

SOUND WAVE INNOVATION CO., INC.

Developing proprietary LIPUS (Low-Intensity Pulsed Ultrasound) brain therapy by activating the human body's self-healing power such as angiogenesis and neural regeneration

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<https://sw-innovation.com>

Founded in 2020
Founder: SHIMOKAWA Hiroaki, PhD
No. of employees: 14
Type of Ownership: N/A

May 2024: Focused on early-stage Alzheimer's disease, a phase 3 clinical trial with 220 patients is in progress at 19 medical institutions in Japan from September 2023 through December 2026.

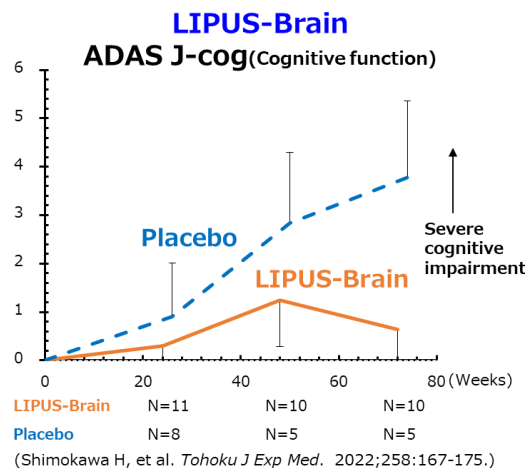


Venture Valuation (VV) interviewed Dr. SHIMOKAWA Hiroaki, Founder & CMO, Mr. KATO Hajime, CEO, and Mr. MANO Takamitsu, Corporate Director.

VV: You are applying LIPUS for treating early-stage Alzheimer's disease for the first time in the world.

Shimokawa: LIPUS has been used as non-invasive ultrasound physiotherapy that stimulates regenerative and anti-inflammatory effects on biological tissues. Low-energy physical stimulation by LIPUS activates the human body's self-healing power such as angiogenesis and nerve regeneration via a chemical response in the vascular endothelium.

We conducted a double-blind, placebo-controlled, pilot study in 2022 with 22 early-stage Alzheimer's disease patients and proved the efficacy and safety of LIPUS brain therapy over 72 weeks of treatment. The chart shows the encouraging result of the LIPUS brain therapy compared to placebo.



We are currently in the process of a phase 3 clinical trial with 220 early-stage Alzheimer’s disease patients in Japan. It is a randomized, double-blind, placebo-controlled trial at 19 medical institutions.

VV: LIPUS brain therapy is provided in medical institutions. Outpatients lie down at rest for a set of three 20-minute irradiations (with 5-minute interval) on a regular basis for the 72-week treatment.

Shimokawa: As the images below show, with the portable device, LIPUS is applied to cover the whole brain through both temples to activate blood vessels. The treatment gradually decreases amyloid beta deposition, upregulates neurotropic factors, stimulates angio-neurogenesis, and enhances oligodendrocytosis.



The treatment costs to patients will be determined after LIPUS brain therapy is approved as a medical device. We have no doubt that they will be much more reasonable than treatment with lecanemab, a new monoclonal antibody drug for early-stage Alzheimer’s disease patients. Treatment with Lecanemab costs 3 million yen (approximately 20,000 USD) per year. It requires intravenous infusion over 1 hour, once every 2 weeks, over a minimum of 18 months.

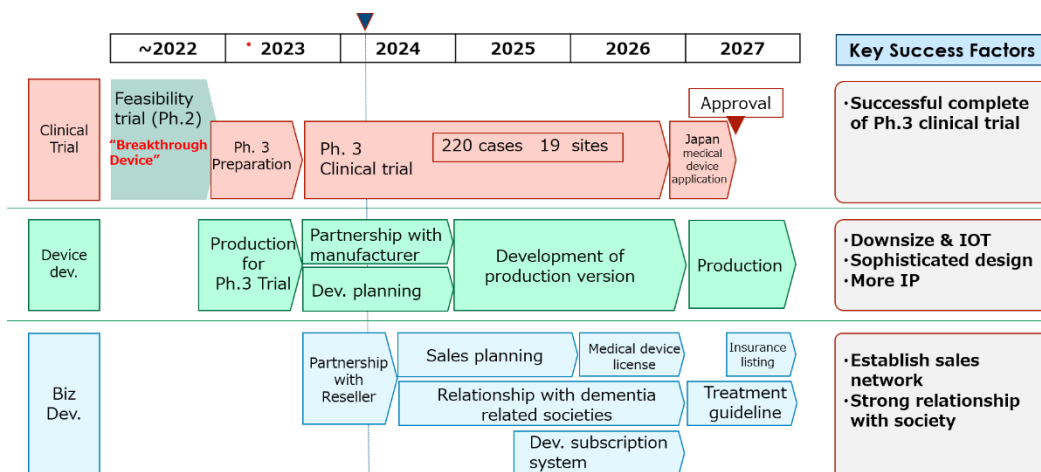
VV: Your priority is to get LIPUS brain therapy approved as medical device in Japan after completion of the phase 3 clinical trial in 2026.

Shimokawa: We are first focusing on Japan. It has the highest proportion of elderly in the world. Around one third of the population is over 65, estimated to be 36 million. As dementia typically affects the elderly, it is a matter of urgency that effective and affordable treatment be available.

Most dementia patients (~70%) are suffering from Alzheimer’s disease. In Japan, nearly 15 million people are at risk of dementia of which 7 million are diagnosed with mild cognitive impairment.

VV: You have a business plan toward 2027 to expand business activities globally. How about fund-raising?

Shimokawa: Our business plan (see chart below) displays that, along with the clinical trial, device development is in progress. As a startup company requiring financial support as well as broad distribution networks, we are looking for partnership opportunities with global medical device manufacturers as well as distributors for our future business development.



VV Comments after the interview:

Novel modalities to treat Alzheimer’s disease such as LIPUS brain therapy raise hopes for people at risk of dementia. Treating patients diagnosed with mild cognitive impairment will be especially beneficial to prevent severe dementia.

One hopes that Sound Wave Innovation’s clinical trial in Japan will complete successfully, and non-invasive and affordable LIPUS brain therapy will be available worldwide. The global dementia population is estimated to reach 78 million in 2030 and increase to 139 million by 2050. Much of the increase will be in developing countries¹.

In the editorial, “Are We There Yet (and How Do We Get There...)?” in PubMed², an expert in Alzheimer’s disease points out that “...there may be different rates of amyloid pathology prevalence across races and potentially across ethnicities, and that multiple factors may impact higher risk of dementia among communities of color....We must also invest in therapeutic approaches that will be lower cost and

¹ <https://www.alzint.org/about/dementia-facts-figures/dementia-statistics>.

² <https://pubmed.ncbi.nlm.nih.gov/37899618/>

more widely accessible around the world than frequent antibody intravenous infusions.”

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