

## Frontier Business Meeting – FBO Showcase –

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| <b>[Date]</b>               | Wednesday September 8, 2021 13:00 – 15:03<br>(Total: 123 minutes, Presentation: 73 minutes, Q&A: 50 minutes) |
| <b>[Venue]</b>              | Webcast  |
| <b>[Number of Speakers]</b> | 11   |
|                             | Hiroshi Nomura Representative Director, President, and CEO   |
|                             | Toru Kimura Representative Director, Executive Vice President,<br>Chief Scientific Officer                   |
|                             | Hiroyuki Baba Senior Executive Officer   |
|                             | Takehiko Nomura Senior Director, Frontier Business Office  |
|                             | Seiji Hori Officer, Business Development & Portfolio Strategy,<br>Frontier Business Office                   |
|                             | Tetsuya Uyama Officer, Frontier Business Office  |
|                             | Yukako Nishimaki Officer, Business Promotion, Frontier Business Office                                       |
|                             | Yasushi Ochiai Officer, Planning and Development, Frontier<br>Business Office                                |
|                             | Miwako Harada Senior Director, Corporate Communications  |
|                             | Mr. Junichi Kato COO, Aikomi Ltd.  |
|                             | Dr. Mark Kasuya CEO, MELTIN  |

## Presentation

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**Harada:** Thank you very much for taking time out of your busy schedule to join us today for the Sumitomo Dainippon Pharma Co., Ltd. Frontier Business Meeting - FBO Showcase -.

FBO is the abbreviation for Frontier Business Office. We would like to introduce the vision, portfolio, and major projects of Frontier Business.

Today's presentation material was emailed to you and is also available on our website. You can also see it on the screen; however, the slides for each part are not numbered sequentially, so please note that the page numbers are different from those in your handouts.

There will be time for questions after the presentation. Please note that this meeting will be recorded for later distribution on the website.

I would now like to introduce today's attendees.

From left to right, the first row of the screen: Representative Director, President and CEO, Mr. Nomura. Representative Director, Executive Vice President, Chief Scientific Officer, Dr. Kimura. Senior Executive Officer, in charge of Frontier Business, Mr. Baba. Second row, from left, Senior Director, Frontier Business Office, Dr. Nomura. Officers Mr. Hori, Mr. Uyama, Ms. Nishimaki, and Mr. Ochiai. I am Harada of Corporate Communications and will serve as moderator today.

We also invited some project partners. Mr. Kato, COO of Aikomi Ltd. Dr. Kasuya, CEO of MELTIN. Thank you.

President, Mr. Nomura will begin our presentation with an introduction.

## Frontier Business Domain

In anticipation of environmental changes in the future, such as the spread of preventive medicine and digital technology, Frontier Business is launched with the aim of providing new solutions to address social issues in the healthcare area other than pharmaceuticals



**Hiroshi Nomura:** Everyone, my name is Nomura, the President. Thank you very much for taking time out of your busy schedule to join us today at the Frontier Business Meeting - FBO Showcase -.

I am very grateful for this opportunity to present our Frontier Business as a whole today, although we have been partially informing you about it in our earnings announcement and other press releases.

We originally explored healthcare solutions outside of medicine as part of our Beyond the Pills initiative, and our employees came up with many ideas as we formulated our mid-term business plan started in 2018. We have positioned these ideas as Frontier Business and have decided to tackle it in earnest company wide.

I believe that some of the themes that we will present to you today were included at that time. The Frontier Business aims to provide solutions to health issues that cannot be solved by medicines in areas that are close to our businesses. We plan to carefully nurture this business to make it the next growth engine along with the pharmaceutical business.

## Establishment of Frontier Business Office: April, 2019



- Focusing on areas in which synergies can be expected with the group's pharmaceutical business

Psychiatry  
&  
Neurology

Motor  
Dysfunction

Lifestyle  
-related  
disease

Oncology

- Building a business foundation on, among others, core technologies (information, engineering, etc.) and networking (via alliances, investment in venture businesses, etc.)
- Initiating and developing multiple pilot solution projects, including the coordination of initiatives for prevention, prediction, cure, and care
- Exploring commercialization opportunities primarily in Japan, the U.S., and China



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To this end, we have established the Frontier Business Office, a division dedicated to this business, starting in April 2019. This field is different from pharmaceutical research and development in that if we do not quickly identify clinical and other needs and move ahead, we will get left behind the times. I believe it is needed that there is always a close connection between the needs of the field and what we are doing, and that means of solving problems are technologically new.

We are constantly reviewing and revising our running projects from this perspective.

We will proceed with the Frontier Business in areas that are close to our existing businesses. However, we believe that we will be able to create solutions in areas where we are not strong, such as new technologies of software and devices, by working with partners and utilizing the experience of both companies.

We would like to expand the business to cover a wide range of Patient Journey in healthcare from prevention and treatment, to prognosis, and we expect to expand this business in Japan, US, and China.

Now, I would like to ask for your participation in the upcoming presentations and also in the thematic presentations.

**Harada:** Next, Senior Executive Officer, Mr. Baba will explain the future vision of the Frontier Business.

**Baba:** I'm Baba, in charge of the Frontier Business. Thank you very much again for your time today.

Although it is a bit presumptuous to talk about a vision for the future, I think it is important to have a vision or image of what kind of society we would like to have in the future when planning and promoting the Frontier Business. So I would like to share my thoughts on this.



## A Society Overflowing with “Good People”



### **“Good People”**

#### **People with Good/Big Hearts and Compassion**

**Good-natured people who attend to others, including those in vulnerable positions, with kindness and warmth at all times without seeking compensation or behaving patronizingly**

**Aiming for a world brimming with “good people”—This is the theme that represents the mission of Frontier Business for the future society**



**Increasing the number of “good people” who live healthy lives with respect for the values of their own and others, thereby raising the QOL of society as a whole**

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It is a little sudden to say, but the key concept here is "good people." This word has many definitions, and in some cases it may be used in a negative way, but here we are thinking of something like a utopia, a world full of people with big hearts, good hearts, compassion, and kind hearts.

Of course, if there were only such people, society would become stagnant, so it may be a matter of degree. However, when we consider various trends in society, for example, various incidents occur due to tangled human relationships. There are quite a few tragic incidents that occur in families.

Some people may say that this is the way it has always been, and in a sense, it is human nature, so there is nothing we can do about it.

However, it is said that it is human relationships that largely determine whether people are happy or unhappy. In the next era, or when we move on to the next phase of civilization, I think it would be a good idea to address the fundamental issues of human society with a big concept such as increasing the number of "good people," which may be a bit ridiculous.

## Social Trend and “Good People”



- **Negative incidents in society, troubles with interpersonal relationships**  
⇒ **Help mitigate community alienation by increasing “good people”**
- **Technological innovations such as AI**  
⇒ **Aspiring to “humanity,” human work after reaching the singularity (only goodness and beauty)**
- **Post-COVID-19 pandemic, low growth rate, declining birthrate/aging population**  
⇒ **“Good people” are essential for a society of mutual aid**



On the other hand, due to AI and other technological innovations, or DX, I believe some of the human abilities that have been considered so important will become unnecessary.

However, even in such an age, I believe that the factors that make a person a "good person" will be respected more and more.

On the contrary, in this age of AI, many things will become more open and difficult to hide, so it will be difficult to live unless you are a "good person."

The last point is mutual aid. I think that we are definitely entering such an era. The idea is to move away from the mindset that all that matters is what's good for you, your family, or your friends, and to contribute to society at large, to the community at large, and to others. In an age where people find meaning in this, I think "good people" is an important concept.

However, when we think about it, most businesses, ultimately or indirectly, increase the number of "good people." As FBO, we would like to operate more directly, closer to such objectives.

In terms of operations, the business of FBO is still in the process of development, although it is based on the various findings of our company. In that sense, the above mentioned third point of mutual aid is a strong element. We are currently working together with our business partners.



## Frontier Business's Vision for the Future

# Diversity in Wellbeing



Sumitomo Dainippon  
Pharma

- Expertise cultivated through pharmaceutical R&D for neuropsychiatric diseases
- Integration of projects related to the pharmaceutical business and Frontier Business-related assets



### Business partner

- One and only technology cultivated and developed in-house
- Technical expertise/patents



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I think that wellbeing is a very important concept. The key to this is that each individual should be healthy both physically and mentally. With this as a base, we would like to make society itself healthy. While sharing such a vision for the future, we are thinking about various things.

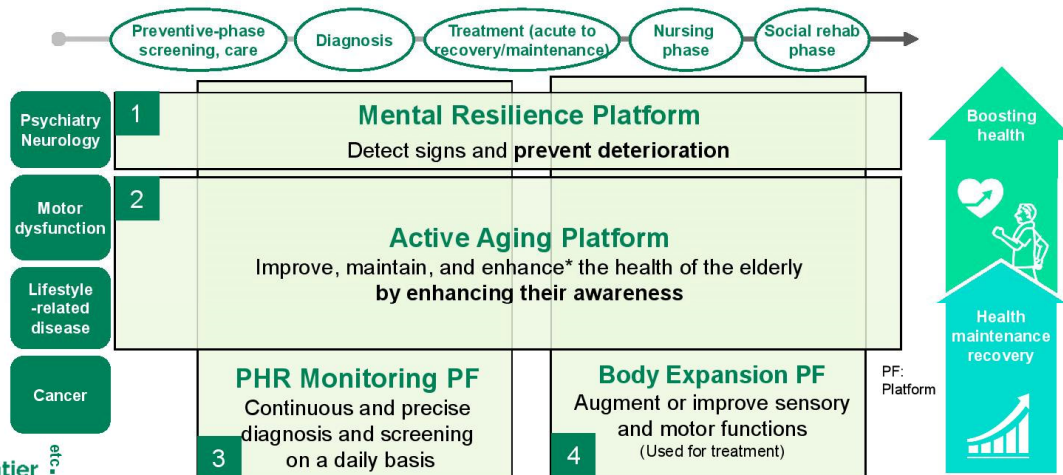
We will be introducing various projects later today. This is a showcase of such collaboration. Please keep your eyes on us. Thank you very much.

**Harada:** The Officers in charge will now introduce each of 3 projects.

First, Senior Director, Dr. Nomura, will give an overview of the business domain, followed by an explanation of the first project, digital device for relieving BPSD.

## Frontier Business Domain

By utilizing technologies and solutions based on monitoring and augmentation of capabilities and functions, we work to resolve unmet needs in maintaining, recovering, and enhancing health, focusing on mental issues (psychiatric diseases) and aging (health issues of the elderly)



\* Includes mental and pain care for cancer patients

**Takehiko Nomura:** I am Nomura from the Frontier Business Office.

Before explaining the individual development themes, I would like to explain the domains that Frontier Business will focus on.

First, on the horizontal axis, from left to right, the so-called Patient Journey is described, including the preventive phase, diagnosis, treatment, nursing phase, and social rehabilitation phase.

The vertical axis shows the disease areas that we focus on: psychiatry neurology, motor dysfunction, lifestyle-related disease, and cancer.

First, let me mention 2 platforms for all Patient Journey.

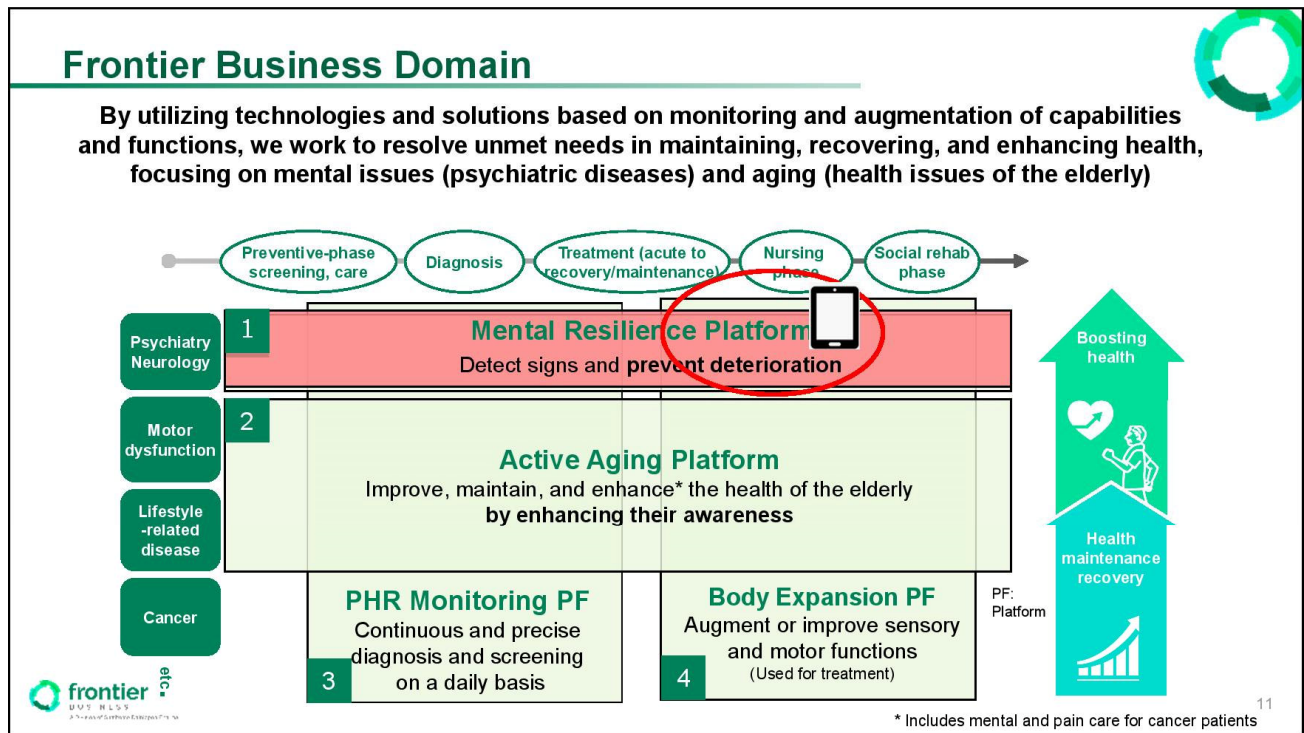
The first domain is the Mental Resilience Platform. The theme is how to recover from mental illness. For this, the concept is to detect signs and prevent deterioration.

The second is the Active Aging Platform. This will literally improve, maintain, and enhance the health of the elderly by enhancing their awareness, and will cover motor dysfunction and lifestyle-related diseases.

A concept focused in part on the Patient Journey is the Personal Health Record (PHR) Monitoring Platform, primarily focused on prevention and diagnosis. This is a solution technology for routine, continuous, and precise diagnosis and screening.

The last one is the Body Expansion Platform focused on the nursing and social rehab phases. This is a solution technology to augment or improve the sensory and motor functions.

In particular, we would like to focus on areas where these platforms overlap, and develop businesses to maintain and restore health, enhance health, and resolve unmet needs.



**Hori:** Hello, everyone. I am Hori from the Frontier Business Office.

I would like to introduce our digital device for relieving BPSD.

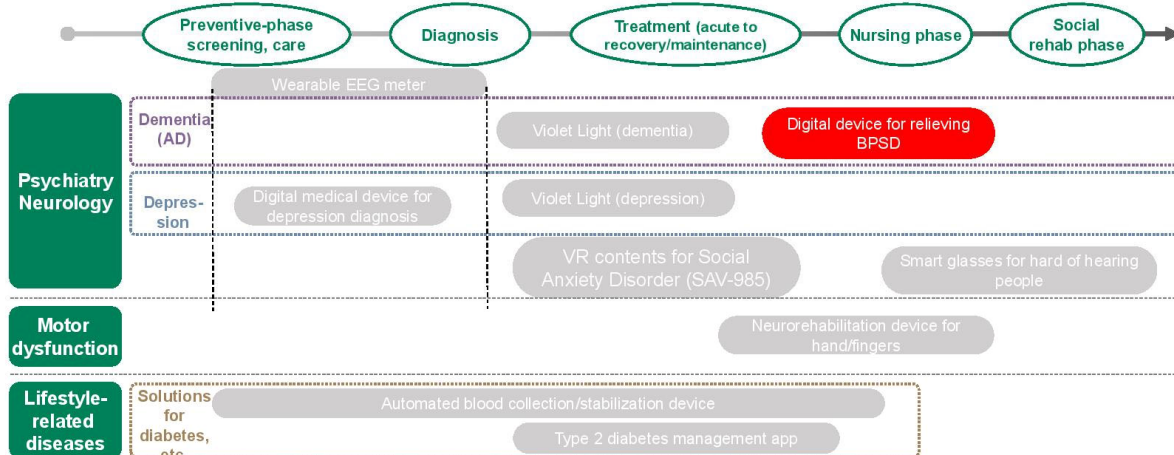
First of all, let me explain the positioning of this project in the portfolio of Frontier Business.

This project is a business domain in the area of psychiatry neurology and of Mental Resilience Platform.

## Business Portfolio by Patent Journey

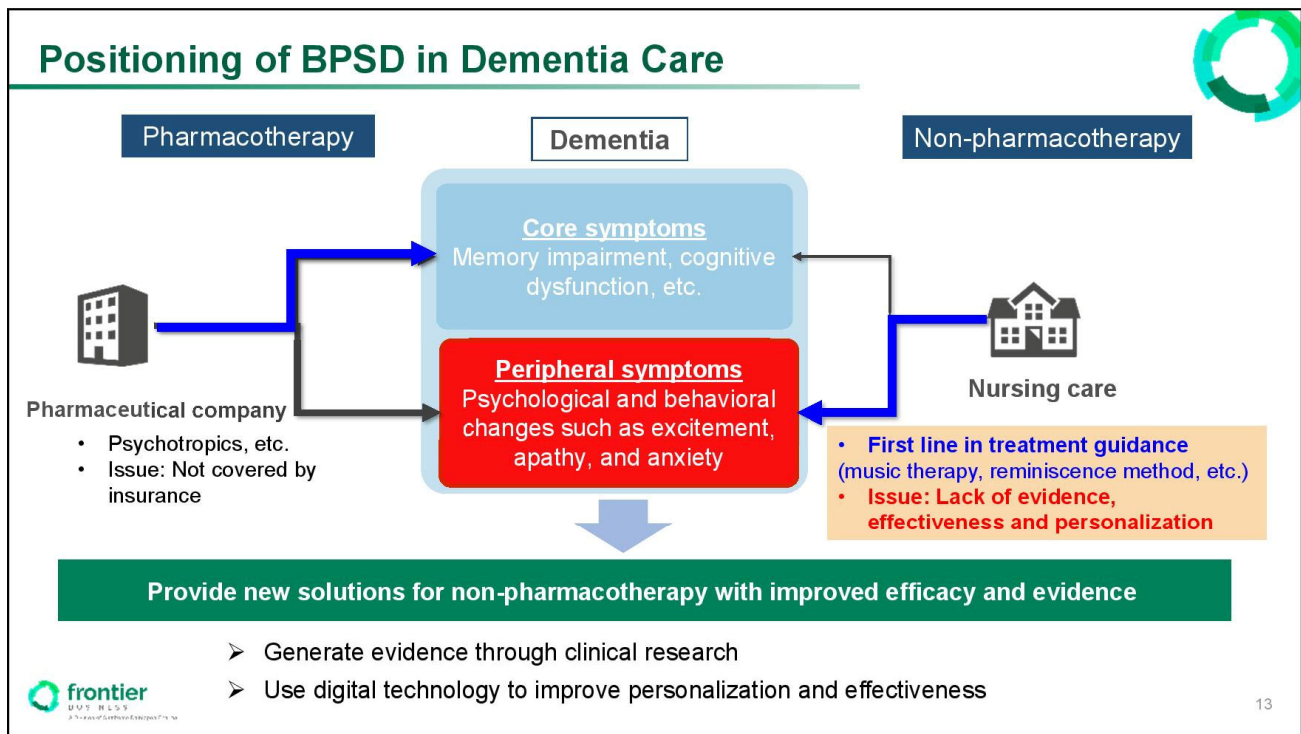


- Through technological innovations such as data analysis and sensory stimulation, we will provide solutions ranging from prevention and early diagnosis to intervention in dementia and depression
- Since medical care and nursing care/social rehabilitation support are integrated in some cases involving CNS disease care (BPSD, etc.), we conduct our business as integrated care
- Plans call for building integrated non-pharmaceutical solutions in Japan that can maximize the value of the diabetes pharmaceutical business



This project targets dementia and is unique in that it focuses on the peripheral symptoms of dementia, which are necessary to be treated during the nursing phase of the Patient Journey.





