COMPANY RESEARCH AND ANALYSIS REPORT

SUSMED, Inc.

4263

Tokyo Stock Exchange Growth Market

2-Nov.-2023

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https://www.susmed.co.jp/en/

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Summary

An R&D-stage startup conducting business with a focus on the development of digital therapeutics, which is attracting interest as a third treatment option

SUSMED, Inc. <4263> (hereinafter "the Company") is a research and development (R&D)-stage startup conducting business with a focus on the development of digital therapeutics (hereinafter, "DTx"), which is attracting interest as a third treatment option other than pharmaceuticals and medical devices. The Company's mission statement is "Continuously provide society with sustainable medicine services by leveraging ICT."

1. Acquisition of regulatory approval of a DTx app for insomnia in the DTx Product segment

In the DTx Product segment, the Company develops DTx apps in multiple disease areas. DTx app is a new modality that provides treatment via apps downloaded by patients onto their smartphones as an alternative to pharmaceutical or medical device-based therapies. Unlike general healthcare apps that anyone can use (diet apps, pedometer apps, etc.), DTx apps must be approved by the regulatory authorities as a medical device, as stipulated by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, based on medical evidence related to efficacy and safety confirmed through clinical trials. As of August 2023, the Company's development pipeline in this segment has 10 products. This includes the SUSMED Med CBT-i® app for insomnia treatment, which received medical device manufacturing and marketing approval from the Ministry of Health, Labour and Welfare (MHLW) in February 2023. The Company is currently discussing National Health Insurance coverage with the MHLW, and working with Shionogi & Co., Ltd. <4507>, which has been granted exclusive distribution rights for the app in Japan, on a launch program (expected within 2023). Once the product has been launched, the Company will receive royalties from Shionogi & Co. based on sales results.

2. Starting system provision for more efficient drug discovery processes in the DTx Platform segment

In the DTx Platform segment, the Company mainly provides services based on expertise gained in the development process for the DTx app for insomnia. These include DTx development support services that use its DTx app development platform, a machine learning automated analytics service that analyzes medical big data, and a general-purpose clinical trial system that supports more efficient drug development. In particular, the SUSMED SourceDataSync® general-purpose clinical trial system employs a monitoring system fitted with blockchain technology to realize the high level of security and data tampering resistance required in clinical trials, while drastically reducing the man-hours and costs related to monitoring. In June 2022, it entered into a contract with Aculys Pharma, Inc. to conduct the world's first corporate clinical trial utilizing blockchain technology and in November 2022, the first clinical trial using SUSMED SourceDataSync started, followed by a second trial started in January 2023.

3. Losses decreased in FY6/23

In the FY6/23 results (non-consolidated), operating revenue increased 67.5% year on year (YoY) to ¥530mn, operating loss was ¥48mn (compared to a loss of ¥229mn in FY6/22), ordinary loss was ¥44mn (compared to a loss of ¥217mn in FY6/22), and net loss was ¥50mn (compared to a loss of ¥233mn in FY6/22). In the DTx Product segment, the Company recorded milestone income associated with SUSMED Med CBT-i from Shionogi & Co. and there was also smooth growth in the DTx Platform segment. As a result, overall losses decreased from the previous period considerably. Sales were roughly in line with targets while profits exceeded target levels due to contributions from efforts including the curbing of recruitment expenses (due to an increase in direct applications and progress on recruitment through referrals). Also, during FY6/23, there were periods where no clinical trials were being held, leading to a decrease in R&D expenses by 22.1% YoY to ¥176mn. Although this was ¥50mn lower than the previous fiscal year, it was ¥25mn higher than forecast.

4. FY6/24 results outlook

The Company's FY6/24 results (non-consolidated) forecast has yet to be finalized. The Company is anticipating smooth growth of revenue in the DTx Platform segment, but in the DTx Product segment, it thinks that it is difficult to reasonably estimate revenue from SUSMED Med CBT-i at the start of the fiscal year. It states that it will disclose forecasts as soon as it is feasible to do so. Also, the Company received an upfront payment from KYORIN Pharmaceutical Co., Ltd. Related to SMD403, a DTx app for tinnitus, but it has not yet been determined when the revenue will be recognized. In regard to key measures, in the DTx Product segment, the Company aims to start selling SUSMED Med CBT-I, and it plans to make progress on its development pipelines (starting pivotal trial preparations for SMD402, which is Software as a Medical Device (SaMD) for Advance Care Planning (ACP), and renal rehabilitation app SMD201; launching clinical research on SMD403, which is a treatment for tinnitus; and starting a proof-of-concept trial for SMD105, a treatment for patients suffering from post-mastectomy pain syndrome). In the DTx Platform segment, it plans to acquire new projects for the SUSMED SourceDataSync and to start building registries based on blockchain technology.

