## Social Implementation of the Heart Sound AI Diagnostic Assistance System and Development of Heart Sound

Biomarkers (AMI Inc.)



City	Year of Establishment	Founder	Website
Kumamoto	2015	Shimpei Ogawa	https://ami.inc

Partner VC	Latest round of Fundraising	Valuation
Real Tech Holdings Co.,Ltd.	Series B	JPY 4,070 million

#### **Contact Information:**

e-mail:dev\_secretary@ami.inc

Website: <a href="https://ami.inc/">https://ami.inc/</a>

#### O Business Plan

The main focus is on developing a compact, low-noise, and high signal-to-noise ratio super stethoscope, capable of measuring heart sounds and electrocardiograms. By utilizing signal processing and deep learning technologies, we aim to develop and implement heart failure and heart valve disease estimating AI. Through the commercialization of heart sound analysis Doctor to Doctor service, we aim to screen these cardiac diseases and connect individuals to appropriate treatment in preparation for the upcoming heart failure pandemic.

#### Research Outline

In this research and development, we will enhance the accuracy of the severity classification AI for heart valve diseases, conduct clinical performance trials, and apply for regulatory approval. Additionally, we will develop two new AIs capable of identifying cardiac conditions, and expand the suite of diagnostic assistance functions. Furthermore, we will have end users utilize the remote auscultation heart sound analysis Doctor to Doctor service and conduct surveys to gather feedback. Using this feedback, we will make interface improvements and assess business viability, and aim for an official release.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2023∼2024FY	JPY 183 million	North America, Asia

#### OInternational collaborative technology demonstration

- Contract with local partners
- Relationship development with potential local partner

In this research, the following actions will be taken targeting North America and Asia:

- Market research and business plan formulation for phonocardiogram devices in North America and Asia.
- Selection of local partners and manufacturers for research and development purposes in North America and Asia, as well as design and development of phonocardiogram devices.
- Conducting rule-making surveys for phonocardiogram devices and examining testing methods, as well as preparing for FDA submissions (510(k), pre-sub).

  As of January, 2024

## Integration of surgical support AI technology with next-generation medical devices and global expansion (Anaut inc.)



City	Year of Establishment	Founder	Website
Tokyo	2020	Nao Kobayashi	https://anaut- surg.com

Partner VC	Latest round of Fundraising	Valuation
ANRI	Series A	Non-Disclosure

Contact Information:

e-mail: info@anaut-surg.com

Business Plan

There is room for technological innovation regarding visual and cognitive support in surgical care. Aiming to realize safer future treatment devices, we will implement AI and other advanced technologies in the operating room.

Research Outline

Aiming to integrate with next-generation medical devices, the company will improve qualitative and quantitative accuracy and conduct demonstration tests to bring it closer to practical application. In addition we will also actively conduct overseas expansion activities.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2023∼2025FY	JPY 299 million	Japan, United States, Europe

OInternational collaborative technology demonstration

- Contract with local partners
- Local base establishment
- Supply chain development

We are currently in discussions with several overseas academic institutions and will conduct joint research to improve accuracy. In addition, we are planning to develop a base in the U.S. and will put it into action.

Website: <a href="https://anaut-surg.com">https://anaut-surg.com</a>

As of February, 2024

## Development of Mass-Production Technology for the Clinical Implementation of Innovative CAR-T Cell Therapy (A-SEEDS Co., Ltd.)



City	Year of Establishment	Founder	Website
Matsumoto, Nagano	2020	Yozo Nakazawa	https://www.a- seeds.co.jp/en- home

Partner VC	Latest round of Fundraising	Valuation
_	Seed	Non-Disclosure

**Contact Information:** 

tel: 81-263-31-5882

e-mail: kiyohito.tani@a-seeds.co.jp

O Business Plan

A-SEEDS, an innovative biotech company sprouted from Shinshu University, is dedicated to pioneering advanced treatments for life-threatening cancers. Harnessing the potential of non-viral genetic engineering, our cutting-edge immune cell therapy opens up new horizons of hope for patients seeking effective and transformative solutions.