Next, I would like to discuss the positioning of BPSD in dementia care, which is a unique feature of this project.

First of all, the core symptoms of dementia, such as memory impairment, are currently being treated with pharmacotherapy. On the other hand, for psychological and behavioral peripheral symptoms such as excitement, apathy, and anxiety, the first choice in treatment guidance is non-pharmacotherapy. However, non-pharmacotherapy still has challenges such as lack of evidence and effectiveness and personalization.

We have been searching for technology to provide a new solution to the problem of non-pharmacotherapy of BPSD.

## Targeted Vision of the World



We aim to build a world in which the elderly with dementia can lead autonomous lives

### Current Issues

Non-pharmacotherapies **recommended for BPSD care lack evidence and systematic application**  
Dementia care is a specialized and personalized business area with high need **for improvement through innovation**

### This solution/device aims to realize:

**Reducing the burden of nursing care by strengthening care relationships between people with dementia, their families, and other caregivers through active communication and engagement**

Improving the QOL of all people involved in dementia care by digital non-pharmacotherapy tailored to the life story background, interests and preferences of people with dementia



Sumitomo Dainippon  
Pharma

- **Creating healthcare solutions** integrated with pharmaceuticals for neuropsychiatric diseases
- **Integration with other care solutions** in the dementia area



- **New digital therapy aimed at comprehensive non-pharmacotherapy** for BPSD
- R&D to improve QOL in person-centered care through personalization/automation

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To solve these issues, we met Aikomi. Aikomi is developing a completely new and comprehensive digital technology for non-pharmacotherapies.

By using this digital therapy technology, we aim to solve issues such as the lack of evidence for non-pharmacotherapies, promote communication and trust building between people with dementia, their families, and care givers, and also provide new care solutions that aim to reduce the burden of care. Ultimately, we hope to realize our goal of an independent senior life for people with dementia.

Mr. Kato, COO of Aikomi, will introduce the digital technology of Aikomi.



## Overview of Aikomi Ltd.



Corporate philosophy: Living with Dementia

- Support providing person-centered care focused on treating patients with dementia as “people” rather than “dementia cases”
- Creating an environment that fosters positive aspects of nursing care
- Improving the QOL of all people involved in dementia care



- 2018 • Spun out from Takeda Pharmaceutical (funded by JVC Kenwood and Takeda Pharmaceutical)
- 2019 • Concluded a joint research agreement with Sumitomo Dainippon Pharma  
• Won the Excellence Award in the Tech for Life Pitch Contest
- 2020 • Won U.K.'s Tech Rocketship Award for “Healthy Ageing – Medical Technology for an Aging Society”  
• Investment by Sumitomo Dainippon Pharma  
• Cooperative agreement with Sumitomo Dainippon Pharma and Sompo Japan Insurance Inc.
- 2021 • Started marketing Aikomi care on a trial basis  
• Awarded Small Business Innovation Research (SBIR) grant jointly with a U.S. care service provider

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**Mr. Kato:** Thank you, Mr. Hori. This is Junichi Kato from Aikomi Ltd.

We signed a joint research agreement with Sumitomo Dainippon Pharma in 2019 and raised funds for the project the following year. Since then, including Sompo Japan Insurance Inc., we 3 companies have been collaborating.

This year, we have started to test and sell our product, Aikomi Care. We have also won awards in business contests in Japan and abroad.

## Three Problems with Dementia



Living with dementia is challenging for most people



**No effective  
treatment**



**Behavioral and  
psychological  
changes**

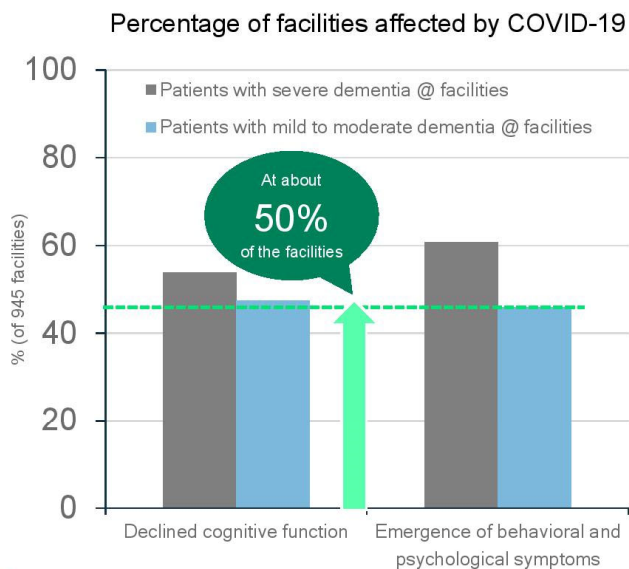


**Loss of  
mutuality**

In our opinion, there are 3 main points that make dealing with dementia difficult.

The first is that there is no cure, the second is that it causes not only cognitive decline, but also behavioral and psychological changes, and the third is that it is easy to lose social reciprocity by suffering from dementia, and furthermore, the loss has a negative impact on dementia.

## Relationship between Dementia and Society in the COVID-19 Pandemic



Lockdown measures in care homes which caused severe access restriction for external visitors to facilities were shown to have adverse effects on dementia patients, such as decline in cognitive function and worsened **behavioral and psychological symptoms**

Source: "The Spread of COVID-19 Shown to Aggravate Symptoms in People with Dementia and Increase the Burden of Care by their Families." Shinya Ishii, Hiroshima University news release, July 30, 2020.

This data was reported in a news article by Hiroshima University last year. It shows that refraining from going out and restricting visits to family members due to the COVID-19 pandemic has a negative impact on dementia.

## Features of the “Aikomi Care” Solution to be Provided



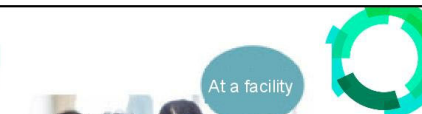
For operation by the caregiver



For viewing by the person with dementia

Communication

**Promote two way communication using two devices (tablets), one for the caregiver and one the person with dementia**  
**Can be operated remotely in preparation of the “new normal” in the post-COVID-19 era**



At a facility

With facility staff



From home afar

Face-to-face

Remotely

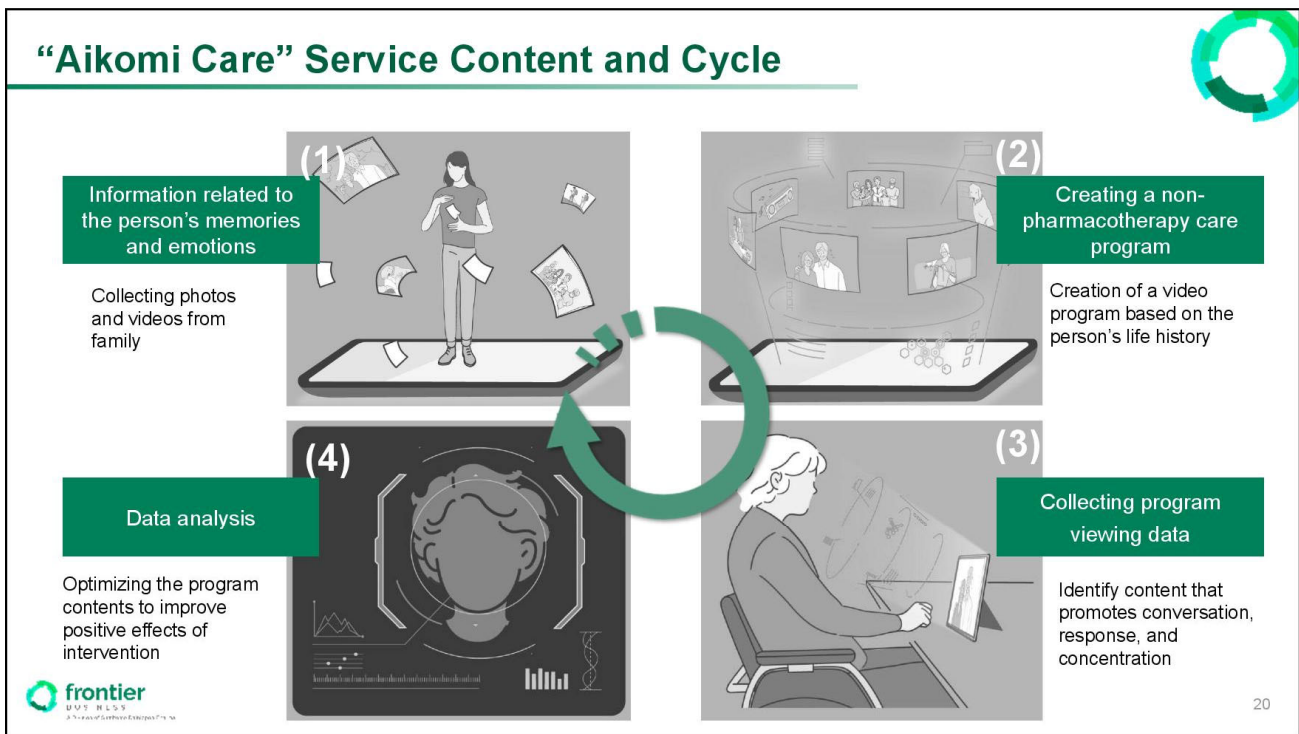


Sitting side by side



Since our founding, we have believed that one solution to dementia is to maintain the connection between people with dementia and the people who work with them. Based on this idea, Aikomi Care is a tool that can create connections between people in institutions, at home, or remotely, while providing non-pharmacotherapies. And the goal is to maintain the social mutuality that we tend to lose.

## “Aikomi Care” Service Content and Cycle



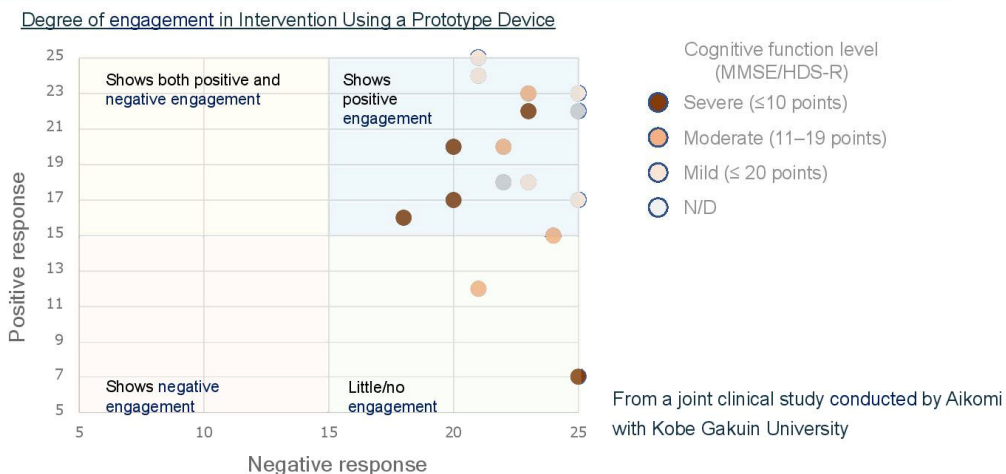
Here is a list of specific Aikomi Care services.

The first step is to interview the family in order to obtain information related to the person with dementia. The next step is to create a video program based on it and collect data as the person watches the program. After that, we will analyze what kind of images the person liked and did not like and improve the program for the next version.

## Results of a Clinical Pilot Study Using a Prototype Device



People with dementia who are unfamiliar with using tablets showed positive engagement with personalized psychological intervention



Evaluation based on the Engagement of a Person with Dementia Scale (EPWDS)



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We have conducted several joint research projects with domestic and international research institutes and have found that psychological interventions using unfamiliar tools for dementia, such as tablets, are highly important for people with dementia.

The following video will show you how Aikomi Care is used in practice.

First, let's take a look at the changes in behavior of people with dementia when using Aikomi Care.

[video plays]: Video of a patient with dementia using Aikomi Care

**Mr. Kato:** Next, we introduce a voice of a family that uses Aikomi Care.

[video plays]: Video of a family of a patient with dementia using Aikomi Care

## Targeted Vision of the World



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- **Creating healthcare solutions** integrated with pharmaceuticals for neuropsychiatric diseases
- **Integration with other care solutions** in the dementia area



- **New digital therapy aimed at comprehensive non-pharmacotherapy** for BPSD
- R&D to improve QOL in person-centered care through personalization/automation

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**Mr. Kato:** The video shown here is only a small part of our activities, but I believe that the concepts we have been thinking about since our founding are now being verified. In the future, we would like to develop our business with various partner companies, including Sumitomo Dainippon Pharma, so that more people with dementia can realize an autonomous senior life.

After this, Officer, Mr. Horii will talk about future developments.



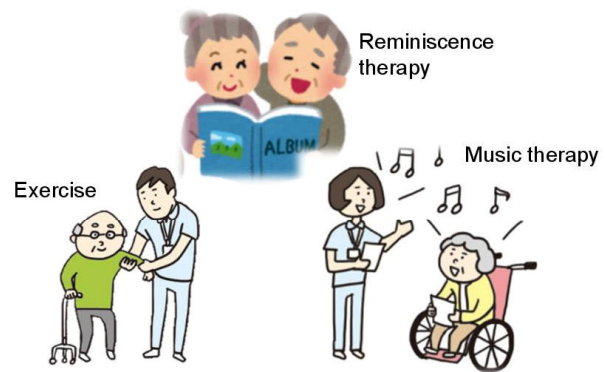
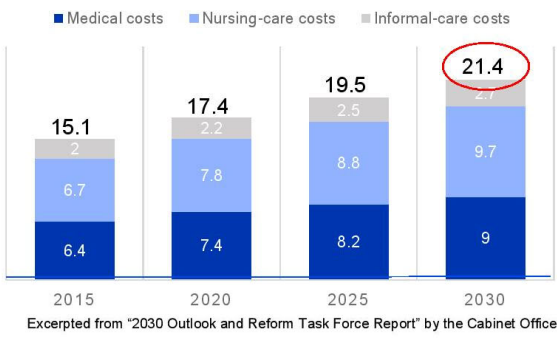
## Current Status of Dementia



Business development for BPSD care requires working with companies familiar with the nursing care business.

Estimates of the future social cost of dementia  
– Exceeding **21 trillion yen** by 2030 –

Non-pharmacotherapies for BPSD  
practiced in nursing care settings



From the Sampo Holdings website  
Supervised by Dr. Hiroyuki Shimada, Director of Preventive Gerontology, National Center for Geriatrics and Gerontology

Hori: Thank you very much, COO, Mr. Kato.

From here, I would like to introduce the future development of this project.

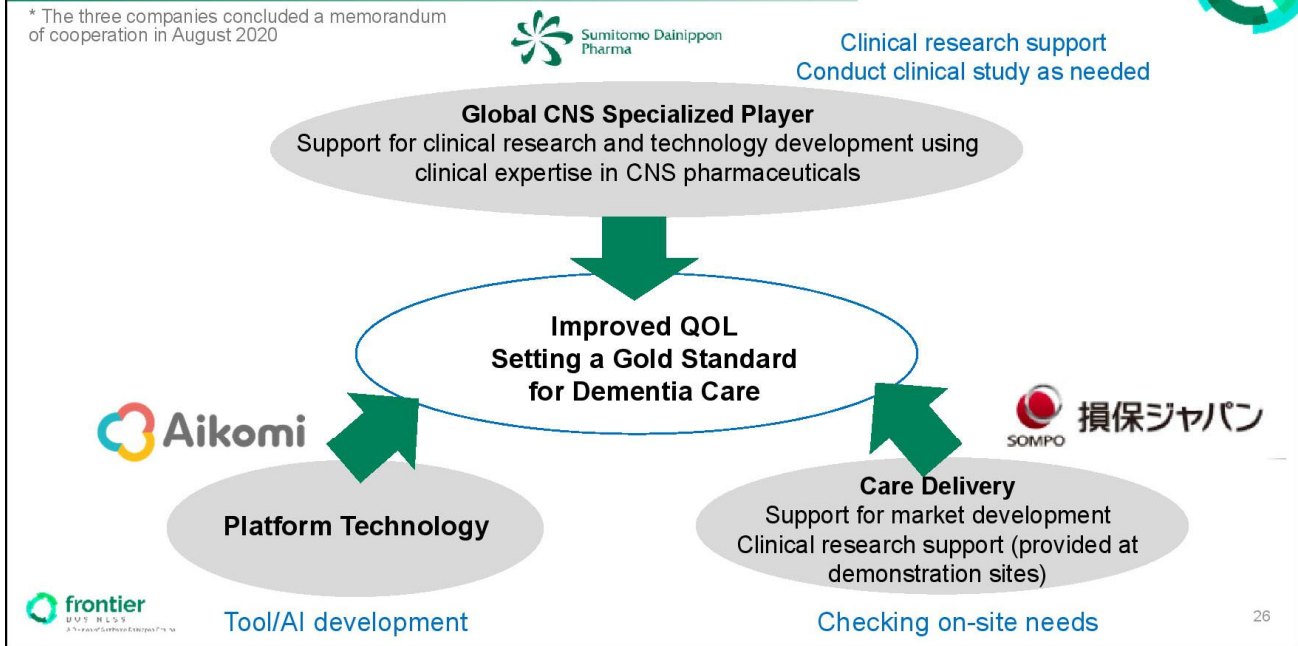
First, let's look at the business environment surrounding dementia care.

According to data released by the Cabinet Office, the social cost of dementia is expected to exceed JPY20 trillion within 10 years. Under these circumstances, care for BPSD is being practiced in various ways in nursing homes. Therefore, we believe that in order to develop this project's business for nursing care applications, we need to collaborate with companies that are familiar with the nursing care business.