5. Advancing measures such as enhancing development pipelines to maximize revenue from a long-term perspective

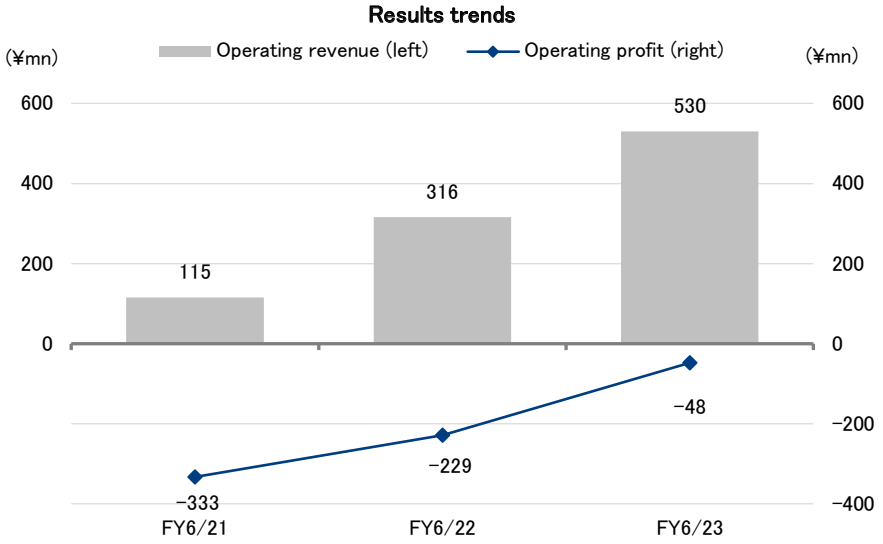
Because it is still in the R&D stage, the Company has not established management indicators that would serve as numerical targets. As part of its growth strategy for the foreseeable future, the Company has identified the increase in the number of development pipelines and the progress of clinical trials as key management indicators in the DTx product segment for maximizing revenue from a long-term perspective. In the DTx Platform segment, it has identified items such as expansions to the number of contracts and enhancements of new services to achieve continuous and accumulative revenue growth as key management indicators. To enhance its performance in these management indicators, the Company is also promoting joint research and alliances with partners such as medical institutions, academic research institutions, and pharmaceutical companies. Furthermore, it plans to develop its DTx Product business overseas and it is currently selecting countries to expand into based on a mix of factors, including the presence of regulatory laws, insurance reimbursement frameworks, market size, and competition.

6. Medium- to long-term growth potential

The Company is an R&D-stage startup, and as it incurs upfront R&D expenses, it is expected to face a continuation of periodic operating loss for the foreseeable future. However, SUSMED Med CBT-i, its first product to gain medical device manufacturing and marketing approval, is forecast to start fully contributing revenues from FY6/25, so at FISCO, we plan to closely watch the sales situation of this app. Another tailwind for the Company is that MHLW is developing an authorization environment to promote widespread adoption of Software as a Medical Device (SaMD) as part of national policy. Therefore, the expansion and advancement of development pipelines are things to look out for. Additionally, growth in the DTx Platform is expected through the use of blockchain technology, as are synergies between the DTx Product and DTx Platform. Considering these factors, we at FISCO believe that the Company has significant growth potential over the medium to long term.

Key Points

- An R&D-stage startup conducting business with a focus on the development of DTx, which is attracting interest as a third treatment option
- SUSMED Med CBT-i app for insomnia treatment to be launched onto the market within 2023
- Losses decreased in FY6/23
- Since progress is being made on development pipelines and the DTx Platform segment is expected to grow smoothly, the Company has considerable medium- to long-term growth potential



Note: The Company newly listed its shares in December 2021.
Source: Prepared by FISCO from the Company's financial results

Company profile

The Company's mission statement is "Continuously provide society with sustainable medicine services by leveraging ICT"

1. Company profile

The Company is an R&D-stage startup that is developing DTx apps, which is attracting interest as a third treatment option other than pharmaceuticals and medical devices. The Company aims to propose DTx apps as new treatment options, optimize development costs by making the drug discovery process more efficient with blockchain technology, and increase the efficiency of the pharmaceutical industry's entire value chain by utilizing medical data. The Company's mission statement, which guides these efforts, is "Continuously provide society with sustainable medicine services by leveraging ICT." Its name is derived from the phrase "SUStainable MEDicine."

