relief for cancer patients.



Gynecology (Adenomyosis):

Market Size: **\$2 billion**

Growth: CAGR 6% (2025–2034)

Key Focus: Non-invasive treatment for adenomyosis.



SUM: Market Opportunity:

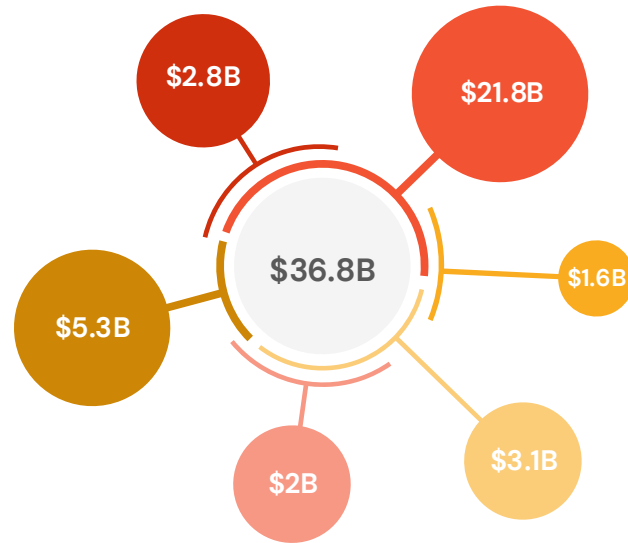
Total Market Size: **\$36.8 billion**

Average CAGR: 10.9%

Market Opportunity

Global Market

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



Roadmap

Initial:

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

Mid-term:

- ▶ Minimally invasive treatments for BPH
- ▶ Prostate cancer

Long-term:

- ▶ Cardiac tissue ablation for arrhythmias.

Regulatory Strategy – FDA 510(k)

Predicate Devices:

- Insightec – MRgFUS – FDA approved
- Philips – MR-HIFU – FDA approved
- Profound Medical – Sonalleve – FDA approved
- HistoSonics – FDA approved

Competitors

- Insightec – MRgFUS
- Philips – MR-HIFU
- Haifu – JC200
- Alpinion – Alpius 900
- Profound Medical – Sonalleve Theraclion – Sonovion
- HistoSonics

Business Model Opportunity

Total U.S potential market size:\$36.8B

Total U.S. Potential: 12,000–17,000 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



Patents

Will be submitted



Method for Assembling an Ultrasound Transducer with Optimized Material Combinations



Pressure-Compensated Closed-Loop Cooling Water System



Method for Direct High-Power Ultrasound Coupling to the Body Surface



Multi-Mode Ultrasound Driver Electronics for Histotripsy and Continuous-Wave Operation



Submitted patents (provisional)

Combined Histotripsy and Thermal Ablation Method Using High Intensity Focused Ultrasound (HIFU) with Cavitation-Guided Feedback – 63/807,927



Robotic Volumetric Ultrasound Treatment with Z-Steered Beam, X-Y Gantry Motion, and Transducer Articulation



Method for Direct Acoustic Feedback of a Cavitation Cloud via Phase Correlation Analysis



Apparatus for Digital Beam Steering in a Switching-Mode Ultrasound Driver

3-year Milestones Plan



The Team

The team successfully founded previous products



Evgeny Belov, B.Sc.

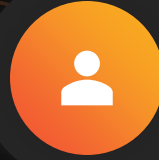
- 16 years of medical device industry experience and commercial leadership.
- Sofwave, Syneron-Candela, Illuminage, Neuronix, Chronisense, Arineta, Horizon 2020



Oleg Prus, PhD.

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

Contact Detail



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