### 3-Company Alliance, Including Sompo Japan Group, which Operates a Nursing Care Business\*

\* The three companies concluded a memorandum of cooperation in August 2020

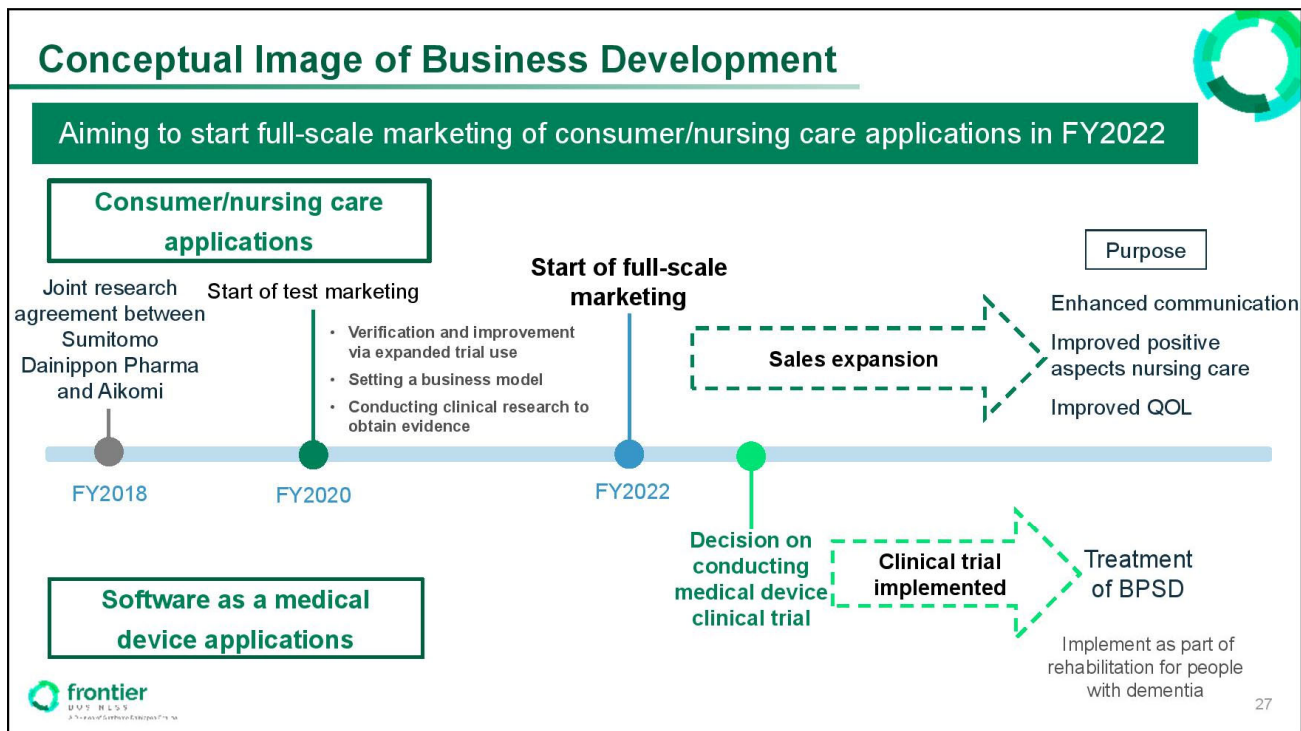


In light of this business environment, we have been promoting a 3-company alliance including Sompo Japan Insurance since August last year. Sompo Japan Insurance has been one of the first companies in the industry to implement a variety of initiatives to address dementia. Within the Group Company, it also operates a nursing care business.

In this collaboration, we are receiving support to create a market for Aikomi Care by verifying its needs in the field of nursing care companies. We believe that it is truly a partner company with expertise in the nursing care field.

In addition, in this 3-company collaboration, we will provide our knowledge such as building evidence cultivated in the pharmaceutical business, and when developing products for medical applications, we will consider taking charge of conducting clinical studies as necessary.

With Aikomi's technology platform at the core, we hope to combine the capabilities of the 3 companies to establish the gold standard in dementia care.



Lastly, here is an image of future business development.

For the time being, we will focus on business development for consumer and nursing care applications. We started test sales for nursing care applications at the end of last fiscal year and are now preparing for full-scale sales. In preparation for full-scale sales, we are examining and improving our service model, establishing a business model, and also considering supporting the acquisition of evidence through clinical research. Full-scale sales for nursing care applications are targeted for FY2022.

As for medical applications, we are preparing clinical research to determine whether or not to conduct clinical studies. When we develop medical devices, we would like to be able to play a part in the rehabilitation of dementia, aiming to treat peripheral symptoms associated with dementia.

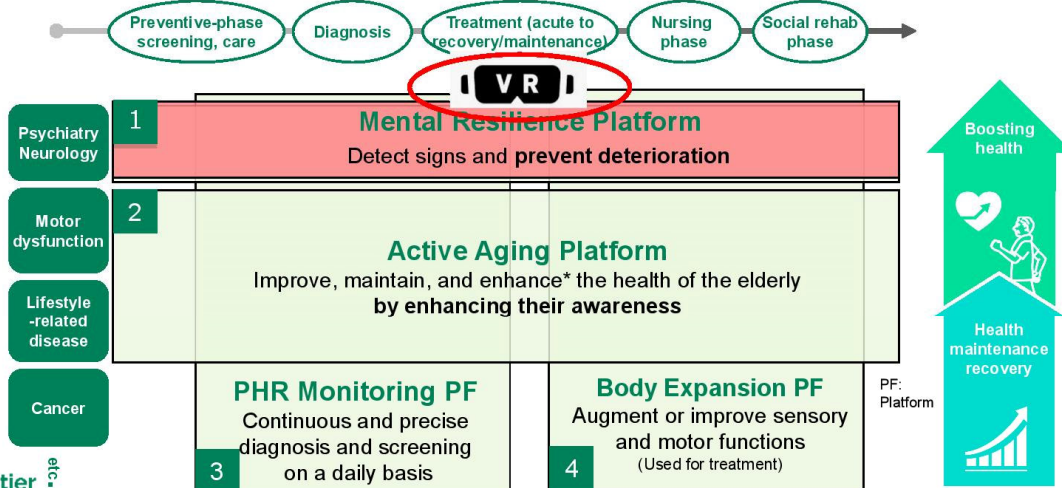
That's all. Thanks.

**Mr. Kato:** Thank you very much.

**Harada:** Next, we would like to explain the VR contents for social anxiety disorder.

## Frontier Business Domain

By utilizing technologies and solutions based on monitoring and augmentation of capabilities and functions, we work to resolve unmet needs in maintaining, recovering, and enhancing health, focusing on mental issues (psychiatric diseases) and aging (health issues of the elderly)



\* Includes mental and pain care for cancer patients

**Uyama:** I am Uyama from Sumitomo Dainippon Pharma America.

From here, we will introduce SAV-985, a VR content development project that Frontier Business is working on in collaboration with BehaVR.

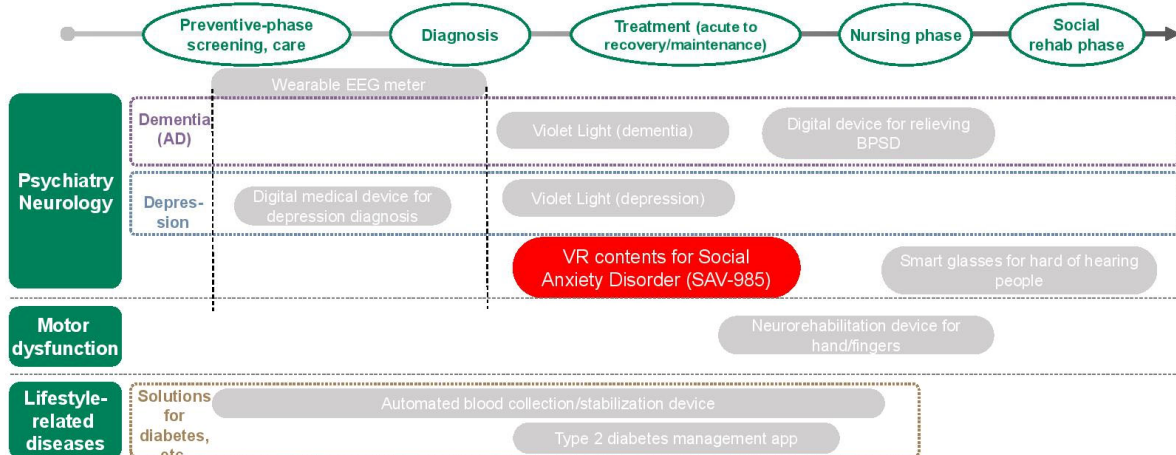
The VR goggles show you the position of this project in the business domain of Frontier Business.

This project is the development of a virtual reality program aimed at alleviating social anxiety disorder and is part of the Mental Resilience Platform lineup.

# Business Portfolio by Patent Journey



- Through technological innovations such as data analysis and sensory stimulation, we will provide solutions ranging from prevention and early diagnosis to intervention in dementia and depression
- Since medical care and nursing care/social rehabilitation support are integrated in some cases involving CNS disease care (BPSD, etc.), we conduct our business as integrated care
- Plans call for building integrated non-pharmaceutical solutions in Japan that can maximize the value of the diabetes pharmaceutical business



The positioning in the Patient Journey is shown by the red label. This project provides patients who are already suffering from symptoms with a VR program to help alleviate or overcome social anxiety disorder.

## Targeted Vision of the World



A world in which people who are unable to receive face-to-face therapy can live with the disease and resume social activities

### Current Issues

Due to the limited number of counselors and therapists, not everyone has access to face-to-face therapy. Due to the nature of the disease and people's hesitation to receive face-to-face therapy, it takes a considerable time before they receive appropriate treatment.

### This solution/device aims to realize:

Taking advantage of the characteristics of VR, joint development is underway for social anxiety disorder. We pursue the possibility of reproducing cognitive behavioral therapy (CBT) with VR content. We will commercialize/market the device as a general wellness product model in the U.S. by the end of 2022, in expectation of marketing it as a medical device (DTx) in the future.



Sumitomo Dainippon  
Pharma



sunovion

- Expertise cultivated through R&D of pharmaceuticals for neuropsychiatric diseases
- Knowledge and experience in the clinical study design of pharmaceutical compounds



BehaVR

- Development experience in reflecting cognitive behavioral therapy (CBT) and mindfulness into best-in-class VR content
- Track record of VR program sales in the U.S.

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The treatment of social anxiety disorder is effectively a combination of medication and cognitive behavioral therapy, or CBT, depending on the patient's symptoms. However, not everyone has access to interpersonal therapy, due partly to constraints caused by the limited number of therapists.

According to the Anxiety and Depression Association of America, an international society that conducts research on anxiety disorders and depression, about 36% of patients with social anxiety disorder do not seek medical attention and begin interpersonal therapy until about 10 years after the onset of symptoms. This is the reality.

In addition, cognitive behavioral therapy and exposure therapy conducted in the real world come with certain limitations and risks. Social anxiety disorder is said to be a disorder that can be improved with proper treatment. In addition to treatment, lifestyle modification is also said to be effective in helping patients regain their social life.

We believe that by providing a self-training menu, which is equivalent to exposure therapy, and a menu to practice changing one's perspective to a positive one, through VR content, we can provide a new tool for patients to learn how to deal with social anxiety disorder at their own pace.

This is the vision of this project: to be able to bring back to oneself social activities such as shopping, eating, or working.

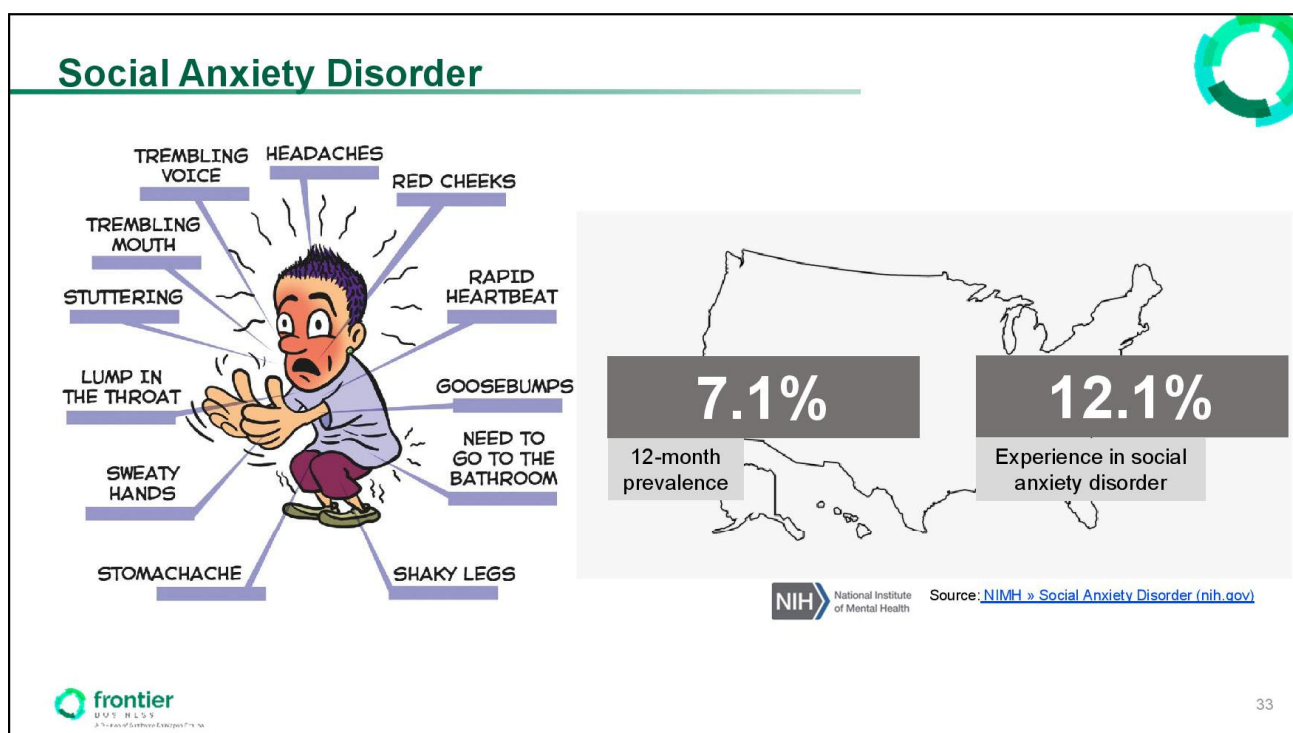
As its name suggests, BehaVR's strength is in developing VR content that aims to promote behavioral change. We have developed VR programs for stress management, chronic pain relief, and prenatal and postnatal mental care, and have already started selling these programs in the United States.

Our strength is in clinical studies in the field of neuropsychiatry, and we have the advantage of having experience in drug development, negotiating with the FDA, and relationships with key doctors and customers.

These 2 companies are collaborating to develop VR programs for social anxiety disorder with the common understanding that they can propose a new way of healthcare by applying VR modalities. First, we are aiming to commercialize the product as a general wellness product that does not require FDA review.

Next, I would like to introduce our partner company, BehaVR.

[video plays]: [Introduction video of BehaVR, Inc.]



**Uyama:** Next, I would like to talk about social anxiety disorder in detail.

Social anxiety disorder is one of the most common mental disorders. The illustration shows the main physical symptoms. The disorder is characterized by their very extreme intensity.

This can lead to a pattern of not wanting to be seen, giving up on dinner invitations, attending parties, attending meetings at work, and on public presentations, and gradually withdrawing from social life.

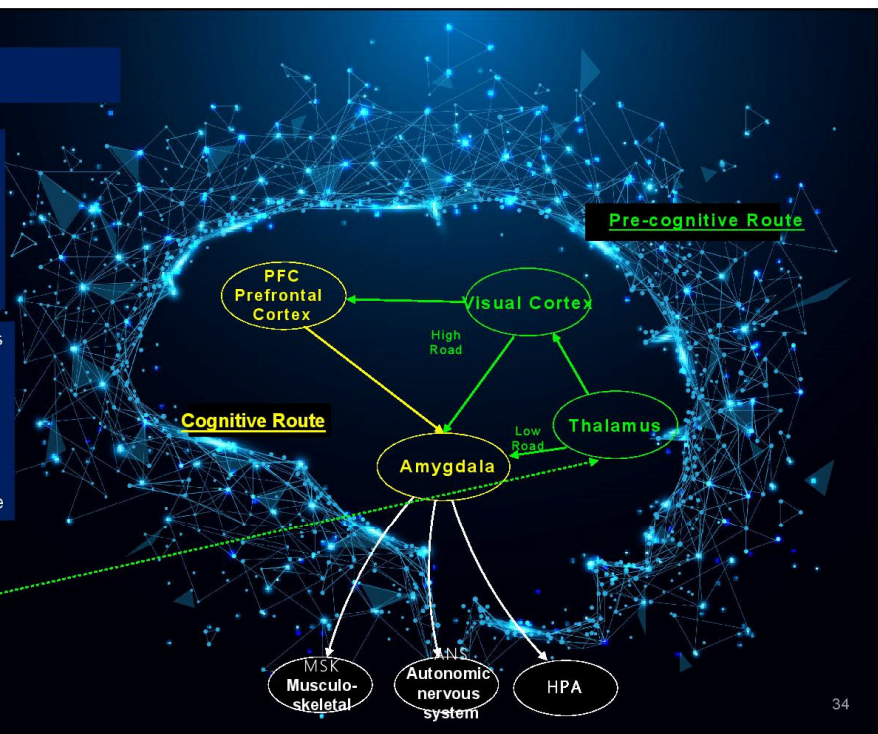
According to the NIMH, the National Institute of Mental Health, the 12-month prevalence rate in the US population over the age of 18 is as high as 7.1%. In addition, according to a 2013 report by the American Psychiatric Association, approximately 12% of the adult population in the United States is experiencing social anxiety disorder.

The next slide explains the mechanism of why we think VR is superior for the treatment of this social anxiety disorder.



## Why VR?

- Activating both the **cognitive** and **pre-cognitive routes** may improve the effectiveness of signal transmission to the musculoskeletal, autonomic, and neuroendocrine systems
- Exposure therapy on the person's body is time-consuming for securing a condition suitable for the person and may be dangerous. It is also difficult to standardize the therapy
- The implementation of conventional exposure therapy is limited to clinics where therapists can control it in real time



There are 2 routes by which the human brain catches external input and sends signals to the muscles, skeleton, and autonomic nervous system: the cognitive route and the pre-cognitive route. Without VR, the input is first received by the prefrontal cortex, and from there it is sent to the amygdala, which in turn transmits it to the bones, muscles, autonomic nervous system, and neuroendocrine system. The flow of the cognitive route is shown in yellow and white.

In contrast, when wearing a VR headset, the brain also catches the input in the thalamus and sends signals from there through the visual cortex to the prefrontal cortex and amygdala. The pre-cognitive route is shown in green. This is the mechanism that makes the VR experience a powerful stimulus compared to a 2-dimensional screen.

Exposure therapy in VR is characterized by the activation of both cognitive and pre-cognitive routes. It has been suggested that it may be more effective than traditional imaginal exposure therapy. In addition, there are various limitations and risks involved in conducting exposure therapy on the person's body, but with VR exposure therapy, we do not have to worry about these difficulties.