Research Outline

The objective of this project is to develop mass-production technology for CAR-T cell therapy, a novel approach to cancer treatment, utilizing non-viral gene editing methods. Our focus extends to establishing a manufacturing base in collaboration with pharmaceutical formulation development and manufacturing support companies, both domestically and globally. This foundation will support the conduct of international clinical trials and the pursuit of regulatory approvals.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2024 - 2025FY	JPY 79 million	

Website: <a href="https://www.a-seeds.co.jp/en-home">https://www.a-seeds.co.jp/en-home</a>

## Technological Enhancements and Business Validation Toward International Development of Microbial Gene

Database (bitBiome, Inc.)



City	Year of Establishment	Founder	Website
Shinjuku, Tokyo	2018	Masahito Hosokawa, Ph. D.	https://bitbiome.bi

Partner VC	Latest round of Fundraising	Valuation
_	Series B2	Non-Disclosure

**Contact Information:** 

tel: 03-6205-5662

e-mai: info@bitbiome.bio

Website: https://bitbiome.bio

#### Business Plan

bitBiome, Inc. contributes to solving R&D and production issues in the bio-manufacturing industry through the realization of the discovery and improvement of optimal genes by using our core technologies: the one and only single-cell genome analysis technology "bit-MAP®", a vast and highly accurate microbial genome database "bit-GEM", an enzyme discovery and modification platform with world-class accuracy and speed "bit-QED". This grant project aims to support entry into the primary market for biomanufacturing utilizing microbial gene resources in the United States. It involves the improvement of our microbial single-cell genome sequencing technologies that enable efficient analysis of overseas environmental samples.

#### Research Outline

In this R&D effort, we will improve our existing microbial genome analysis technology to enable efficient analysis of environmental samples, adapt it to the U.S. market, and also demonstrate its performance and feasibility for commercialization.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Food & Agriculture	PCA 2023∼2027FY	JPY 440 million	United States

- OInternational collaborative technology demonstration
- · Local base establishment
- Supply chain development

Through the international demonstration activities, we will investigate the feasibility of commercialization in the U.S. market, clarify the necessary technical specifications, and then improve the technology and implement it overseas. The following activities will be undertaken: 1) research on business feasibility and regulations, 2) development of lab or office in the U.S., and 3) demonstration of microbial genome analysis and genetic data collection performance of overseas environmental samples using the improved technology.

### GMP manufacturing of cells with CellFiber<sup>TM</sup> Technology (CellFiber Co., Ltd.)



City	Year of Establishment	Founder	Website
Tokyo, Japan	2015	Aki Adachi, Shoji Takeuchi, Teru Okitsu, Hiroaki Onoe	https://cellfiber.jp/

Partner VC	Latest round of Fundraising	Valuation
JAFCO Group Co., Ltd.	Series A	JPY 2,300 million

**Contact Information:** 

e-mai: takahashi.tsubasa@cellfiber.jp

Website: <a href="https://cellfiber.jp/">https://cellfiber.jp/</a>

O Business Plan

While cell therapy has grown in popularity and effectiveness, the manufacturing process still relies heavily on manual labor.

technology is a technique for encapsulating and culturing cells in hollow hydrogel tubes, which should facilitate large-scale production of cellular products.

Under this project scheme, we aim to implement this technology in GMP environment and confirm effective production of cellular products.

Research Outline

We plan to achieve below items by collaborating with business partners in and out of Japan.

- 1. Develop GMP manufacturing process of CellFiberTM
- 2. Optimize GMP manufacturing process of Investigational New Drug with CellFiberTM technology
- 3. Comply with necessary regulations including GMP for drug cellular products.
- EA, Single-use Kit and Reagent shall comply with GMP

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA FY2023-2025	JPY 394 million	

### Launching a resource recycling business applying microalgae to precious metal recycling adsorbents.

(Galdieria, Co., Ltd.)



City	Year of Establishment	Founder	Website
Chuo-ku,	2015	Tadashi	https://galdieri
Tokyo		Tanimoto	a.com/en/

Partner VC	Latest round of Fundraising	Valuation
MIYAKO CAPITAL	Series B	JPY 3,500 million

**Contact Information:** 

tel:+81-45-716-8753

Website: <a href="https://galdieria.com/en/">https://galdieria.com/en/</a>

#### Business Plan

Developing precious metal adsorbents made from natural materials utilizing the properties of the microalgae Galdieria, this project aims to recycle precious metals from low-concentration waste liquids that are currently being discarded, while also reducing environmental impact. In this business, adsorbents manufactured at a commercial scale (4 tons per month) will be used to conduct a Proof of Concept (POC) in the customer's actual recovery process, thereby performing the final validation for product-market fit.