The Company is headquartered in the Nihonbashi Honcho district of Chuo-ku, Tokyo. As of the end of FY6/23, the Company had total assets of ¥5,101mn, net assets of ¥4,870mn, share capital of ¥40mn, and an equity ratio of 95.3%. The number of shares issued by the Company was 16,622,500 (no treasury shares) as of the same date. As of the end of August 2023, it has 39 employees.

2. History

The Company was founded in July 2015 as a limited liability company, SUSMED LLC. In February 2016, it was reorganized into a stock company. Subsequently, the Company newly listed its shares on the Mothers Market of the Tokyo Stock Exchange (hereinafter, "TSE") in December 2021, and it transitioned to a listing on the Growth Market of the TSE in connection with the TSE's market restructuring in April 2022.

In terms of business development, the Company initiated clinical trials of its DTx app for insomnia in September 2016. In June 2018, it initiated a verification test of its clinical development support system using blockchain technology. In February 2019, the Company began providing DTx development support services, and in May 2019, it began providing a machine learning automated analytics system. In December 2021, the Company entered into a commercialization agreement with Shionogi & Co., Ltd. regarding the DTx app for insomnia. In February 2023, the Company obtained regulatory approval for medical device manufacturing and marketing of the DTx app for insomnia.

SUSMED, Inc.

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Company profile

History

Date	Description
July 2015	Founded as SUSMED LLC in Bunkyo-ku, Tokyo
October 2015	Selected for the NEDO Technology Commercialization Program (NEDO: New Energy and Industrial Technology Development Organization)
February 2016	Reorganized into a stock company
March 2016	Selected for the NEDO Entrepreneurs Program
September 2016	Began clinical trials of the digital therapy app for insomnia at two domestic facilities
April 2017	Selected for the NEDO R&D Venture Support Program
August 2017	Relocated Headquarters (Nihonbashi Honcho, Chuo-ku, Tokyo)
June 2018	Began a verification trial of a clinical development support system using blockchain technology
November 2018	Selected for Commercialization Support Program for Startups Cooperating with Other Companies
February 2019	Began providing the DTx development support service Selected for the HIYAKU Next Enterprise Program of the Ministry of Economy, Trade and Industry (METI)
April 2019	The verification plan for new technologies concerning the verification of clinical research monitoring using blockchain technology was approved by the Minister of Health, Labour and Welfare, and the Minister of Economy, Trade and Industry
May 2019	Began providing a machine learning automated analytics system
July 2019	Selected for the J-Startup Program, which is an initiative to support startups by METI, Japan External Trade Organization (JETRO), and NEDO "Development of an artificial intelligence (AI) platform to support decision-making at clinical sites" was selected as a NEDO AI-related technology development project.
December 2019	Relocated headquarters (Nihonbashi Honcho, Chuo-ku, Tokyo)
April 2020	Joint research with the National Cancer Center Japan was selected for Health and Labor Sciences Research Grants (comprehensive research project to fight cancer)
May 2020	Entered into a capital and business alliance with SUZUKEN CO., LTD. <9987>
July 2020	"Development of an artificial intelligence platform to understand the patient journey and support decision-making in clinical development" was selected as a NEDO AI-related technology development project for two consecutive years.
August 2020	Entered into a capital and business alliance with SUMITOMO CORPORATION <8053> and Nippon Chemiphar Co., Ltd. <4539>
September 2020	Entered into a capital and business alliance with Sawai Pharmaceutical Co., Ltd.
October 2020	Entered into a capital and business alliance with CMIC Co., Ltd. on development support for digital therapeutics
December 2020	Replacement of the monitoring process in clinical trials with the use of blockchain technology was approved by METI and MHLW
February 2021	Began the joint development of a DTx app for patients with chronic kidney disease with Tohoku University and the Japanese Society of Renal Rehabilitation
April 2021	A joint project with Tokyo Medical and Dental University to develop a monitoring technique using blockchain technology was selected as an R&D promotion network project of the Japan Agency for Medical Research and Development (hereinafter, "AMED")
June 2021	Entered into a business alliance with EPS Holdings, Inc. to achieve efficient clinical trials using the Company's blockchain technology
July 2021	Began joint research with National Cancer Center Hospital East to optimize constipation treatment, including opioid-induced constipation
August 2021	The development of a DTx app for breast cancer patients was selected as an AMED project for innovative R&D and resilient development structure for medical devices, etc.
October 2021	Relocated headquarters to present site (Nihonbashi Honcho, Chuo-ku, Tokyo)
December 2021	Newly listed shares on the TSE Mothers Market Entered into a commercialization agreement with Shionogi & Co., Ltd. <4507> regarding a DTx app for insomnia
February 2022	Filed for marketing authorization for the digital therapeutic app for insomnia
March 2022	Invested in Collabo Create Co., Ltd. Began joint research with Kyushu University concerning the development of an AI model to propose expert treatment for percutaneous catheter ablation for atrial fibrillation, which was selected as an AMED research project.
April 2022	Transitioned to a listing on the Growth Market of the TSE in connection with TSE market restructuring
May 2022	Began joint research with the National Center of Neurology and Psychiatry (hereinafter, "NCNP") for FY2022 "Research and Development Grants for Comprehensive Research for Persons with Disabilities" of AMED
June 2022	Concluded a contract with Aculys Pharma, Inc. on conducting a clinical trial using blockchain technology
September 2022	Began joint research with Shiga University on fundamental AI technology for causal discovery
October 2022	A joint development project with Nagoya City University (DTx apps for patients with functional disorders) was selected as an AMED FY2022 project for "Practical Research for Innovative Cancer Control" Began a project with Yokohama City University regarding the development of digital medicine programs for treating mental illness in young people Began a project with the NCNP regarding the development and social implementation of a platform with a remote mental healthcare system
November 2022	Concluded a joint research, development, and marketing agreement with KYORIN Pharmaceutical Co., Ltd. concerning a DTx app in the otolaryngology field
January 2023	Entered into a business alliance with Linical Co., Ltd. <2183> and ClinChoice K.K. to build a full support service system for clinical trials
February 2023	Acquired regulatory approval for the DTx app for insomnia Received a patent evaluation from the European Patent Office in relation to technology concerning the DTx app for insomnia