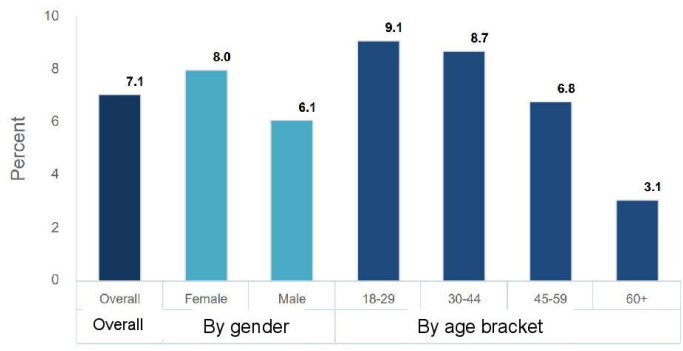
# Social Significance



## Social Anxiety Disorder Patient Segment in the U.S.

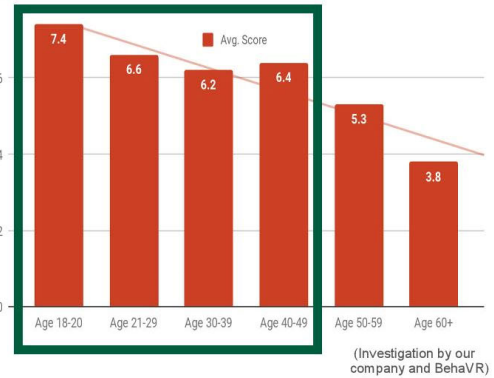
### Prevalence of Social Anxiety Disorder in the U.S. (12 Months)

Data from National Comorbidity Survey Replication (NCS-R)



Source: NIMH » Social Anxiety Disorder (nih.gov)

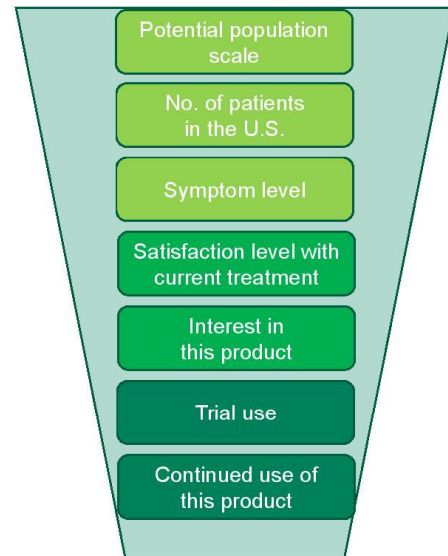
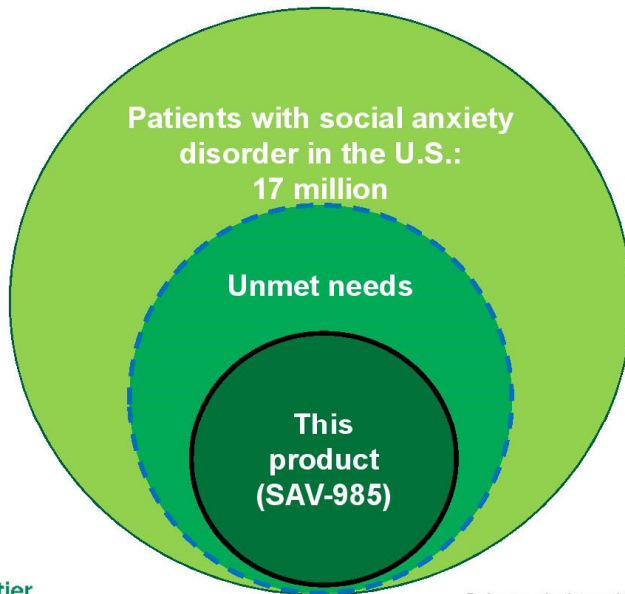
### Effects of Social Anxiety Disorder (Scale of 1 (min.) to 10 (max.))



As you can see, in terms of age structure, the prevalence tends to be higher in the 18-year-old to early 40 age group. In terms of gender, this disease is characterized by a higher percentage of females compared to males. In terms of the impact of social anxiety disorder on daily life, we and BehaVR have found that the 18-year-old to 20-year-old and 21-year-old to 29-year-old age groups tend to score higher in terms of perceived impact on social situations in daily life.



## Prospective Scales of Target Markets



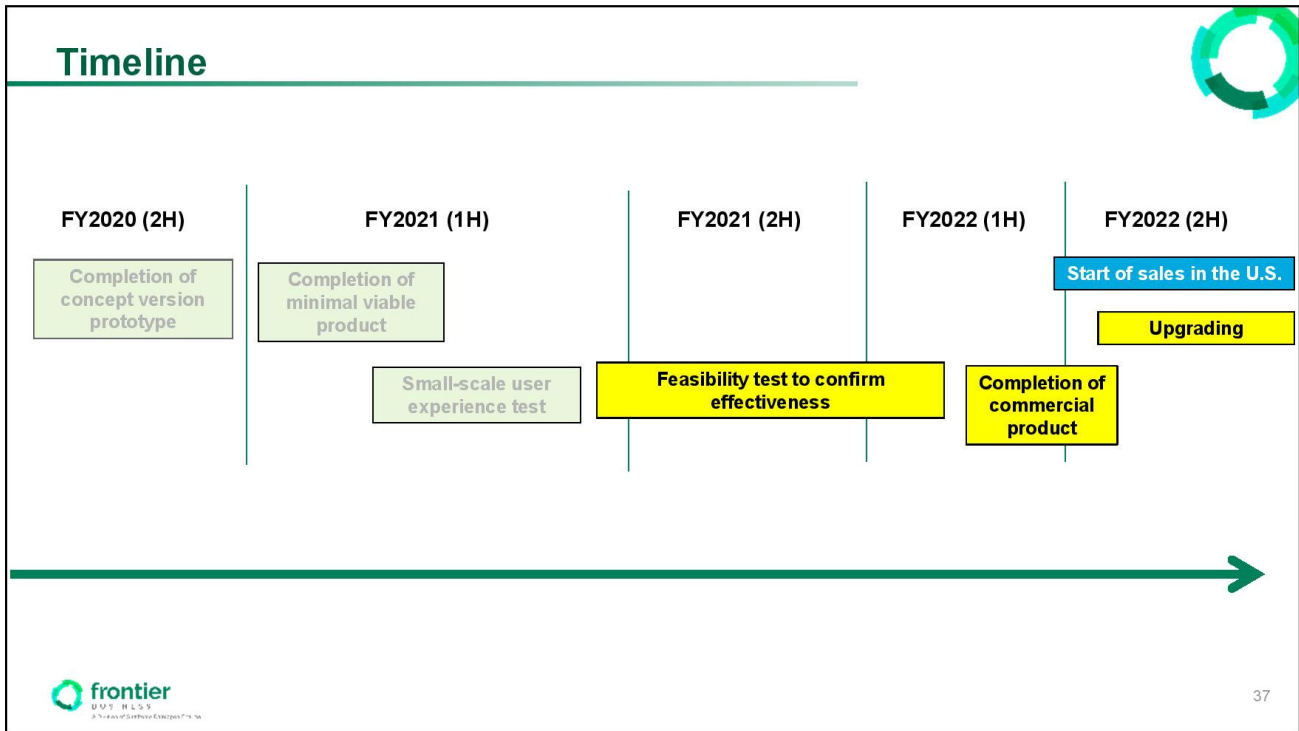
Reference: Anxiety and Compression Association of America. (2017)

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I will talk about the scale and timeline of the impact of social significance that this project assumes.

In the US, the number of patients with social anxiety disorder is estimated to be around 17 million. For these people to be satisfied with our product, factors that will be taken into consideration include the strength or weakness of the individual's symptoms, whether or not the individual is already receiving treatment for his or her symptoms, the level of interest in using VR, and whether or not the product has content that will allow each user to experience a response.

We believe that reaching as many users as possible will lead to the implementation of our Frontier Business vision of contributing to mental resilience, and we will work with BehaVR on marketing strategies to make this a success.



Today, it is September 2021. Based on the results of small-scale User Experience (UX) tests, we are now preparing feasibility tests to confirm the effectiveness.

Based on the feedback from these tests and studies, we will finalize the commercial product and start selling the general wellness product in the United States. Preparations are underway with the expectation that sales will start around October 2022.

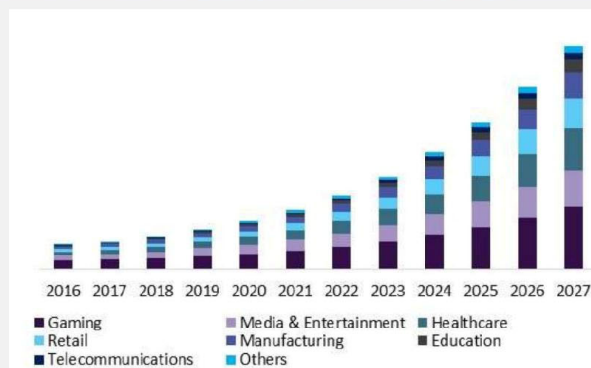
We are also planning to upgrade the version with improvements based on the feedback and data we receive after the sales launch.

## Summary



A future in which healthcare is much closer to patients through virtual reality

Fig.15 North America VR headset market by application, 2016 - 2027 (USD Million)



Source: Grand View Research, Virtual Reality Headset Market Size, Share & Trends Analysis Report 2021-2028



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VR technology will not only bring joy and excitement to people through games and entertainment but will also be used in various training and educational fields.

I believe that the day is coming soon when VR modalities will be applied as a new way of healthcare, in addition to the traditional way of healthcare, such as receiving and taking medication, and seeing a doctor at a clinic or hospital.

Through VR technology, we will strongly promote our partnership with BehaVR toward the realization of a future where healthcare is more accessible and a society that is more in tune with people and their lives.

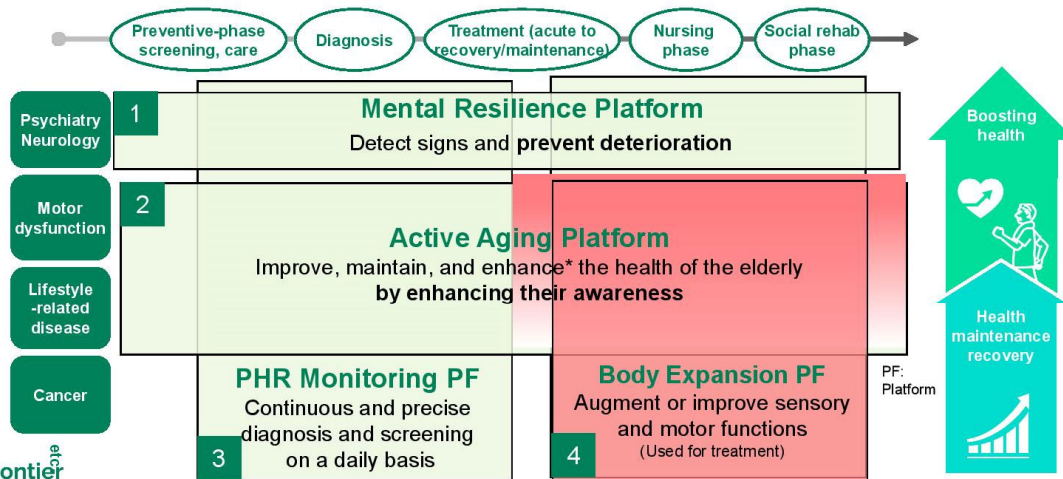
This is an introduction to SAV-985, a VR program development project we are working on with BehaVR.

Thank you very much for your attention.

**Harada:** Next, we would like to explain about the third item, the neurorehabilitation device for hand/fingers.

## Frontier Business Domain

By utilizing technologies and solutions based on monitoring and augmentation of capabilities and functions, we work to resolve unmet needs in maintaining, recovering, and enhancing health, focusing on mental issues (psychiatric diseases) and aging (health issues of the elderly)



\* Includes mental and pain care for cancer patients

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**Nishimaki:** I'm Nishimaki from the Frontier Business Office.

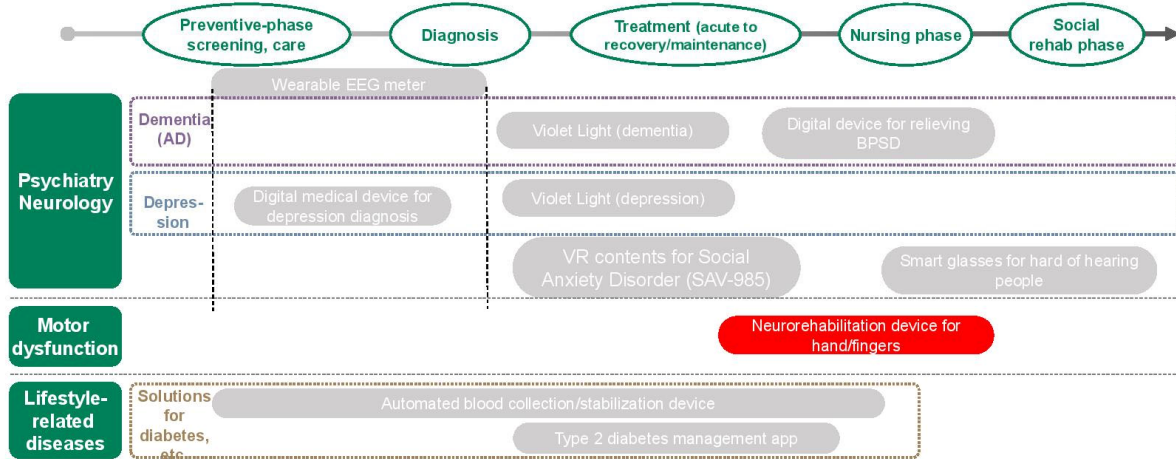
Today, together with CEO, Dr. Kasuya of MELTIN, who will be introduced later, I would like to introduce the development of a neurorehabilitation device for hand/fingers that the Company is working on with MELTIN.

First of all, the positioning of the MELTIN project in the Frontier Business domain is between the Active Aging Platform, which focuses on motor dysfunction, and the Body Expansion Platform.

## Business Portfolio by Patent Journey



- Through technological innovations such as data analysis and sensory stimulation, we will provide solutions ranging from prevention and early diagnosis to intervention in dementia and depression
- Since medical care and nursing care/social rehabilitation support are integrated in some cases involving CNS disease care (BPSD, etc.), we conduct our business as integrated care
- Plans call for building integrated non-pharmaceutical solutions in Japan that can maximize the value of the diabetes pharmaceutical business



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In the Patient Journey, it focuses on motor dysfunction in the treatment and nursing phases.

## History of MELTIN



### Venture company for cyborg technology founded in 2013 out of academic research

#### History

July 2013: Registration of incorporation

Jan. 2016: Seed round

Sep. 2017: Adopted for NEDO STS/Tokyo Metropolitan Government's medical device grant

Dec. 2017: Series-A round

June 2018: Selected as a J-Startup (a unicorn company candidate in Japan) by METI

Oct. 2018: Series-B round; a joint R&D agreement concluded with Sumitomo Dainippon Pharma

May 2019: Office moved to Kayabacho due to business expansion

Sep. 2020: R&D Center opened in Minamisoma, Fukushima Pref.



**Mark Kasuya, Ph.D.**  
**CEO, MELTIN**



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MELTIN is a cyborg venture started in 2013 while Dr. Mark Kasuya was a university student, and Sumitomo Dainippon Pharma has been working with the Company since they signed a joint research and development agreement in October 2018.

CEO, Dr. Kasuya, please give us a few words.

**Dr. Kasuya:** I'm Dr. Kasuya, the President of MELTIN. Thank you all for your cooperation today.

## The Future Envisioned by MELTIN & Sumitomo Dainippon Pharma



**Nishimaki:** MELTIN and Sumitomo Dainippon Pharma hit it off because they share the same vision of the future. We are working together to realize a future where everyone can maximize their potential in their own way, unconstrained by limitations.



## Targeted Vision of the World



**A Future in which Everyone Can Maximize  
Their Creativity without any limitations**



- Expertise, knowledge, and experience cultivated through basic research and clinical development in neuropsychiatric diseases
- Integration of active aging and body augmentation platforms

Medical - Engineering  
collaboration



**MELTIN**

- Robotics technology that moves a multi-joint robot as flexibly and powerfully as the human body
- Possesses high-speed, high-precision algorithms that convert biosignals into high-dimensional body movement

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In order to achieve this goal, we would like to combine the robotic and bio-signal processing technologies of MELTIN with the knowledge, expertise, and experience of Sumitomo Dainippon Pharma.

From here, CEO, Dr. Kasuya will introduce the core technology of MELTIN.

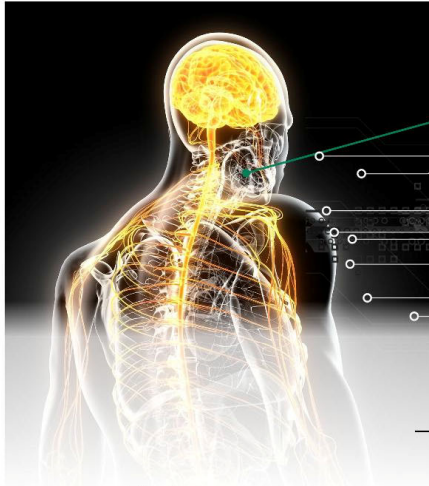
CEO, Dr. Kasuya, please.



## Our Technology

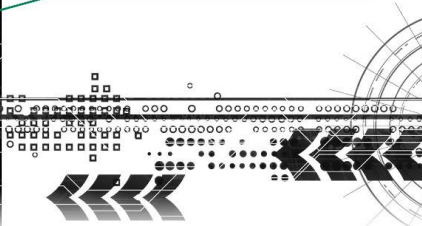
### What is cyborg technology?

Technology that fuses people and machines to open up new possibilities

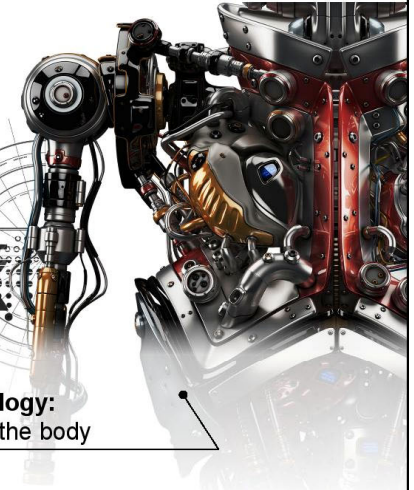


Electromyogram/  
neural signals, EEG

**Biosignal-interface:**  
Sensor Technology and analyzing  
algorithm



**Avatar consisting of robotic technology:**  
Technology for artificially constructing the body



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**Dr. Kasuya:** Thank you very much.

Now I would like to introduce the core technology of MELTIN.

First of all, we define cyborgs as a fusion of 2 things: a biological interface and an artificial body composed of robotic technology.

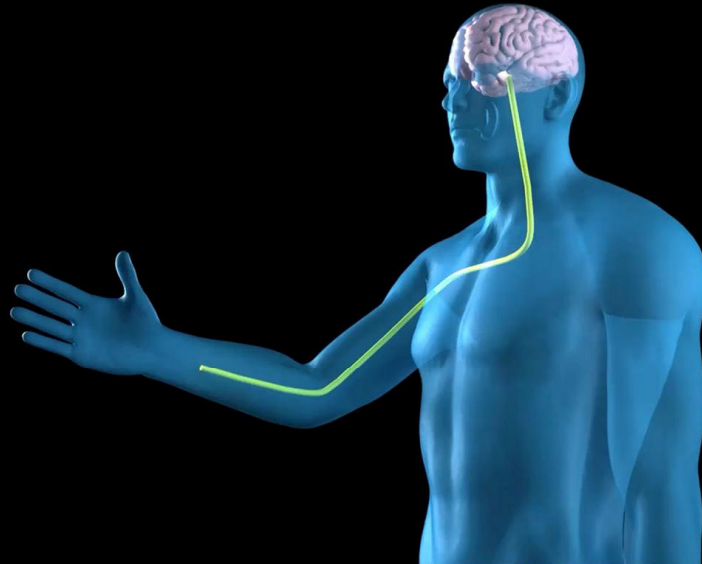
You are probably familiar with robots to some extent, but you may not be familiar with this biological interface, especially biological signals.

These bio-signals are actually electrical signals flowing through our bodies in the form of so-called EEG, electromyogram, and neural signals.