#### Research Outline

In this research and development effort, we aim to commercialize precious metal adsorbents using the microalgae Galdieria, and are developing a cultivation facility capable of producing 4 tons per month. Based on the developed high-functionality precious metal adsorbents, the goal is to enhance the recycling rate in urban mines and reduce environmental impact by substituting for existing chemical products.

Furthermore, the verification of the food application of the cell contents not used as precious metal adsorbents is also being advanced simultaneously.

The product-market fit for the developed precious metal adsorbents will be verified based on the following three criteria:

- 1. Completion of production facilities capable of shipping initial model products.
- 2. Verification that the recovery demonstration at potential customer companies is recognized as successful and contracts are made for sample shipments.
- 3. Verification that the incineration ash containing recovered precious metals is purchased.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Materials	PCA 2023∼2025FY	JPY 299 million	

## Commercialization development of Gram staining automated AI medical device and overseas demonstration project (GramEye Inc.)



City	Year of Establishment	Founder	Website
Ibaraki City, Osaka	2020	Yu Hiraoka	https://gramey e.com/

Partner VC	Latest round of Fundraising	Valuation
SAMURAI INCUBATE INC.	Series A	Non-Disclosure

**Contact Information:** 

tel: 81 80 9437 2026

Website: <a href="https://grameye.com/">https://grameye.com/</a>

O Business Plan

In response to the problem of drug-resistant bacteria, which is a global medical issue, we provide AI-equipped medical devices that automate microbial testing "Gram staining". With the aim of acquiring mainstream customers in Japan and overseas, this project will provide paid samples to multiple innovator facilities, develop AI for estimating bacterial species, develop AI for estimating Mycobacterium tuberculosis, and develop business development for market expansion in the U.S. market.

#### Research Outline

In this R&D, we will achieve the following PoCs for AI-equipped medical devices that automate microbial testing "Gram staining" in order to make them products that will acquire mainstream customers in Japan and overseas.

- (1) Notification of Magenta, an Al-powered automated gram staining device, as a medical device and introduction to innovator facilities
- (2) Development of AI for estimation of bacterial species, collection of datasets for AI learning using paid samples
- (3) Completion of development of Mycobacterium tuberculosis estimation AI and introduction to innovator facilities as paid samples

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2023∼2025	JPY 419 million	U.S.A., Europe

#### OInternational collaborative technology demonstration

#### Supply chain development

Searching for ways to launch the device through marketing research in the U.S. market, raising awareness of the device by contacting overseas KOLs and exhibiting at academic conferences, and designing and developing an automatic gram dyeing device that fits the overseas market

Research and development of base manufacturing towards commercialization of oral vaccine/feed additives for

swine (KAICO Ltd.)



City	Year of Establishment	Founder	Website
Fukuoka City	2018	Yamato Kenta	http://www.ka icoltd.jp/englis h-home/

Partner VC	Latest round of Fundraising	Valuation
FFG Venture Business Partners Co., Ltd.	Series A	JPY 2,000 million

**Contact Information:** 

tel: 092-707-4016

e-mail: info-kaico@kaicoltd.jp

Website: http://www.kaicoltd.jp/english-home/

#### O Business Plan

Injectable vaccination for disease prevention in swine is one of the heavy labor burdens for pig farmers.

To solve this pain, KAICO developed oral vaccines for swines, which can be mixed into pigs' daily feed. This practical usage of the oral vaccine enables the reduction of medical equipment and inoculation costs.

In certain developing countries, growth retardation in swine caused by infectious diseases has been a notable issue due to the limited availability of vaccines.

KAICO contributes to the better productivity of local farmers in such countries by commercializing the oral vaccine as feed additives and democratizing easier disease prevention for swine.

#### Research Outline

In this research and development, KAICO's objective is to reach the mass production verification phase in FY2025. To accomplish this goal, we will validate quality control measures and determine appropriate dosage and administration before introducing the product to the initial target market, which is Vietnam. In Vietnam, KAICO will assess product specifications to ensure they align with the needs of the market and achieve product-market fit.