Source: Prepared by FISCO from the Company's website and news releases

Business overview

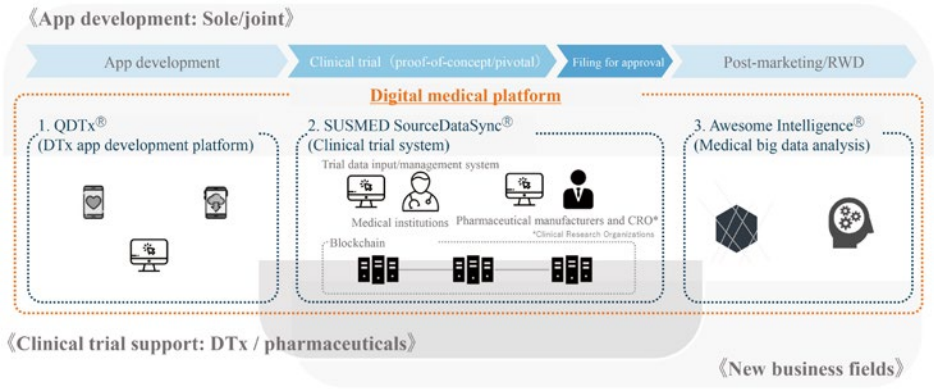
Two business segments: DTx Product and DTx Platform

1. Business overview

The Company's business segments are the DTx Product segment, in which it develops DTx apps used by patients and medical professionals, and the DTx Platform segment, in which it supports pharmaceutical and medical device companies make clinical trials more efficient with its proprietary platform on which clinical trial management system and a machine learning automated analytics system are implemented. As of the end of FY6/23, pipelines of DTx apps are still at the development stage and no products have been launched to market as yet. On the DTx Platform segment side, revenues are accounted as service usage fees from business customers.

Additionally, the Company has strong track records of building relationships with key opinion leaders (KOL) in academia (universities, research institutes, etc.) and academic societies who are essential for creating treatment algorithms and promoting DTx apps. Through joint research and development, it is accumulating expertise and enhancing its development pipelines. As of August 2023, it has 20 projects adopted by governmental agencies such as AMED and NEDO, it is conducting 19 joint research projects, it holds 21 patents (including overseas patents and joint filings), and it has 10 pipelines of DTx apps.