## Technology (Movie)



Introducing by movie (Live / recorded distribution only)



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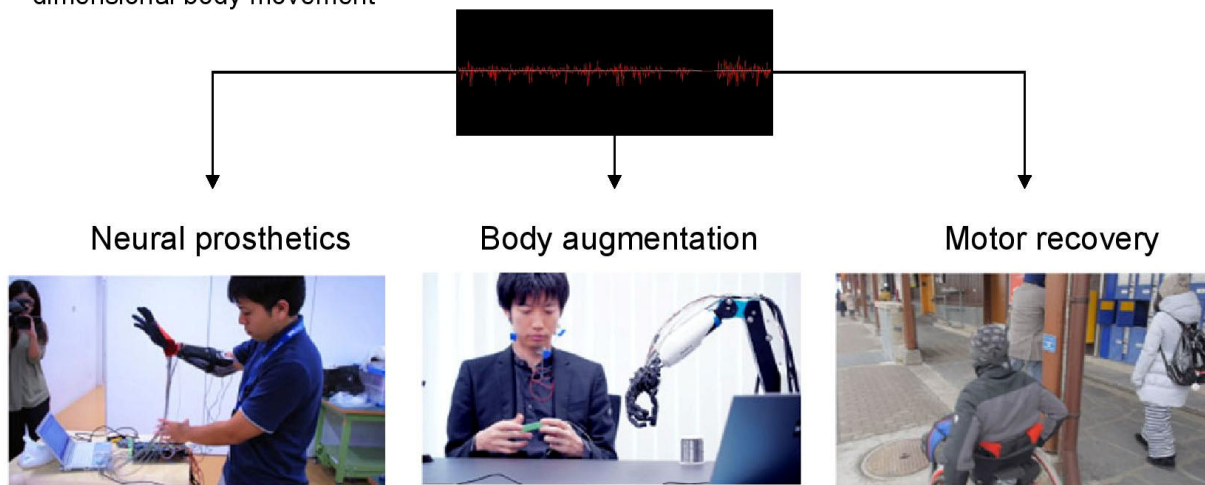
For example, when we move our hands, the intention to move our hands from our brain is transmitted through the nerves and reaches the muscles in the form of electrical signals. As a result, our hands move by muscle contraction, and the muscles that fire are different depending on the difference in the movement of the hand. The waveform will be different depending on that.

By using our technology to distinguish the differences in these waveforms, we are able to decipher what kind of movements people are making or want to make from just the nerve signals that are being emitted.

## Integrated Technology



Infinite Possibilities via Combining Robotic Technology with Biosignal  
Possesses **high-speed, high-precision** algorithms that convert biosignal into high-dimensional body movement



For example, in the example on the left, a person who lost his right hand in an accident has a robotic hand that we have developed attached to his right hand. The robot hand itself senses the bio-signals that the person is producing and can distinguish whether the person wants to grip an object or turn his wrist, and by actually controlling the hand, it can act as if the person has a right hand, even though the person does not actually have.

In the middle is a body augmentation, where I am temporarily using a third hand, which is a robotic hand, using my biological signals. This would allow us to do complex tasks that could only be done with 3 hands.

Thirdly, this person also suffered a spinal cord injury in an accident and is unable to move his lower body at all. As you can see in this video, by attaching electrodes and sending electrical signals through it, we can reactivate the body that is not moving. For example, by adjusting the timing of the right and left legs and balance, he will eventually be able to pedal a bicycle like this. The combination of the bio-signal and the robot technology will provide new possibilities for human beings. This is such an area of technology.

## Targeted Vision of the World



### A Future in which Everyone Can Maximize Their Creativity without Any Limitations

#### Current Issues

The percentage of post-stroke hemiplegic patients recovering a functional hand is lower than that of lower limb recovery. Unless hand/finger extension manifests on the hand at an early post-stroke stage, the hand is likely to become nonfunctional. In such cases, treatment focuses on compensatory rehabilitation such as changing hand dominance, leaving the rehabilitation of the paralyzed hand inadequate.

Recent neuroscience research has revealed that appropriate rehabilitation can induce plasticity change and improve motor function even after brain damage. Thus, there is a growing need to realize neurorehabilitation aimed at reconstructing the neural network by taking advantage of the plasticity of brain nervous system tissues.

#### This solution/device aims to realize:

The robotic neurorehabilitation device is designed to read the patient's motion intention from surface electromyography (EMG) signals and operate the robot attached to the hand/fingers in sync with the intention. By learning the activity of the motor cortex of the brain and the motor sensation of the hand/fingers, we are examining how to demonstrate the function to support the reconstruction of a series of motor mechanisms, with the aim of recovering "functional hand/fingers," even if the device is removed.

**Nishimaki:** Thank you very much, CEO, Dr. Kasuya.

Both companies are doing well in developing and deploying the robotic neurorehabilitation device that is developed based on this kind of technology, so let me give you a little clinical background.

## Epidemiology of Motor Paralysis (in Japan and Overseas)



- ✓ Brain stroke is the most common causative condition of motor paralysis
- ✓ There are about 1.2 million patients with brain stroke in Japan

|  | Japan                   | Overseas   |
|--|-------------------------|--|
| Annual incidence of brain stroke <sup>1)</sup> | 300,000                 | 17 million worldwide   |
| No. of patients with brain stroke              | 1,115,000 <sup>2)</sup> | About 7.2 million in the U.S. <sup>3)</sup><br>About 13 million in China <sup>4)</sup> |

- ✓ No.1 cause of being bedridden in Japan and 2nd of requiring nursing care<sup>2)</sup>

- 1) <http://www.jsa-web.org/citizen/95.html> (Message from the Japan Stroke Association and the World Stroke Organization)
- 2) <http://www.seikatsusyukanbyo.com/statistics/disease/cerebral-hemorrhage/> (Japan Preventive Association of Life-style related Disease website)
- 3) *Circulation* 2017; 135:e146–603 (AHA report)
- 4) <http://j.people.com.cn/n3/2020/0930/c94475-9766118.html> (People Daily Japanese edition: Report on Cardiovascular Diseases in China 2019)

Although robotic neurorehabilitation devices are indicated for motor dysfunction, brain stroke is by far the most common cause of motor dysfunction, with approximately 1.2 million patients in Japan, 7.2 million in the United States, and 13 million in China.

Brain stroke is the number 1 cause of bedridden patients in Japan and the number 2 cause of nursing care and has become a social issue.

## Estimated Percentage of Patients with Post-Stroke Hand/Finger Paralysis (in Japan)



Percentage of Patients with Post-Stroke Hand/Finger Paralysis  
(Questionnaire survey of doctors)



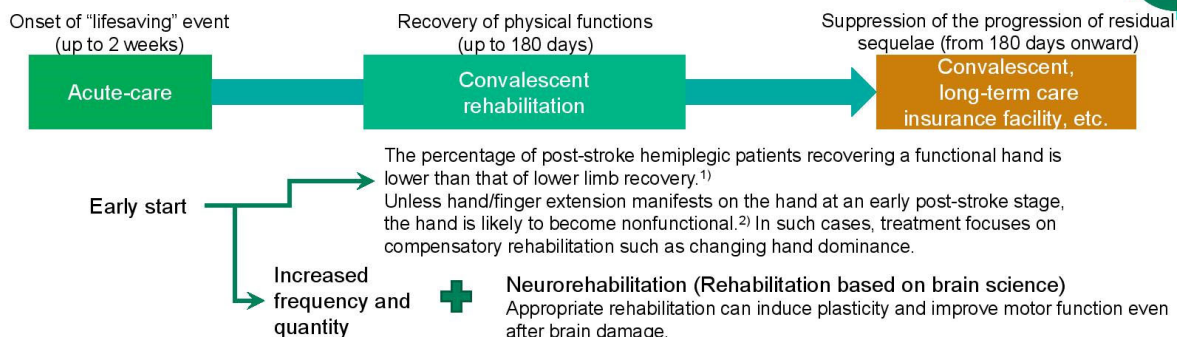
Calculated from the number of stroke patients examined by doctors in the last month, the proportion of patients with severity of finger paralysis at admission, and the number of patients undergoing rehabilitation (Survey in 1st half of 2020, more than 100 doctors in both acute and convalescent facilities)

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The MELTIN device can be used to treat hand paralysis, which is the most common form of motor dysfunction. There are few epidemiological reports on the percentage of patients with hand paralysis after stroke. We conducted a questionnaire survey of physicians and estimated that 80% of patients have hand paralysis at the time of admission, whether in the acute or chronic phase.



## Issues of Stroke Rehabilitation



### Realizing Neurorehabilitation via Bio-signal × Robotics

The robotic neurorehabilitation device is designed to read the patient's motion intention from surface electromyography (EMG) signals and operate the robot attached to the hand/fingers in sync with the intention. By learning the activity of the motor cortex of the brain and the motor sensation of the hand/fingers, we are examining how to demonstrate the function to support the reconstruction of a series of motor mechanisms, with the aim of recovering "functional hand/fingers," even if the device is removed.

Although there are some robotic rehabilitation devices for simple grasping movement, or for large joints such as elbows, no robotic neurorehabilitation device has been developed for the severe hand/fingers paralysis yet.



1) Heller A, et al., Arm function after stroke: measurement and recovery over the first three months. J Neurol Neurosurg Psychiatry. 1987; 50: 714-719  
 Nakayama H, et al., Recovery of upper extremity function in stroke patients: the Copenhagen Stroke Study. Arch Phys Med Rehabil. 1995; 76: 27-32.  
 2) Kazuhisa Domen, Stroke Function Evaluation/Prognosis Prediction Manual. Igaku-Shoin Ltd. 2013, pp. 186-194

For those patients, rehabilitation is commenced immediately after admission. However, the percentage of patients who are able to recover to a level where they can actually use their hands in daily life is lower than that of patients with lower limb paralysis, and in patients who cannot expect early recovery of hand movement functions, compensatory rehabilitation such as changing the dominant hand may be focused on without waiting for recovery of the paralyzed hand.

Therefore, the emergence of a method that can obtain improvement in motor functions by implementing rehabilitation based on brain science, i.e., neurorehabilitation, is expected, in addition to starting rehabilitation early in hospitalization and increasing the frequency and volume.

In response to this expectation, the neurorehabilitation device reads the patient's motor intentions from body surface electromyography and operates the robot attached to the fingers in conjunction with the motor intentions. By learning to link the activity of the motor cortex of the brain with the motor sensation of the fingers, the function of supporting the reconstruction of a series of motor mechanisms is demonstrated, so that the user can expect to regain "usable fingers" even after the device is removed.

There are several robotic rehabilitation devices that are attached to large joints such as the lower limbs and elbows, but there are no robotic neurorehabilitation devices for the fingers yet.

CEO, Dr. Kasuya, clinical studies have already started using this device, right?

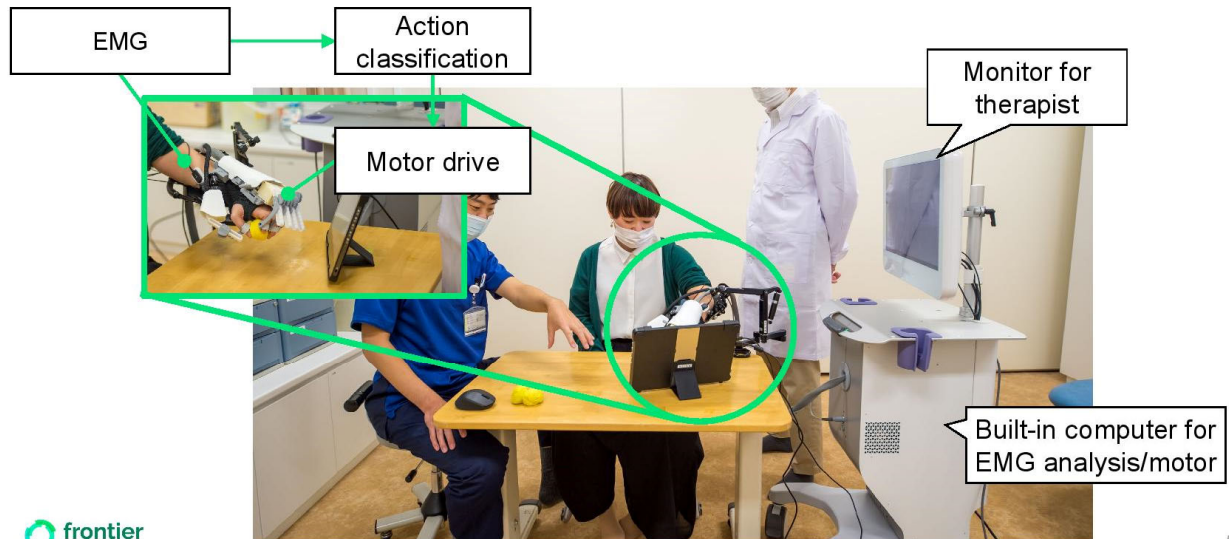
**Dr. Kasuya:** Yes.

**Nishimaki:** Can you tell us about the composition?



## Overview of Robotic Neurorehabilitation Device for Hand/Fingers

The device is driven in accordance with biosignal then moves the patient's body



**Dr. Kasuya:** The overall image of this device is as shown in the photo. It is a device that wraps around the back of the hand like this.

This is where our core technology comes in: it measures bio-signals in the forearm, and based on those signals, it uses an algorithm to determine how the person wants to move the fingers, and depending on that, even if the person's fingers don't move, the device can lift the fingers or make them clench, so that the person can exercise his/her fingers.

Most of the device is housed in this cart-shaped housing on the right, which also contains the computer that analyzes the bio-signals and the motor that actually drives the fingers.

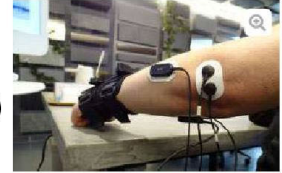
**Nishimaki:** What are the features of this device?

## Features of Robotic Neurorehabilitation Device for Hand/Fingers



### Features

1. Powerful, cable-driven finger traction
  - Lightweight and compact design, yet powerful enough to support spasticity
2. Identifies the user's motion intention even with feeble biosignal (surface EMG)
  - To achieve neurorehabilitation with movement in time with the user's intention
3. Algorithm that classifies movement by the bio-signal "waveform"
  - The device will not be distracted by spasticity, unlike conventional devices
4. A wearable exoskeleton that assists occupational therapy in sync with the user's motion intention
  - No mechanism on the palm side, facilitating occupational therapy
  - Independent control of 5 fingers allows holding objects of various sizes and shapes



For reference:  
Differences from  
other technologies

Investigated  
by MELTIN



|                                  | MELTIN                | A                         | B                      | C               |
|----------------------------------|-----------------------|---------------------------|------------------------|-----------------|
| Control                          | EMG waveform          | EMG amplitude (intensity) |                        | Constant rhythm |
| Drive method                     | Cable driven          | Direct drive              | Electrical stimulation | Pneumatic       |
| Responsiveness to patient intent | ○ Supports spasticity | ○                         | ○                      | ×               |
| Pinching                         | ○                     | ×                         | △                      | ×               |

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**Dr. Kasuya:** Earlier, I explained that the motor is housed in a box a little farther away from the actual device, but the reason for this is actually here: people who are paralyzed have a strong grip on their fingers in the form of spasticity. It takes a rather large amount of force to bring this to open. Therefore, if we put a large motor in here, the device would become larger and heavier, so by placing it in a remote location, we were able to create a very light and compact housing while generating enough power to defy the spasticity. This is the first feature.

The second feature is that when a person suffers from paralysis due to brain stroke or other disease, the bio-signals become quite weak. By amplifying the weak bio-signals and analyzing them with our algorithms, we are able to provide neurorehabilitation by performing the movements at the timing when the person actually wants to grip or open the hand.

Third is the identification of movement by the waveform of bio-signals. This is also related to the spasticity I mentioned earlier. When you have spasticity, you are basically applying force in the direction of gripping. With conventional devices, for example, the bio-signal in the direction of gripping the hand and the bio-signal in the direction of opening the hand are compared, and control is applied to the larger of the 2. For example, if the bio-signal in the direction of gripping is stronger, it means that the person is trying to grip. If the bio-signal to open is stronger, the person must be trying to open. But if we do that, as people with spasticity is basically putting power into the direction of gripping, the device can only determine that the person wants to grip.

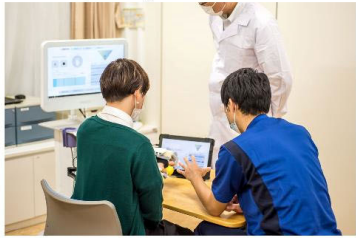
On the other hand, our device doesn't analyze which bio-signal is bigger, but the difference of waveform of bio-signals. So even if the person is gripping all the time, it can identify the movement by the subtle differences in the waveforms, whether the person is trying hard to open the hand or really trying to grip. Our equipment can be used even for people with spasticity. This is third feature.

The fourth is that it can be used for occupational therapy, as the device is located on the back of the hand. There is nothing completely on the palm side of the hand. By being on the back side of the hand, you will be able to work such as grabbing something. Furthermore, in addition to this, independent control of the 5 fingers allows for a firm and stable grip with 5 fingers on, for example, a round or square object, a large or small object. It has those characteristics.

By combining these features 1 to 4, the neurorehabilitation device for hand/fingers that can perform occupational therapy and also cope with spasticity can be created.

## Clinical Development Status of Neurorehabilitation Device for Hand/Fingers

Juntendo University and MELTIN concluded a joint research agreement on the therapeutic effects of using a robotic neurorehabilitation device on post-stroke upper limb paralysis



- ◆ Targets: Post-stroke hemiplegic patients
- ◆ Population size: 30
- ◆ Study period: May 2020 to April 2022

Randomized assignment

→

Group A: 40-minute training with EMG controlled robot conducted twice weekly for 4 weeks

→


Completion test

→

Follow-up test at 4 weeks

Primary endpoints: Fugel-Meyer Assessment upper limb parameters  
 Secondary endpoints: Box and Block (BBT),  
 Jebsen-Taylor Hand Function Test (JTT),  
 Motor activity Log-14 (amount of use ) (MAL-14 AOU),  
 Modified Ashworth scale (finger, wrist, elbow)  
 electrophysiological testing

**(Clinical study protocol No.: jRCTs032200045)**



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**Nishimaki:** The specific clinical research at Juntendo University is still in progress, so I guess the results are not yet available, but have you heard about the patients who are wearing the device?

**Dr. Kasuya:** Yes. People who have been doing rehabilitation for a long time seem to have a hard time seeing the effects of rehabilitation because they are unable to move their own bodies.

In fact, when some patients saw the waveform of bio-signals as EMG, and the actual movement of the device in response to the waveform, they began to work on rehabilitation in a positive and proactive way, although they had almost given up because they could not move hands at all. I've seen such people, and I hope that our devices will contribute to rehabilitation in this way.