#### [Main objectives]

- 1. Validate manufacturing procedures and quality system control to ensure compliance with regulations governing veterinary pharmaceuticals.
- 2. Evaluate sample production to ensure adherence to the established procedures mentioned above.
- 3. Verify dosage and administration through trial studies involving pigs.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Food & Agriculture	PCA 2023∼2025FY	JPY 172 million	Japan, Vietnam

#### OInternational collaborative technology demonstration

Relationship development with potential local partner

In collaboration with Sojitz (a Japanese trade company), KAICO has forged a business partnership with a local distributor named GreenVet, specializing in the wholesale distribution of veterinary pharmaceutical products, in our primary target market, Vietnam. GreenVet assumes responsibility for submitting the product application to the Vietnamese relevant authorities. Once product registration is finalized, GreenVet will initiate test marketing activities with local farmers and gather feedback from consumers.

## Development of the drug discovery platform based on 64Cu to expedite the R&D of new-generation drugs (LinqMed Inc.)

## Link for Life



City	Year of Establishment	Founder	Website
Chiba	2022	Yukie Yoshii Hiroaki Kurihara Hiroki Matsumoto Atsuo Waki	https://www.linqm ed.net

Partner VC	Latest round of Fundraising	Valuation
DBJ Capital Co., Ltd.	Series A	Non-Disclosure

**Contact Information:** 

tel: +81-3-6661-7661

e-mai: linqmed@linqmed.co.jp

O Business Plan

In this project, a large-scale production of 64Cu will be developed. 64Cu is a unique radioisotope that emits radiation for diagnostic and therapeutic purposes and that easily binds to a variety of molecules. This project will establish Japan's original drug discovery support platform that can rapidly develop "visible" cancer treatments using 64Cu as new-generation drugs. This platform will create a new fundamental for the drug industry.

#### Research Outline

During this project period, we will collaborate with some companies to establish a drug discovery support platform based on 64Cu. Through this, we will develop a large-scale RI production technology that will take on the challenge of creating the next generation pharmaceutical industry infrastructure, and aim to solve economic and social issues.

- (1) Establishment of a large-scale production technology of 64Cu
- (2) Establishment of manufacturing technology for 64Cu with high specific radioactivity
- (3) Long-term stabilization of 64Cu pharmaceuticals

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2023∼2025FY	JPY 1,000 million	

Website: <a href="https://www.linqmed.net">https://www.linqmed.net</a>

## Development of flexible-arm photoacoustic imaging system (Luxonus Inc.)



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Using photoacoustic 3D imaging technology which obtains high-definition 3D images of blood vessels without radiation exposure or contrast agent, a new concept photoacoustic imaging system that is compact and enables imaging in any direction will be developed. The system is easy to use for medical professionals with minimal patient burden, and its applications can be expanded.

City	Year of Establishment	Founder	Website
Minato-ku, Tokyo	2018	Sadakazu Aiso	https://www.luxon us.jp/

Partner VC	Latest round of Fundraising	Valuation
_	Series C	Non-Disclosure

Research Outline

In this R&D, a flexible-arm photoacoustic imaging system will be developed with improving hemispherical ultrasound detectors. The following PoCs will be attained to realize the expansion of clinical applications.

- ① Realization of a flexible arm type sensor module that enables imaging in any directions.
- ② Demonstration of simultaneous 3D imaging of oxygen saturation and lymphatic vessels.
- ③ Evaluation of imaging performance of photoacoustic imaging systems by a medical institution.

**Contact Information:** 

tel: +81-44-742-8681

e-mai: lux-info@luxonus.jp

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2023-2025FY	JPY298 million	

Website: <a href="https://www.luxonus.jp/">https://www.luxonus.jp/</a>

### Innovative medical device based on contactless bioinformation measurement using mmwave radar

(MaRI Co., Ltd.)



City	Year of Establishment	Founder	Website
Kyoto	2017	Hirofumi Taki	https://sites.googl e.com/marisleep.a pp/mari/home/

Partner VC	Latest round of Fundraising	Valuation
MedVenture Partners, Inc.	Series B	JPY 1,600 million

#### **Contact Information:**

tel: 81-75-315-8997

e-mail: admin@marisleep.co.jp

#### Website:

https://sites.google.com/marisleep.app/mari/home/

#### O Business Plan

In order to provide a low-cost, easy-to-accept and easy-to-continue treatment for obstructive sleep apnea patients who have withdrawn from standard nasal continuous positive airway pressure (CPAP) therapy, we are developing an innovative sleep apnea treatment device based on contactless bioinformation measurement using mmwave radar and will promote its use in Japan and the United States.

