

Realization of Manufacturing for a Next-Generation Ultrasound Therapeutic Device, Domestic Regulatory Approval, and U.S. Market Expansion  
(Sonire Therapeutics KK)



|                |                             |                                              |
|----------------|-----------------------------|----------------------------------------------|
| City           | Year of Establishment       | Founder                                      |
| Chuo-ku, Tokyo | 2020                        | Tohru Satoh<br>Jun Okamoto<br>Shin Yoshizawa |
| Partner VC     | Latest round of Fundraising | Valuation                                    |
| -              | Series C                    | Non-Disclosure                               |

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○ Business Plan  
This project aims to develop and manufacture a minimally invasive HIFU-based therapeutic device for pancreatic cancer and other indications, obtain regulatory approval in Japan, and advance clinical development in the U.S. toward global expansion.  
By integrating proprietary cavitation-based visualization technology, the device enables safe treatment under real-time monitoring and supports scalable manufacturing to accelerate clinical adoption.

○ Research Outline  
In this R&D initiative, we will develop a next-generation HIFU device that advances conventional ultrasound-guided approaches by incorporating a novel cavitation-based focal visualization technology. Through the following PoC milestones, we aim to obtain regulatory approval for difficult-to-treat cancers and enable global deployment:

1. Clinical data acquisition for pancreatic cancer treatment in Japan
2. Safety and efficacy evaluation through exploratory clinical studies in the U.S.
3. Design transfer to mass production and establishment of consumables manufacturing processes

|                     |                    |                       |                                                      |
|---------------------|--------------------|-----------------------|------------------------------------------------------|
| Business Area/Field | Research Period    | Research Grant Amount | International collaborative technology demonstration |
| Healthcare          | DMP<br>2026～2027FY | JPY 1,999 million     | United States Expansion                              |

○International collaborative technology demonstration  
- Local base establishment  
We will build a clinical development framework in the U.S. to accelerate the global adoption of therapies for difficult-to-treat cancers.  
In the U.S., we will conduct an exploratory clinical study (SUNRISE-II) of a next-generation HIFU device for pancreatic cancer, complete patient enrollment, and evaluate its safety and efficacy.