**Nishimaki:** I'm looking forward to the results.

**Dr. Kasuya:** Yes.

## Summary: What the Robotic Neurorehabilitation Device for Hand/Fingers is Pursuing

### Clinical Needs

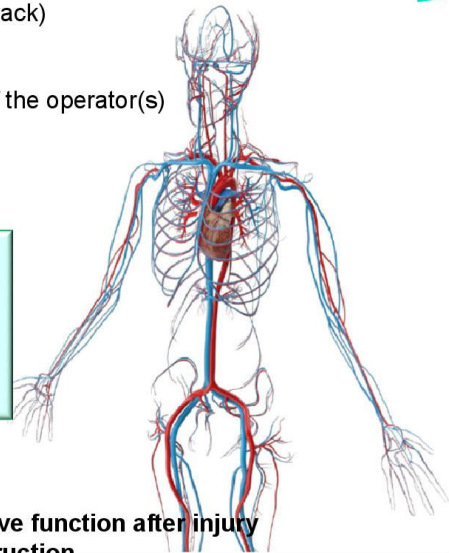
- Response to and visualization of biosignal (bio-feedback)
- Conducting exercise with purpose (issue-dependent)
- Repetition with the device, etc. (quantity-dependent)
- Usage independent of the number and experience of the operator(s) (handing over expert skills)

### Functionality Pursued as a Medical Device

An easy-to-use robotic neurorehabilitation device that detects and visualizes EMG even from paralyzed hand/fingers so that it can accurately classify the user's motor intention from feeble EMG to assist exercise with no time lag

### Clinical Benefits

- Rehabilitation aimed at promoting the recovery of nerve function after injury
- Promotes brain plasticity and neural network reconstruction



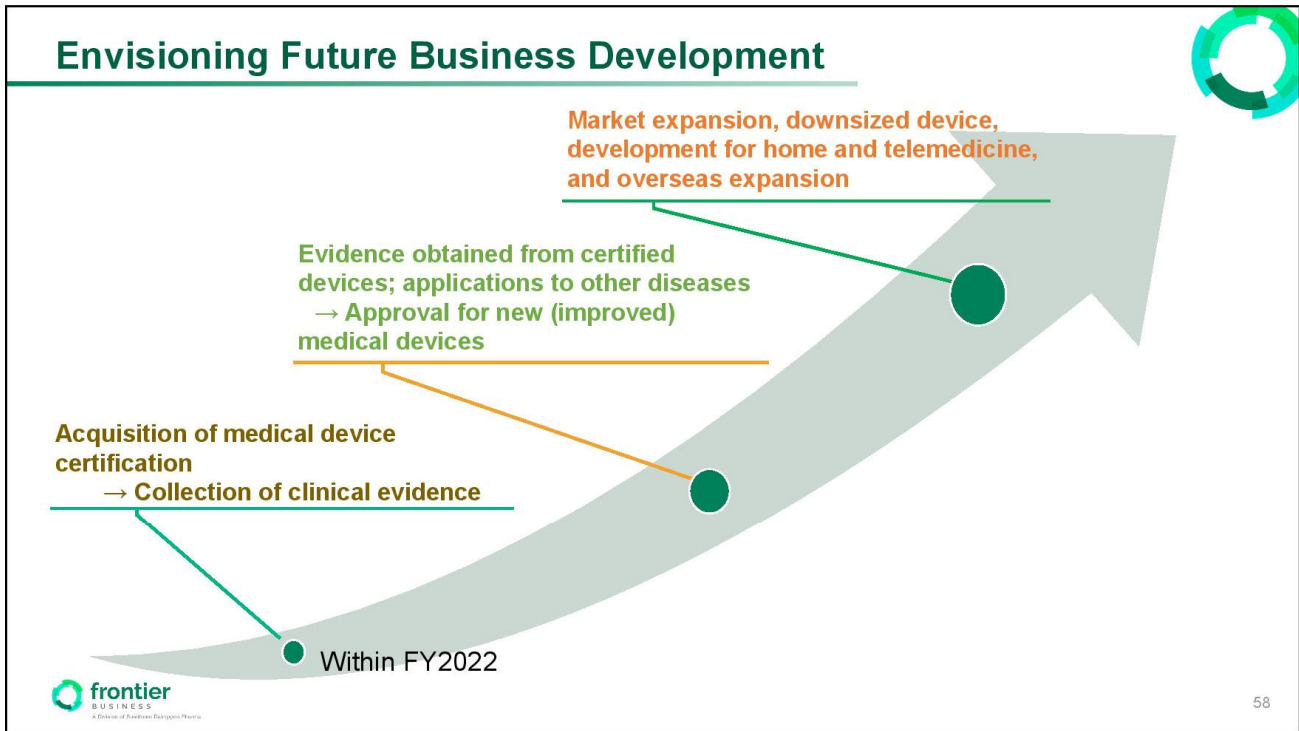
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**Nishimaki:** Thank you very much.

I would like to summarize what we have presented today.

In clinical rehabilitation, there are various issues such as bio-feedback, issue-dependency, quantity-dependency, and handing over expert skills. Our goal is to provide an easy-to-use robotic neurorehabilitation device for hand/fingers that detects and visualizes EMG even from paralyzed hand/figures so that it can accurately classify the user's motor intention from feeble EMG to assist exercise with no time lag.

This is expected to facilitate neurorehabilitation to promote recovery of neurological functions after injury, and to promote brain plasticity and reconstruction of neural networks.



Finally, as for the future business development, we are planning to acquire a certification of existing devices with generic names as certified devices.

After certification, we plan to start selling the device on a small scale, collect evidence in actual clinical practice, upgrade the device to a new version based on the evidence, and conduct another test on the upgraded device to obtain approval as a new medical device or improved medical device.

After that, the miniaturization of the device will allow us to expand the market for home and remote medical care, and we would like to expand the market including overseas development.

That's all for today. I've introduced our project with MELTIN. Thank you for your attention

**Dr. Kasuya:** Thank you very much.

**Harada:** Now, at the end of the presentation, Dr. Takehiko Nomura, Senior Director of Frontier Business Office, will give us an overview of the entire portfolio.

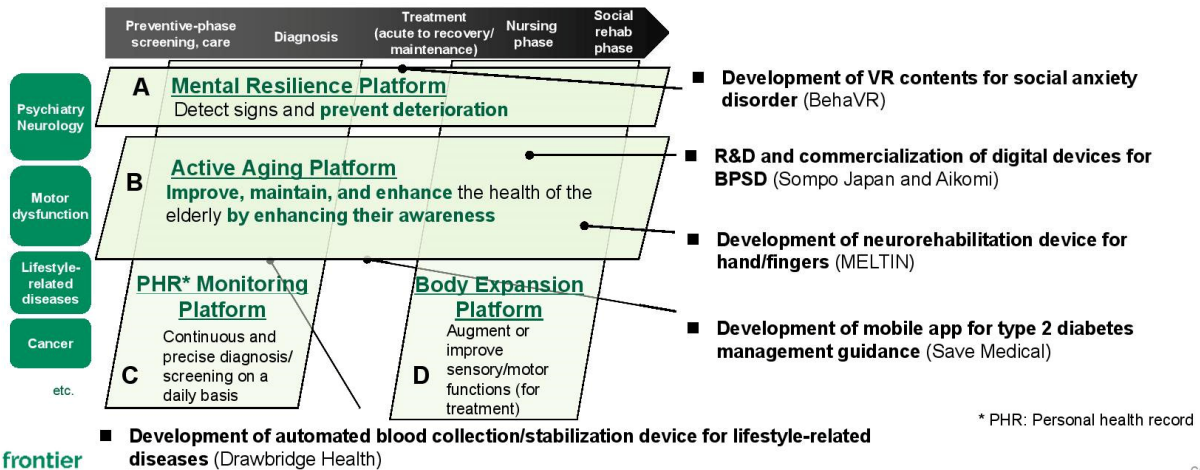


# Establishing Growth Engines: The Challenge of Launching New Businesses



## Accelerating the Development of Frontier Business

Investing in promising technologies and businesses in each disease area, with the aim of contributing to all stages of the patient's journey from recognizing the disease to social rehabilitation

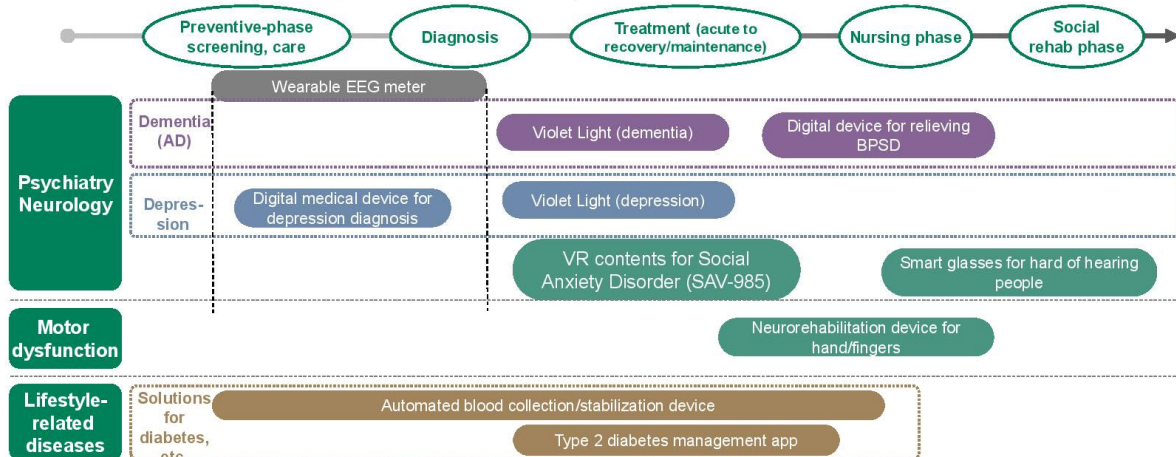


**Takehiko Nomura:** I would like to conclude by explaining the status of the entire portfolio, including the 3 products that we explained in detail today, as well as other products in development.

As part of our med-term business plan, we have set the goal of accelerating the development of Frontier Business as a challenge to launch new businesses in order to establish a growth engine. In addition to the 3 products introduced today, we have already announced a mobile application for type 2 diabetes management guidance, which belongs to the lifestyle-related diseases field, and an automated blood collection and stabilization device that also specializes in the Personal Health Record Monitoring Platform.

## Business Portfolio by Patent Journey

- Through technological innovations such as data analysis and sensory stimulation, we will provide solutions ranging from prevention and early diagnosis to intervention in dementia and depression
- Since medical care and nursing care/social rehabilitation support are integrated in some cases involving CNS disease care (BPSD, etc.), we conduct our business as integrated care
- Plans call for building integrated non-pharmaceutical solutions in Japan that can maximize the value of the diabetes pharmaceutical business



We have plotted with the horizontal axis representing the Patient Journey, which consists of the prevention phase, diagnosis, treatment, nursing phase, and social rehab phase, and the vertical axis representing the disease areas we focus on, such as psychiatry & neurology, motor dysfunction, and lifestyle-related diseases.

Using this chart, I will introduce other Frontier Business-related themes that we are currently considering.



## Wearable EEG Meter



- Target Diseases: Neuropsychiatric diseases (details undisclosed)
- Partner Company: NeuroSky Co., Ltd.
- Anticipated Product Profile:
  - Wearable EEG meter that can be used with ease by anybody, anywhere
  - A wide range linking of EEG data is expected, from healthcare to medical care

### Features

- Medical device certification is expected as a telemetry EEG meter
- Measurement by a 2-point dry sensor on the forehead
- Enabling EEG measurement at home makes it easier to assess EEG trends, which has previously been difficult



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First, let me explain about the wearable EEG meter.

This is an excerpt from the reference material. The wearable EEG meter can measure EEG with dry sensors at 2 points on the front of the head, enabling measurements at home and making it easy to evaluate EEG trends that could not be grasped in the past. We are planning to obtain approval for medical devices and would like to develop business in the field of mental disorders.

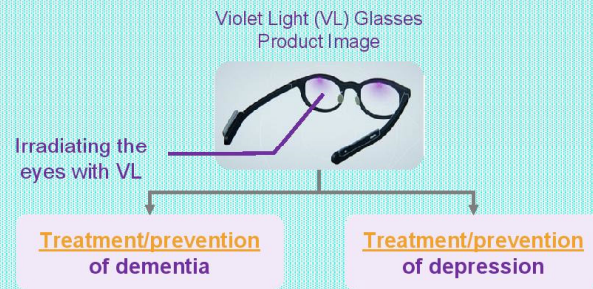
## Violet Light (Depression, Dementia)



- Target Diseases: Depression, dementia
- Partner Company: Tsubota Laboratory, Inc.
- Anticipated Product Profile:
  - Neuromodulation technology to treat/prevent dementia and depression by irradiating the eyes with violet light (VL)
  - Treatment/prevention method with high safety and low risk of adverse reactions
  - Excellent usability (worn just as glasses) leading to high adherence

### Features

- Since violet light is almost invisible to the human eye, a wearable device in the form of glasses is expected to have excellent usability without causing any discomfort in daily life
- Tsubota Laboratory is a venture company originating from Keio University School of Medicine and possesses proprietary technology and expertise in violet light



Source of image: JIINS press release (August 7, 2019) ([https://www.jiins.com/jp/topics\\_detail.html?info\\_id=198](https://www.jiins.com/jp/topics_detail.html?info_id=198)) <sup>77</sup>

Next, I will explain about Violet Light, which is being developed for dementia and depression.

This is also from the reference material. Violet Light is developed through a partnership with Tsubota Laboratory, Inc., a venture company from Keio University School of Medicine, to develop a neuromodulation device that aims to prevent and treat depression and dementia by irradiating the eyes with violet light.

Since violet light is almost invisible to the human eye, we expect superior usability by making it a wearable device in the form of glasses, which can be used in daily life without any discomfort.

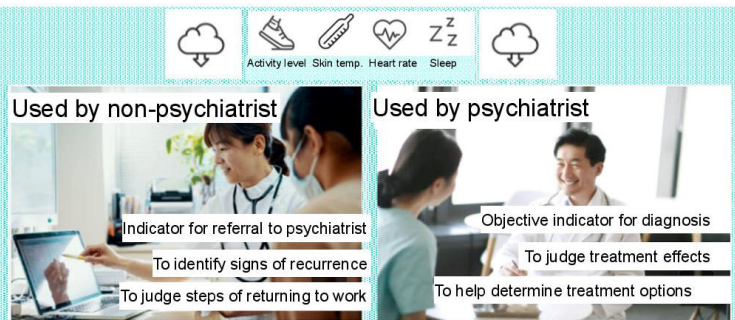
## Digital Medical Device for Depression Diagnosis



- Target Disease: Depression
- Partner Company: i2medical LLC
- Anticipated Product Profile:
  - Enabling objective, quantitative, and simple screening and severity assessment using day-to-day patient data
  - Enabling continuous, out-of-hospital/remote monitoring of the patient condition
  - Standardizing assessments regardless of doctor's specialty or experience

### Features

- Facilitates more frequent and detailed clinical assessment than previously possible levels
- Contributes to appropriate treatment interventions for appropriate patients
- Enables early referrals to specialists and early detection of depressive episodes



Next, I would like to introduce the development of a digital diagnostic medical device in the same area of depression.

This is also the reference material. The device is to enable simple screening and assessment of severity of illness by objectively, quantitatively, and continuously monitoring patients' daily data with an activity meter, also utilizing AI technology. We aim to standardize depression assessment regardless of physician's specialty or experience.



## Smart Glasses for Hard of Hearing People



- Target Disease: Communication issues due to hard of hearing
- Partner Company: Pixie Dust Technologies, Inc.
- Anticipated Product Profile:
  - Smart glasses that display the content of speech as subtitles so that the speaker can understand it clearly
  - A glasses-like form for excellent usability with less hassle
  - Solving the communication problems in a one-on-multi-person conversation that is highly challenging for hearing aids

### Technology/Features

- As shown in the image on the right, the speech of each speaker is identified and subtitled so that the wearer can visually understand who is saying what
- Pixie Dust Technologies possesses proprietary wave control technology and expertise in user interfaces for people with disabilities



An image of how smart glasses "see" speech

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Next, and last in our neuropsychiatry portfolio, I will introduce smart glasses for hard of hearing people.

This is also from the reference material. This is a partnership with Pixie Dust Technologies, Inc. to create smart glasses that display real-time subtitles of what was said by any speaker, even in situations where there are multiple speakers, with the aim of overcoming communication challenges caused by hard of hearing.

This solves communication issues in one-to-many conversations that are difficult to solve with conventional hearing aids.

In this section, I have introduced the positioning of the development themes based on the Patient Journey and disease areas.

## Competitive Landscape



- **Digital device for relieving BPSD (Aikomi)**
  - Dthera Sciences (USA): Discontinued development during clinical trials using reminiscence therapy
  - Not in competition with pharmaceutical BPSD treatment (primarily targeted at improving psychiatric symptoms)
    - Aikomi's target: Anxiety/autistic disorders
    - Aikomi solution (non-pharmacotherapy) + pharmacotherapy can be used in combination
- **VR contents for Social Anxiety Disorder: SAV-985 (BehaVR)**
  - FDA approved drugs indicated for SAD: SSRI/SNRI (symptomatic therapy) only
  - Development of VR solutions for SAD:
    - Psious (Spain): Has already launched VR treatment kit for doctors, which includes content for SAD, GAD, and compression
    - Oxford VR (UK): Has already launched VR program for anxious social avoidance, which is used by patients, as operated by medical professionals
- **Neurorehabilitation device for hand/fingers (MELTIN)**
  - There are several competitive development companies in Japan and overseas pursuing functional recovery and motion assist of upper limbs using EMG and robotic technology
  - MELTIN's competitive advantage
    - Recognizes the shape of the EMG waveform itself and responds to the user's intention with AI (competitors: recognize the amplitude and intensity of the EMG waveform)
    - A wire drive powerfully drives the knuckles, precisely assisting even pinching with the hand/fingers (other companies: motor drive)

The following is a summary of the competitive situation for the 3 development items introduced in this report.

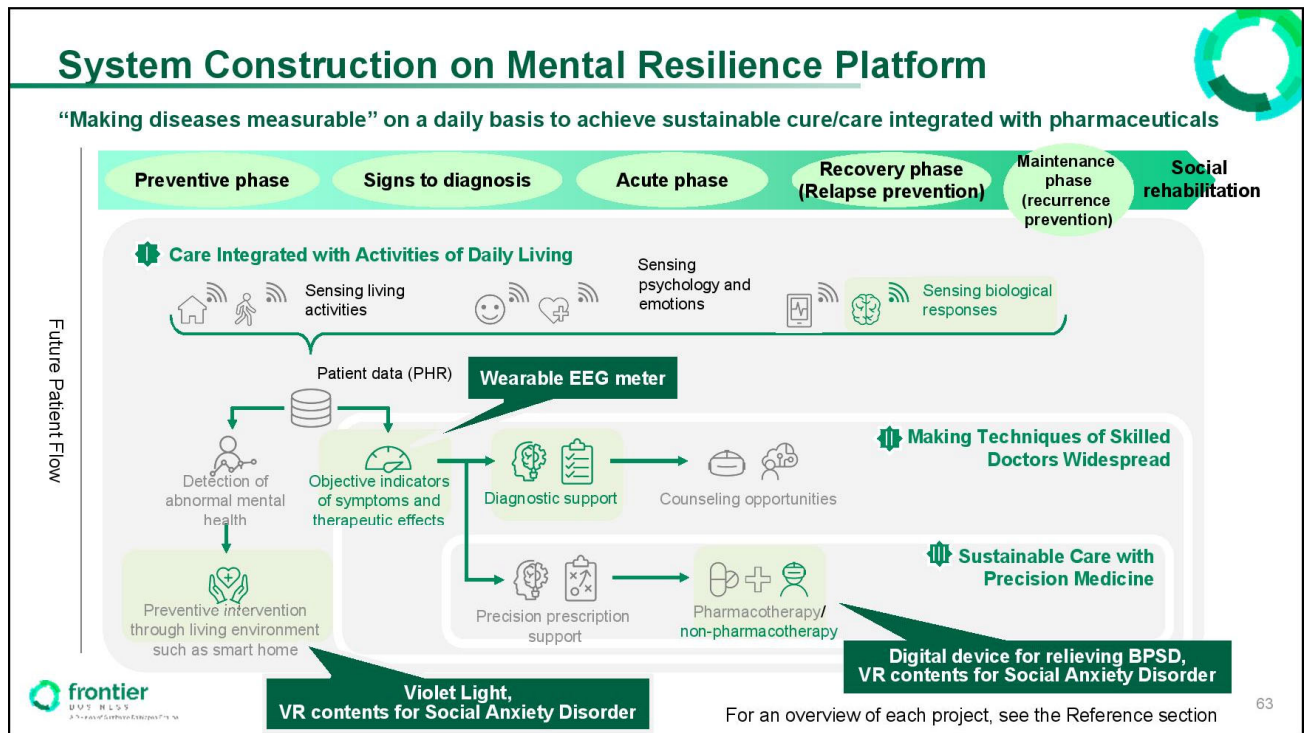
Regarding devices for relieving BPSD, Dthera Sciences in the US was conducting clinical studies using reminiscence therapy, but the development has been discontinued. The treatment of BPSD with pharmaceuticals mainly targets improvement of mental symptoms and is not considered to be in competition with this case.

Next, regarding the VR contents for social anxiety disorder, the only drugs approved by the FDA for social anxiety disorder are SSRI and SNRI, which are symptomatic treatments. As for the development of VR solutions for social anxiety disorder by other companies, Psious in Spain and Oxford VR in the UK have already launched VR content. However, the strength of BehaVR is that it can present VR sessions that are most suitable for each user's needs using its unique algorithm.