#### Research Outline

In this project, we will establish medical evidence through domestic clinical trials. In addition, we will proceed with regulatory approval procedures in Japan and prepare for entry into the U.S. market by conducting clinical trials in the United States. Specifically, the following three items will be progressed sequentially.

- ① Improvement of basic technology and completion of prototype development for the development of mass-produced devices
- 2 Establish medical evidence and obtain regulatory approval
- 3 Conduct market research and search for collaborators and clinical trial sites in the U.S.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2024 - 2026FY	JPY 500 million	United States, Europe

#### OInternational collaborative technology demonstration

- Plans to conduct joint research with U.S. universities
- Plans to establish own bases overseas
- · Plan to tie up with local partners for business development
- Plans to establish a supply chain in the U.S.

In order to expand business in the U.S., a major market, it is essential to conduct clinical studies on U.S. subjects and establish medical evidence. We plan to conduct joint research and clinical trials with Stanford University School of Medicine. After establishing medical evidence in the U.S., we plan to establish our own base in the U.S. and build a supply chain to sell medical devices in the U.S. with local medical device manufacturers.

As of April, 2024

### Development of small, low-cost Doppler LiDARs and accuracy verification methods for mass production.

(Metroweather Co.,Ltd.)



City	Year of Establishment	Founder	Website
Uji City, Kyoto	2015	Junichi Furumoto	https://www.metr oweather.jp

Partner VC	Latest round of Fundraising	Valuation
Drone Fund	Series A	JPY 1,300 million

**Contact Information:** 

tel: 0774-46-2002

Website: <a href="https://www.metroweather.jp">https://www.metroweather.jp</a>

#### Business Plan

We aim to develop a service to provide 3D wind information to enabe us to find the most suitable flight pass for safe UAV(unmanned aerial vehicle) and AAM (Advanced Air Mobility) to monitor the detailed wind information near the drone-port and verti-port. This service will provide the inportant information to continue or stop their operation for the operators of UAV and AAM.

In order to obtain the conprehensive wind map even at the complex terrestrial region such as urban area, we will develop a compact-sized and low-cost Doppler LiDAR. The data validation method is also established to improve the value and reliability of our product.

Our new product is provided to the potential users in the United States and obtained the important feedback to improve our product.

#### O Research Outline

This research and development will achieve the downsized, light-weight, maintenance-free, and cost-effective Doppler LiDAR. We will release line-up of the multi product to suit the needs of customers. The cost reduction of Doppler lidar is very important to start the business to the first look customer and useful to construct the wide liadr network. The certificate of data precision is also very important tool to expand our business. The data verrification method will be established in this research.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Energy & Infrastructure	PCA FY2023∼2025	JPY 676 million	United States (Scheduled in Texas).

#### OInternational collaborative technology demonstration

- · Commissioned and collaborative research with overseas business companies/universities, etc.
- Establishing or planning to establish company branches overseas.
- Partnering or planning to partner with local partners for research and development, business development, etc. We will provide the prototype of new product to the oversea (mainly in United States) potential customer to obtain the important feedback to improve our product.

To establish this framework, we will establish a maintenance base in the United States and hire engineers and customer service staff for the quality control and maintenance.

## Development of MylcMAT products using immortalized monocytic cells aMylc (MiCAN Technologies, Inc.)



City	Year of Establishment	Founder	Website
Kyoto	2016	Kazuo Miyazaki	https://www. micantechnolo gies.com/en/

Partner VC	Latest round of Fundraising	Valuation
Real Tech Holdings Co.,Ltd.	Series B	Non-Disclosure

**Contact Information:** 

tel:+81-75-381-3008

e-mail: info2@micantechnologies.com

Website: <a href="https://www.micantechnologies.com/en/">https://www.micantechnologies.com/en/</a>

#### Business Plan

We will complete a new pyrogen test product that will be rolled out globally using immortalized monocytic cells (MylcMAT cells), which are obtained by introducing a unique immortalization gene into monocytic cells extracted from peripheral blood mononuclear cells.

The aim is to develop the product domestically and overseas, improve the product by providing prototypes, establish manufacturing methods, and build a quality assurance system so that the product can be sold promptly after the project is completed, and the product is completed within the project organization.

#### ○ Research Outline

In order to make MylcMAT products suitable for the global market, we will conduct research and development on six items related to manufacturing, quality, and market development to achieve our goals.