Lastly, regarding neurorehabilitation device for hand/fingers, there are several development companies in Japan and overseas that use EMG and robotic technologies to assist in the functional recovery and movement of the upper limbs. The competitive advantage of MELTIN is that it recognizes the EMG itself and responds to the person's intentions with AI, which is different from devices of other companies that recognize the amplitude and strength of EMG. In addition, while other companies use a motor-driven mechanism, the MELTIN is differentiated by its wire-driven mechanism that powerfully drives the finger joints and firmly assists the pinching action of the fingers.

As for the sales method of these products, for non-medical devices, in addition to the case of direct sales to users, we envision sales through the facilities to which the users belong and the use of employee benefit programs through contracts with employers. In the case of medical devices, the scheme is basically the same

as that for pharmaceuticals, where the product is provided to the patient through a doctor's prescription, subject to insurance reimbursement.



With the Frontier Business portfolio we have described, we will build systems in each business domain we focus on, and in the future we hope to provide total solutions.

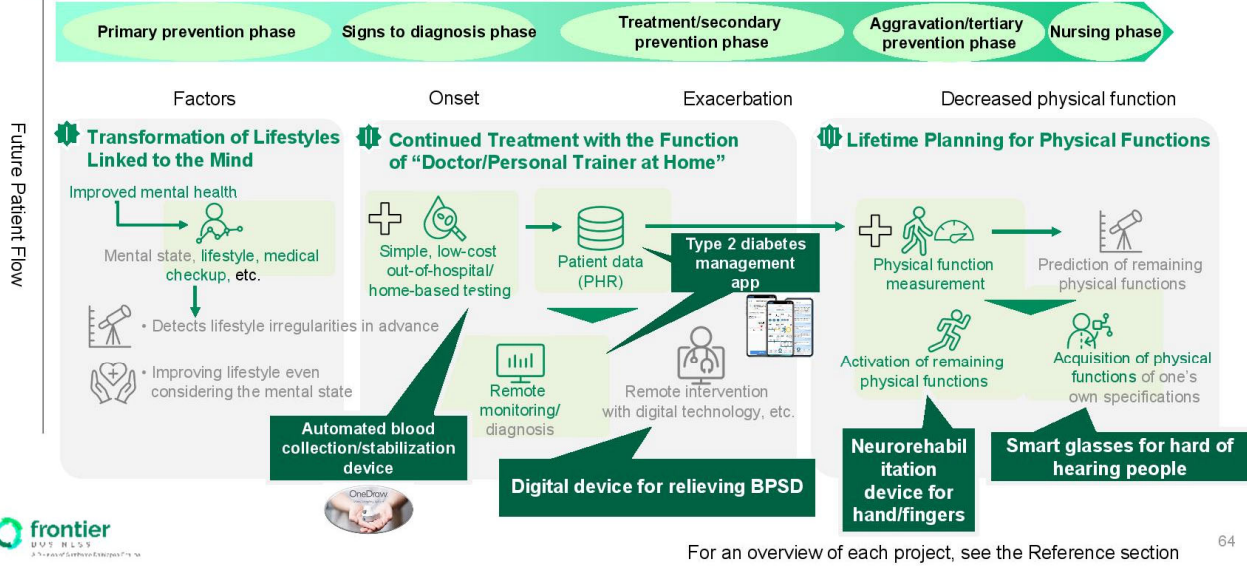
First of all, in the area of mental resilience, which is shown here, we aim to realize sustainable cures and care that are integrated with medicine by having the system building concept of “making diseases measurable” on a daily basis.

Specifically, we believe that care that is integrated with activities of daily living is important for all Patient Journeys. In other words, we provide sensing of lifestyle behaviors, psychology and emotions, vital data, and other biological responses. These data are stored as PHR to detect mental health changes and provide preventive interventions. An example of this solution is the Violet Light and VR contents for social anxiety disorder products for general wellness.

In addition, PHR can be used as objective indicators of symptoms and treatment effects, so-called digital biomarkers. For example, by using wearable EEG meter to measure brain waves on a daily basis, it may be possible to detect signs of mental illness from changes in brain wave trends. In addition, we believe that digital device for relieving BPSD and VR contents for social anxiety disorder as medical devices can be mentioned as non-drug treatment options in conjunction with drug treatment to support precision prescription.

## System Construction on Active Aging Platform

Provides options for life design and its realization based on the patient's physical function and work/lifestyle to accompany the patient throughout life



In the construction of systems in the Active Aging Platform, we aim to provide solutions that can accompany patients throughout their lives by offering life planning and realization options based on their physical functions, jobs, and lifestyles.

First of all, by improving mental health as mentioned earlier, we can promote the transformation of lifestyle habits linked to the mind. As a means to achieve this, we believe that automated blood collection and stabilization devices will enable simple and low-cost home testing. In addition, we believe that an application for type 2 diabetes management guidance may play a role in centralizing PHR accumulated through the device. Furthermore, digital device for relieving BPSD can be positioned as one of the devices that enable remote intervention through digital technology. With these solutions, it becomes a home doctor and personal trainer function, encouraging the continuation of treatment.

We also aim to develop solutions that can provide continuous monitoring of physical functions and life planning even after treatment. Neurorehabilitation device for hand/fingers can be used to activate the remaining functions of the body, and smart glasses for hard of hearing people can be used to acquire self-specified physical functions.

As described above, we would like to build a total care system by enriching solutions that have affinity with platforms such as mental resilience and active aging.



## Approach to New Business Creation: Investing in Kicker VC



Sumitomo Dainippon Pharma invested in Kicker Ventures I, L.P., a venture capital fund consisting of human resources with extensive experience and a wide network in the digital healthcare business (up to approximately 2.0 billion yen in February 2021). The goal is an integrated implementation of discovery, investment, and development of future pipelines.

### In-House Lab: Co-Studio



**Masayasu Sawada**  
CEO, Co-Studio Co., Ltd.

#### Open Innovation Promotion

- Business development at large companies
  - New business development at Omron Corporation
  - Development of new dementia insurance by Sompo Japan
- Set up 7 digital healthcare/community companies within 1.5 years



### VC



**Masashi Kiyomine**  
Managing Partner

#### Venture Capitalist

- Former Head of Life Sciences, Mitsui Global Investment
- Venture capital investment experience:
  - 13 years of experience in the U.S.
  - Management experience in 11 digital health, medical device, medical service, and drug discovery ventures

### Global BD Capabilities



**Tomoko Ishikura**  
Partner

#### Business Development Professional

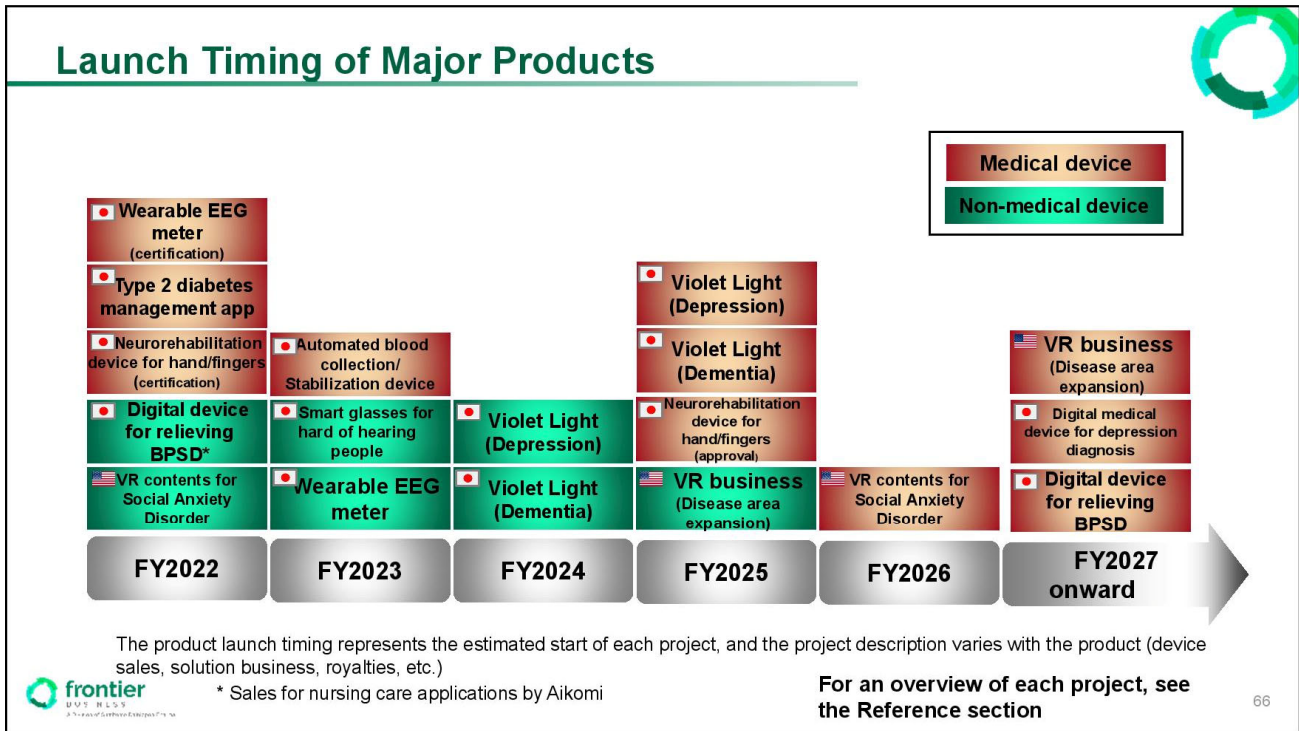
- Global experience in developing and investing in medical devices and healthcare businesses
- Extensive cross-cultural partnership experience

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I have introduced our existing portfolio so far, but in the field of digital healthcare, technologies become obsolete quickly, so it is important to constantly watch the latest technologies and search for new business seeds.

Therefore, we are investing up to approximately JPY2 billion in Kicker Ventures, which consists of people with deep experience and a broad network in the digital healthcare domain.

One of the features of this VC is that Mr. Kiyomine, a venture capitalist, has extensive venture investment experience in the US and management experience in digital health and other ventures. In addition, as a global BD function, Ms. Ishikura, a business development professional, can advise us on potential partnerships with promising startups. Furthermore, for projects that have already started business development, Mr. Sawada of Co-Studio, in-house lab function, will use his experience in business development at large companies to quickly establish a system to confirm the POC.



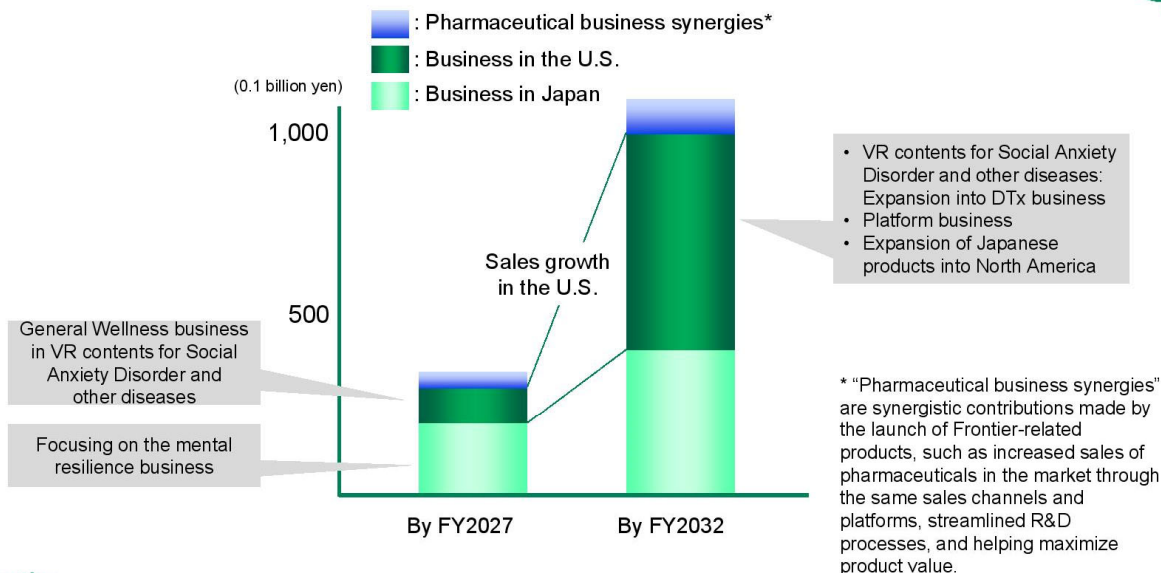
This page shows the scheduled launch dates for the main items among the development items introduced today. Non-medical devices and medical devices are color-coded.

First of all, the digital device for relieving BPSD and VR contents for social anxiety disorder, which we explained in detail today, are scheduled to be launched as non-medical devices in Japan and the US, respectively, by the end of FY2022. For other non-medical devices, we are planning to launch several products between FY2023 and FY2025.

Next, in the area of medical devices, we plan to launch VR contents for social anxiety disorder as a non-medical device in the US, acquire real-world data, begin development as DTx, and hope to obtain approval in FY2026. In the same way, for the digital device for relieving BPSD, Aikomi will first start a non-medical device business in the nursing care field, and then conduct clinical studies and obtain approval as a medical device development.

In addition, the neurorehabilitation device for hand/fingers is scheduled to be certified as a medical device by the end of FY2022, and after upgrading the device, clinical studies will be conducted to obtain approval as a rehabilitation device by FY2025. In addition, we are aiming to launch medical device products related to diabetes, lifestyle-related diseases, and mental disorders in the time frame shown here.

## Business Potential Based on Frontier Portfolio (Target)



We show here the target values as future business potential based on Frontier portfolio.

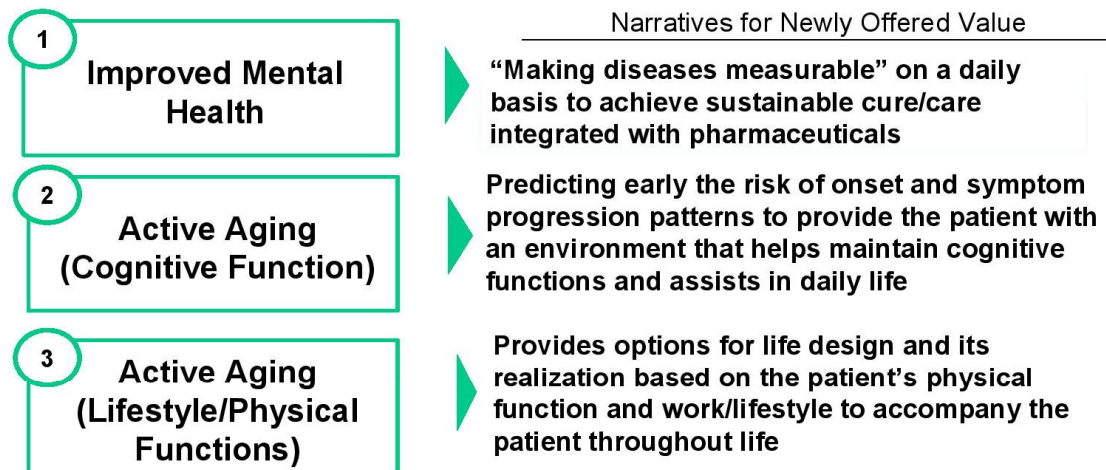
First, we are targeting sales of JPY20 billion to JPY30 billion for the period up to FY2027, which is the period of the next mid-term business plan.

The main components of the business are the businesses in the Mental Resilience Platform in Japan and the general wellness business using VR contents for social anxiety disorder and other disorders in the United States.

Furthermore, by FY2032, 5 years from FY2027, in addition to the expansion of the domestic business, we would like to expand sales in the US by expanding the existing business in the US, especially by expanding the general wellness business to the DTx business and by considering the development of domestic products in North America. We will grow the business to a business that support the pharmaceutical business with sales of JPY100 billion range in Japan and the US.

In addition, by selling Frontier-related products through the same sales channels and platforms as existing drugs, we expect to generate synergies such as increased sales of drugs currently on the market.

## Value Provided by System Construction in Each Business Area



Finally, I would like to summarize the value provided by system development in each of the business domains we have described.

The first is the Improved Mental Health. By “making diseases measurable” on a daily basis, we can achieve a sustainable cure and care that is integrated with medicine.

Secondly, in the Active Aging area, as for cognitive function, we would like to predict the risk of onset and the pattern of symptom progression at an early stage and provide an environment that supports the maintenance of cognitive functions and life.

Finally, for lifestyle/physical functions in the area of Active Aging, we will provide life planning and realization options based on the patient's physical functions and work/lifestyle and provide the value of solutions that can accompany the patient throughout life.

That’s all. Thanks

## Question & Answer

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**Questioner 1:** I would like to address the first question to COO, Mr. Kato of Aikomi or CEO, Dr. Kasuya of MELTIN. How much value do you think you have added by working with Sumitomo Dainippon Pharma? Also, what do you think can be expected in the future? I'm sure you had a variety of partners in mind when you started your business, but I'd like to know why you chose Sumitomo Dainippon Pharma, what your expectations were, and how the results have been so far.

**Takehiko Nomura:** Let's start with COO, Mr. Kato from Aikomi.

**Mr. Kato:** This is Kato from Aikomi. Our products are intended to treat the mental and structural changes and peripheral symptoms of dementia. As you know, Sumitomo Dainippon Pharma has a great deal of experience in the area of psychiatric disorders and connections with a range of experts. This is one of the reasons why we are currently working with Sumitomo Dainippon Pharma. In addition, there are opportunities like the FBO Showcase where Sumitomo Dainippon Pharma can come together to support startups like ours, or where people like Officer, Mr. Horii can work together with us to support our business. Including these types of factors, we have benefited in many ways.

**Takehiko Nomura:** Now, I would like to pass the question to CEO, Dr. Kasuya from MELTIN.

**Dr. Kasuya:** Thank you very much. As I mentioned earlier, I was a student when we registered in 2013, and I finally graduated in 2016 and started fundraising. As a result, it was great to have the support of Sumitomo Dainippon Pharma. The Company has a wealth of knowledge in this field. This was our first venture, and the medical industry has a lot of regulations, so it was great to have their support. In particular, as I mentioned earlier, Officer, Ms. Nishimaki and I traveled all over the country to look for joint research partners. We were able to receive strong support in terms of strategy, such as what kind of devices and concepts should be developed. I'm very grateful for that. Another factor is that I think shared vision is quite significant. At first, I thought that the pharmaceutical industry was not that related to our robotics and biological signal work. However, I was surprised to find that Sumitomo Dainippon Pharma has a vision in relation to this. They can provide drugs for the nervous system and conduct related research. In fact, when we talked to them, we found that we could expect considerable synergy in terms of both actual research and product development, as well as in terms of vision, we decided to ask them to support us.

**Questioner 1:** Thank you very much. I have a question for someone from Sumitomo Dainippon Pharma. I would like to ask you to introduce the profit structure of these frontier projects. To put it another way, could you describe the basic concept of sharing costs and profits, and explain if there is anything common to each project? If each project is different, could you please tell us how the sales and profits are organized for the 3 projects you mentioned today?

**Takehiko Nomura:** Thank you for your question. I will respond to your question. We have not yet established clear sales forecasts for each project. The business potential shown at the end of my presentation is only a target, not an accumulation of earnings forecasts for each project. Therefore, the profit and loss structure for each project is not yet clear. There are a number of projects that require business model finalization. We will need to clarify this in consultation with our partners and through market research.

**Questioner 1:** Is there a common basic concept among the partner companies regarding risk, cost sharing, and profit sharing, such as 50/50 or a given percentage?

**Takehiko Nomura:** Basically, I think it is done on a case-by-case basis. In many cases, the R&D costs and other expenses are split 50/50, and in some cases, we bear a little more. Depending on the situation, we will decide how to divide the profit after the launch of sales.