- 1. Development of a production method for MylcMAT cells with quality assurance
- 2. GMP manufacturing of MylcMAT products
- 3. Setting up our own manufacturing room
- 4. European development: Determining the European expansion method through finishing and testing of products for the European market
- 5. Domestic development: Completion of validation test Phase III at JaCVAM and preparation for release
- 6. US market: Usage research and determination of product specifications for introduction into the US market

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2023∼2024FY	JPY 399 million	Europe

#### OInternational collaborative technology demonstration

- Local base establishment
- Relationship development with potential local partner
- Supply chain development

In order to finalize the product for the European market, we will establish a European development office as a development base, and use this as a base to provide prototypes to local customer candidates and conduct discussions including the establishment of a future supply chain.

### Development of innovative EV component design environment utilizing metamaterials

(Nature Architects, Inc.)



City	Year of Establishment	Founder	Website
Tokyo	2017	Taisuke Ohshima	https://nature- architects.com/

Partner VC	Latest round of Fundraising	Valuation
_	Series B	Non-Disclosure

Contact Information:

e-mai: contact@nature-architects.com

Website: <a href="https://nature-architects.com/">https://nature-architects.com/</a>

Business Plan

We aims to revolutionize product design in the manufacturing industry based on our proprietary design technology that utilizes metamaterials called DFM (Direct Functional Modeling).

By utilizing DFM, it is possible to realize functions that surpass those of conventional products in products involving physical phenomena such as deformation, vibration, acoustics, and heat, and to design products that take manufacturing costs and mass production into consideration.

DFM can be applied to a wide range of products, including automobiles, industrial machinery, and aerospace.

Research Outline

Targeting the development of EV, this R&D aims to establish a design environment for the development of components with excellent electrical cost efficiency, thermal management, and noise reduction by utilizing our technology.

- 1 Establishment of basic shape search technology
- 2 Establishment of detailed shape optimization technology
- ③ Establish DB/visualization technology for design shapes
- 4 Modeling of prototypes that can be proposed to future collaborative partners.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Information & Communication	PCA 2023∼2024FY	JPY 300 million	United States, Europe (Italy, German, UK)

OInternational collaborative technology demonstration

Relationship development with potential local partner

Local partners overseas will take the lead in researching EV development trends, interviewing major OEMs and Tier 1 manufacturers, and introducing potential customers. Specifically, we will conduct initial interviews to see if it is possible to develop new products by utilizing our technology, and if full-scale collaboration is to be pursued, we will aim to connect our Japanese team with potential customers.

# Research and development for practical application of next-generation focused ultrasound therapy system for refractory cancer (Sonire Therapeutics Inc.)



City	Year of Establishment	Founder	Website
Tokyo Chuo-ku	2020	Tohru Sato Jun Okamoto Shin Yoshizawa	https://www.s onire- therapeutics.c om/

Partner VC	Latest round of Fundraising	Valuation
_	Series B	JPY 5,000 million

**Contact Information:** 

tel: 03-5843-6764

e-mail: info@sonire-t.com

Website: https://www.sonire-therapeutics.com/

#### Business Plan

The objective of our business is to develop a next-generation High-Intensity Focused Ultrasound (HIFU) treatment device and obtain its approval as a medical device through clinical trials, thereby providing a new treatment method for pancreatic cancer and other cancer patients. This project focuses on cavitation bubbles and aims to dramatically improve safety by developing a "next-generation type" that can visualize cavitation bubbles, and to obtain regulatory approval and insurance coverage in developed countries.

#### Research Outline

This grant project will accelerate the implementation of pancreatic cancer clinical trials in Japan and expansion to other oncologies, as well as pancreatic cancer clinical trials in the United States, which is the largest market.

In addition, by achieving the PoC listed below, we aim to achieve the following

- (1) Conduct and accelerate domestic clinical trials (pancreatic cancer)
- (2) Start domestic clinical trials (other than pancreatic cancer)
- (3) Start of clinical trials (pancreatic cancer) in the U.S.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2023∼2025FY	JPY 971 million	United States

- OInternational collaborative technology demonstration
- Contract with local partners
- Relationship development with potential local partner

The clinical trial protocol will be developed in collaboration with the partner hospital in the United States. In addition, an IDE application will be filed with the FDA to initiate the clinical trial.