**Questioner 1:** Is it correct to say that what you introduced on slide page 67 is not the scale of the market, i.e., the sales that Sumitomo Dainippon Pharma will eventually record, but rather the final level of added value?

**Takehiko Nomura:** Yes. This target has been set since April 2019, when the Frontier Business Office was established, and since the beginning of the strategy-planning process.

**Questioner 1:** At this point, I guess it would be difficult for you to indicate the contribution to profit, even if it is just an image?

**Takehiko Nomura:** Yes, that's right. At this point, I think it is still difficult to say.

**Questioner 2:** I would like to ask about slide page 67. I was able to understand the explanation of each product and service very well with the help of the video and other information. However, when it came to the diagram of sales and business potential, it was difficult to fill in the gap between the sales scale and each product. I would like to know more about this. Although it is not a detailed breakdown, I would like to know more about what is behind these numbers. For example, which products will contribute more to growth? Regarding slide page 66, if it is a medical device, will it be reimbursed by insurance, or if it is a consumer product, will the consumer be the source of money? In addition, when you say that there will be a large jump from 2027 to 2032, why will there be such a large jump? The reason for this jump is probably the expansion of the number of products, but could you tell us about this change?

**Takehiko Nomura:** Thank you for your question. I will answer this as well. First of all, as for the JPY20 billion to JPY30 billion target by FY2027, we will focus on the mental resilience business in Japan, which includes both medical devices and non-medical devices. We would like to discuss a framework that would allow us to contribute to the profits of the nursing care business currently being conducted by Aikomi, which I mentioned today. Also, overseas, the VR contents for social anxiety disorder introduced today will be mainly for the general wellness business. The challenge for the future is how to uncover potential patients with social anxiety disorder, and users who are not yet ill. This will be a challenge for us in the future. We would like to maximize our business value by developing platform technologies that can solve such problems, and we have set targets for these as well. Also, by 2032, I believe that the VR contents for social anxiety disorder that I just mentioned will contribute to sales. We will also have the launch of DTx products. All of these are expected to contribute to sales. In terms of revenue, I think you know that the scale of revenue will be larger than that of general wellness products, so one of the things we will do in this area is to target indications other than social anxiety disorder. In addition, there are projects that we are currently considering in Japan that we have the rights to develop overseas, especially in North America. We will gradually develop and launch such projects in North America.

**Questioner 2:** I understand. Thank you. Also, in this chart of slide page 67, it seems to me that the synergy with the pharmaceutical business is quite modest. How do you view the scale of sales in this synergy with the pharmaceutical business?

**Takehiko Nomura:** Regarding the synergy effect, as you can see in the bottom right corner of the diagram, these products will be sold through the same types of channels as pharmaceutical products. We also expect this to increase recognition of our pharmaceutical products. We believe that by developing a platform that recognizes both the pharmaceutical and non-pharmaceutical businesses, there will be a synergistic effect between them. However, we don't have concrete numbers yet, so this is just an image of how much quantitative synergy we can expect.

**Questioner 2:** I understand. Lastly, what do you consider to be the potential bottlenecks in achieving these sales? For each technology, there are various issues, such as whether or not the product will be launched

properly, and who will pay for it. I think this business is currently running on a project basis, but when you look at it over the long term, will it become a business that you develop in-house? Or will it be a platform for incubation and sales, where new technologies are constantly introduced by venture companies, incubated, and sold? Please tell us about your image of the future of this business.

**Takehiko Nomura:** I will answer this as well. In the case of general wellness products, as you know, there are quite a few products on the market, some with considerable evidence, and some with almost no evidence. Therefore, I think the important point is how to provide solid evidence as a pharmaceutical company and how to make users recognize the value of the product. There are licensing and approval issues when it comes to DTx. If a DTx product is approved, the question of whether or not insurance reimbursement will be made at the expected price will have a significant impact on profitability. I think that will be a very important point.

**Questioner 2:** I understand. Also, what form will these projects take in the end? Is this a business where you absorb new things all the time and are responsible for sales and development? Can you tell us if you envision your company doing development from a zero-base?

**Takehiko Nomura:** In the future, we aim to accumulate capabilities within our company, such as R&D, in part through the process of collaboration with our partners. We are still in the process of trial and error, so we haven't decided what we will prioritize. We are applying some of the technologies that we have been studying in our own drug discovery activities. We would like to steadily develop those technologies as our own fundamental technologies if possible.

**Questioner 3:** I think that you are currently working on joint development and sales between each company and yourselves. Regarding stake, for example, how much stake do you have in each company? What will happen to that stake if these companies go public in the future? Would there be any intention to incorporate or bring a company within your group? Can you tell us about your stake in each business, and what kind of policies you have in place to manage these issues? I suppose that this may be handled on a case-by-case basis.

**Takehiko Nomura:** President, Mr. Nomura will take your question.

**Hiroshi Nomura:** As for the stake, I think this will vary on a case-by-case basis, depending on the circumstances of the other partner. In some cases, we will invest, and in other cases, we will not. Basically, when we invest in a company, we do so in the hope that it will strengthen our relationship with that company, or that it will enable us to make stronger progress on a project we are working on together. Therefore, whether or not our partners go public is not really relevant to us. As for the share, as Senior Director, Dr. Takehiko Nomura explained earlier, this will vary on a case-by-case basis, depending on the relationship between us and our partners. It also depends on how much each of us contributes until the final product or service is completed. We are still discussing how to create individual solutions, so I think we still have a long way to go before we know what our share will be. We are still discussing how to build a business model.

**Questioner 3:** Thank you very much. I would like to ask you one quick question about technology. First of all, it seems that Aikomi's competitors have stopped clinical studies using reminiscence therapy, and that it did not work out. In Aikomi's case, given what we saw about suffering from anxiety and isolation, it seems like it would help. Is it correct to say you are adopting this approach that uses reminiscence therapy not because there is scientific evidence for reminiscence therapy, but because you think that Aikomi will be able to generate evidence? What factors, if any, contribute to the lackluster performance of reminiscence therapy?

**Takehiko Nomura:** I will hand this over to Officer, Mr. Hori to answer.



**Hori:** I am Hori, the project manager. I will be happy to answer. The first non-pharmacotherapy we are focusing on is based on cognitive activation therapy, which is different from reminiscence therapy, and focuses on digitizing it. Basically, there is some evidence supporting cognitive activation therapy conducted by people, so I think we can expect it to be effective on that basis. There is a small amount of evidence for reminiscence therapy, but it is based on small-scale experiments. Our concept is based on the hypothesis that stimulating as many of the 5 senses as possible can alleviate peripheral symptoms. We are not just relying on reminiscence therapy, but would like to stimulate the senses of hearing, sight, and eventually smell, in order to increase the probability of success.

**Questioner 3:** I see. Thank you very much. I think that other companies have already developed and launched VR solutions, and your company and BehaVR's solutions will be launched as a general wellness product first. On the other hand, in order to develop DTx, from what you said, although the effect will be stronger if VR is used, I couldn't figure out who will be the first to achieve it. Do you think that because your company's algorithm is different, your company will be the only one able to go from general to DTx? Is the algorithm an important differentiator?

**Takehiko Nomura:** Thank you for your question. I will answer this one for you. As you mentioned, some of the general wellness products are already on the market, so I think that would be competitors, which we call the first-generation VR products. What we want to develop with BehaVR is second-generation VR content. This includes VR content and VR solutions that provide the best content for each individual user by inferring the best content from the acquired data, vital data, and other responses. We believe that in developing DTx, we will be able to differentiate ourselves, as you mentioned. So, as we continue to update our general wellness products, I think we will gradually add such functions in the process.

**Questioner 3:** Thank you very much. Lastly, I would like to ask you one question on MELTIN. I think there was a comment that you are aware of, but there is a company called Cyberdyne. Its "HAL" rehabilitation robot can assist in walking and use of the upper limbs. I think the fingers are a different story though. Do these 2 products have a common scientific basis with respect to myoelectricity, moving objects with biological waveforms? Would it be correct to say that your company is differentiating itself by developing hands and fingers? I would be grateful if you could briefly explain the principle behind Cyberdyne's robots and whether or not yours is different.

**Takehiko Nomura:** Thank you for your question. I'll pass this question on to CEO, Dr. Kasuya of MELTIN. Thank you.

**Dr. Kasuya:** Thank you for your question. The use of myoelectricity is the same in the sense that the science behind it is the same. The myoelectric signal is the same. For example, the myoelectric waveform itself, and the kind of sensor used to measure myoelectricity, are probably using the same technology. The clear difference between us and Cyberdyne is how we process the signals from there. For example, with machine learning and AI, which were introduced in the previous lecture, it was possible to judge the strength of the myoelectricity in the "stone" or "paper" when a person gulped. What is different about our device is that even if the EMG is strong in the direction of "stone" for a long time, it can distinguish the subtle differences in waveforms to see if the person is trying hard to make a "paper" even while doing "stone".

**Questioner 3:** Is that an algorithm? The power of AI research itself.

**Dr. Kasuya:** Yes, that's right, yes. That's what's in the algorithm there.

**Questioner 3:** I understand. Thank you.

**Questioner 4:** This is my first question. In the speech by President, Mr. Nomura, you mentioned that you are reviewing the projects that are already running. I would like to know if there were many projects that were cancelled in the early stage, and if so, could you explain the background of those cancellations? I would also like to ask you to comment on what selection factors are being used in the review process, and whether you are deciding which ones to proceed with from the perspective of long-term business feasibility. Thank you.

**Takehiko Nomura:** I would like to pass this question to President, Mr. Nomura.

**Hiroshi Nomura:** Thank you for your question. In the Frontier Business, the first thing to consider is what unmet needs we should appeal to, and what technologies we can use to solve those unmet needs. Can this technology be used to create services or solutions that can actually be provided to patients and others? Another point is, as I mentioned earlier, whether or not it is possible to build a business model that will allow us to receive fair compensation. We consider these 3 points as our priority checkpoints. I can't tell you specifics about the projects have been discontinued so far, but I can tell you that of those 3 main points, the last 2 have been the main issues. I think the key points that will be used to judge the progress of project is whether the solution will be feasible, and whether a business model can actually be built or not.

**Questioner 4:** Understood. Thank you. The second question is a broad one, but you mentioned earlier that you are not necessarily building up the scale of sales. I would like to ask you about the business models for Aikomi, the VR products, and the neurorehabilitation device for hand/fingers. There was a mention of selling directly to consumers, or something through employee benefits. What do you envisage as being the biggest area of sales? For example, if you are selling neurorehabilitation equipment, do you sell the product and then that's it? Or would you operate a subscription package?

**Takehiko Nomura:** Thank you for your question. You mentioned 3 items, but is it alright to talk about each individually?

**Questioner 4:** Yes. That would be great.

**Takehiko Nomura:** First of all, a few words about VR contents for social anxiety disorder. As I mentioned a little bit earlier, in terms of general wellness products, the biggest challenge is how to attract users at a certain price. This is where an Employee Assistance Program could be useful. We would like to consider targeting employers, having them use the product for the purpose of employee benefits. That seems to have the most potential. In the case of DTx, the sales route will be similar to that of pharmaceuticals, since it will be prescription-based and managed by doctors. Officer, Mr. Hori, the person in charge of Aikomi, will explain more about it.

**Hori:** I am Hori, the project manager. I will be happy to answer your questions. I mentioned that there are 2 uses for the Aikomi project. The first is for nursing care application and the second is for medical use. First of all, we have not yet made a decision on the development of the product for medical use, so we cannot say at this time about how we plan to obtain approval from the authorities, or the planned business model. As for the nursing care application, we have already started trial sales. Since these are trial sales, we are trying to figure out the best service model. One of them is a business model in which the family of the person with dementia and Aikomi enter into a service provision contract, and there is a monthly subscription fee.

**Takehiko Nomura:** Next, I would like to hand over to Officer, Ms. Nishimaki to talk about MELTIN.

**Nishimaki:** I'm Nishimaki. Thank you. As for the rehabilitation equipment developed by MELTIN, it is a medical device, so it is covered by insurance reimbursement. It is still unclear how the insurance reimbursement will be categorized. We will have to set up our business model according to the insurance reimbursement we will receive. After approval, we will have discussions with the relevant academic societies and related people to

formulate a model. In any case, I think it will be similar to the model for the distribution of medical devices and pharmaceuticals.

**Questioner 4:** Thank you very much. Understood. I think you mentioned that the general wellness element of VR will be through employee benefit programs. Is this a subscription program, or do you sell the equipment and record the sales?

**Takehiko Nomura:** In terms of VR headsets, we are thinking in terms of rental. Although the contract may be similar to a subscription, I think it is possible to have a large contract. I think that the contract may be slightly different depending on the business owner who becomes a partner.

**Questioner 4:** Understood. Thank you.

**Questioner 5:** As for devices relating to peripheral symptoms of dementia, there are 2 types: non-medical devices and medical devices. What type of device are you envisioning?

**Hori:** We are considering it as a non-medical device. We hope that the device will promote communication between people who have peripheral symptoms of dementia and their families or caregivers and reduce the burden of care. For example, if the symptoms of withdrawal or depression make it difficult for a person to talk, suppressing the symptoms will allow the person to talk and communicate with others. Medical devices, on the other hand, aim at alleviating specific symptoms relating to dementia. For example, when a patient with dementia is admitted to a hospital and has peripheral symptoms, the patient may or may not be treated with medication, but rehabilitation will be conducted, and care for peripheral symptoms will be provided in short-term intensive rehabilitation for dementia. We believe that occupational therapists and others who are involved in the rehabilitation of these patients can use this kind of device as an adjunct to rehabilitation to take care of BPSD, the peripheral symptoms of dementia. We are hoping that the device will be able to show, for example, the extent to which peripheral symptoms have been alleviated.

**Questioner 5:** Can we consider combination therapy of Aikomi's product and drug therapy to be a combination with a medical device?

**Hori:** That's right. When the Aikomi system is used for medical purposes, we believe it can be used in combination with conventional drugs for hallucinations and delusions.

**Questioner 6:** I would like to ask President, Mr. Nomura to comment on the Frontier Business, which was launched in April 2019. It has since launched a variety of projects, as you mentioned today. What is your overall impression so far?

**Hiroshi Nomura:** Thank you for your question. We are at our core a company that manufactures medicines. As I mentioned earlier about the Patient Journey, there are many elements, such as prevention, managing pre-disease states, treatment, nursing care, and reintegration into society. To date, however, the focus has been on treatment, especially drugs. We have been competing in this area. However, with the advancement of science and technology, as you all know, we have a business project in the field of regenerative medicine and cell therapy. Creating nerve cells from cells and transplanting them, or creating tissues and transplanting them, furthermore creating whole organs and transplanting them. These things were unthinkable in the past, and we are moving forward in this area. In that sense, the focus has been on treatment, but with the advancement of various technological fields, especially the advancement of digital technology such as AI, we are finally able to make response on long-standing unmet medical needs. As a company in charge of health

care, we have not been able to address these issues because we did not have the technology to do so. However, now that the technology is available, we will be able to address these issues moving forward. This is the idea behind the Frontier Business. The business was established in April 2019, and in this context, I would say that it has made solid progress so far. We are making good progress. Of course, the US is very advanced in this area, so there is no need to worry too much about the business model. In fact, there is a very high level of acceptance for these digital solutions, so as long as we can create good products, we have a lot of potential. However, in Japan, these digital solutions, both in the area of general wellness and in the reimbursable and regulated area, are still not very widely accepted. In this context, we think that it is difficult to know how we can develop our business. As Senior Director, Dr. Takehiko Nomura explained earlier, we have a concrete plan to launch products in the market, so from that perspective, I think we have made very good progress.

**Questioner 6:** Understood. Thank you very much.

**Questioner 7:** What kind of image should we have of the lifecycle of these projects from the business perspective? In the case of drugs, I get the image that the Company will be in the red for a long time until the product is launched. The breakeven will be in the third year or so, after which the OP margin will be 80%. That's my image, but I understand that each product is different. For example, in the case of Aikomi's business, digital therapy for BPSD, for example, how much will the upfront cost be, how many years will the breakeven be, and how long will it take to, this might not be the right word, but "peak out"? Or will there be a process of upgrades? I'd like to ask you to share what kind of business trajectory for these projects we should be looking at over the next 5 years or 10 years.

**Takehiko Nomura:** Thank you for your question. In the case of Aikomi, I think there is a division between the nursing care business that is currently being promoted by Aikomi and the future medical equipment area.

**Mr. Kato:** This is Kato from Aikomi. First, I think I am only able to talk about the nursing care business. The sales plan is included in the plan shown by Sumitomo Dainippon Pharma on slide pages 66 and 67, and we are planning to increase sales in the nursing care business over the next 4 years to 5 years. In the meantime, the cost of these digital products is lower than hardware, so we expect that we will be able to turn a profit very quickly. However, there are some unforeseen factors that will affect how much it will cost in the future when we start selling the product in various parts of Japan, so we are currently looking at costs in the 4- to 5-year time frame.

**Questioner 7:** It's easy to visualize when the lifecycle of a drug will come to an end. How about with this type of product?

**Mr. Kato:** I think the factor here is the speed at which digital devices become obsolete. In addition, if technological innovation leads to the development of innovative drugs or regenerative medicine that can cure dementia, the life cycle of products for dementia will naturally become shorter.

**Questioner 7:** I understand. Thank you.

**Questioner 8:** I would like to ask President, Mr. Nomura about this business, which is quite different from a conventional pharmaceutical business in terms of cost ratio, manpower requirements, and so on. At this stage, I am not sure how much weight Sumitomo Dainippon Pharma is going to put behind this, but I didn't get the impression that more resources will be used supporting the commercialization of its partners than for the pharmaceutical business. In the future, for example, the current situation is still a question of feasibility, but

you have given us some figures for the next 5 years to 10 years. I would like to have images of when you will establish a division for this business and how big the business will become.

**Hiroshi Nomura:** Thank you for your question. In the first place, the creation of the Frontier Business Office in April 2019 itself is intended to foster the development of these projects separately from other pharmaceuticals. Therefore, the allocation of resources for the development of these projects will be kept separate from other areas. However, as I mentioned earlier, when we look at the unmet needs that we are trying to address and what kind of technology can be applied to those needs, at this point in time, it is difficult to determine what kind of technology can be applied. Both Aikomi and MELTIN already have established technologies to some extent. Therefore, we think that working together with such companies is the quickest way for us to achieve our goals. There has not been much focus on the technical background of these products in the presentation today. However, as I have said many times before, the first thing we need to do is to decide what kind of unmet needs we will address and what kind of technology we will use to meet them. As Senior Director, Dr. Takehiko Nomura mentioned earlier, we will proceed with the frontier business based on our knowledge. There is a possibility that such things will appear in the future. Therefore, I am not sure if all Frontier projects will be the same format or not. So, at this point, we are not at the stage where we see this as a major project. However, when sales start, for example, the distribution mechanism, and the supply chain will be very different from those of pharmaceuticals or regenerative/cellular drugs. So, I think we need to work on these areas. Therefore, at a certain stage, we will start to treat this business as a separate new division from pharmaceuticals or regenerative/cellular therapies. At the present stage, we are already considering how to establish the supply chain for each project. When we have completed the solution and have a business model that allows us to receive fair compensation for it, we will continue our efforts to grow these as independent businesses.

**Questioner 8:** Could you tell me about the timing, in terms of years?

**Hiroshi Nomura:** I believe we showed a rough timetable in the presentation, but to add to that, I think it is also important to achieve a certain scale quickly. As a result, I would like to have something set up within the next 2 years to 3 years.

**Questioner 8:** Thank you very much.

**Harada:** This concludes Frontier Business Meeting. Thank you very much for your time today.

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