Overview of business fields



Source: Republished from Material for Business Plan and Growth Potential

The DTx Product segment, developing DTx apps as a third treatment option

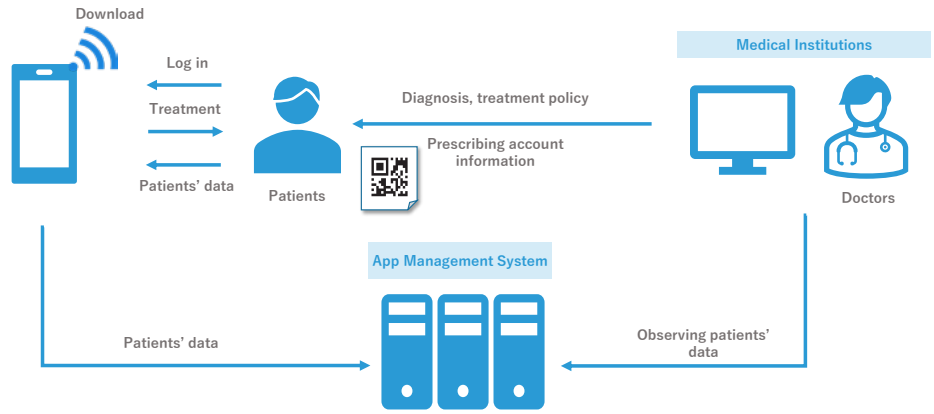
2. DTx Product segment

In the DTx Product segment, the Company develops DTx apps and clinical trial apps. DTx apps are a new treatment option other than pharmaceutical or medical device-based therapies (drug therapy, chemical therapy, surgery, etc.), which provides treatment via apps downloaded by patients onto their smartphones.

Although these apps cannot be used in all disease fields, their use in disease fields where the side effects of drug therapy are a concern, such as lifestyle diseases, psychiatric diseases, and chronic diseases, are intended to reshape patients' daily life habits and thus generate a therapeutic effect. To illustrate how treatment is provided, rather than conduct remote or telemedicine therapy performed by a physician through a screen, the app itself replaces the physician and provides optimal treatment (therapeutic intervention for each patient through an algorithm based on medical practice). Furthermore, the app transmits patient data to medical professionals, allowing for more appropriate medical treatment and therapeutic intervention.

Unlike general healthcare apps that anyone can use (diet apps, pedometer apps, etc.), DTx apps must be approved by the regulatory authorities as a medical device, as stipulated by the Pharmaceutical and Medical Devices Act (Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices), based on medical evidence related to efficacy and safety confirmed through clinical trials. For this reason, there are certain difficulties that must be overcome in order to develop DTx apps. Another distinction between DTx apps and health-care apps is that only patients who have been diagnosed and prescribed treatment by a doctor are authorized to use the app. Therefore, the marketing targets will be doctors and medical institutions, rather than ordinary consumers. Revenue is paid based on the number of prescriptions written by medical institutions that have received medical fees (The medical fee for approved DTx apps consists of a 70% national insurance payment and a 30% co-payment.)

Flow for providing DTx apps



Source: Reprinted from the Company's results briefing materials

For example, in the field of insomnia, Japanese patients are typically treated with drug therapy using sleeping medications and other drugs. However, complications such as side effects and addiction issues, as well as patients' hesitation to take sleeping medications have become issues. In addition, cognitive behavioral therapy (a therapy method that improves the condition of disease by influencing an individual's awareness or behavior) has attracted attention in recent years, and has been recommended by the National Institutes of Health in the United States as the first line of treatment for insomnia. In Japan, however, there is a lack of medical resources to provide cognitive behavioral therapy, and the current reality is that drug therapy remains the predominant treatment. In addressing these issues, DTx apps pose very little risk of complications such as side effects and addiction issues, which are common concerns in drug therapy. DTx apps could become a treatment option for providing patients with cognitive behavioral therapy without being constrained by the availability of medical resources.

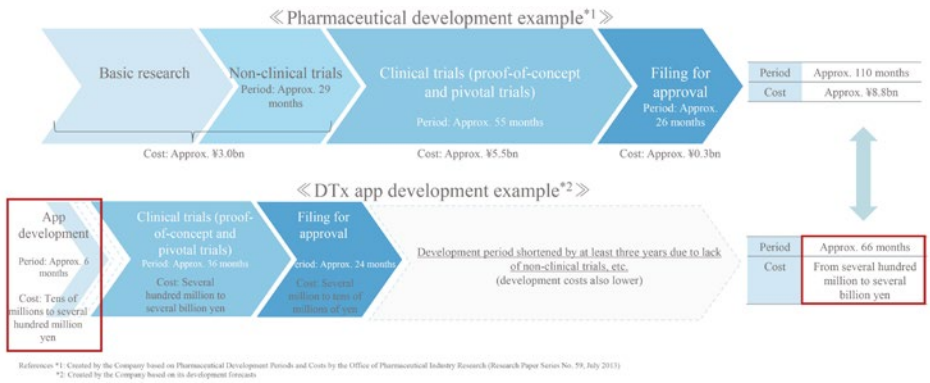
For doctors, the use of DTx apps eliminates the need for their direct involvement. This has benefits such as significantly increasing the number of patients a doctor can treat and enabling a doctor to present proper treatment to patients based on accumulated real-world data. Patients will be able to receive proper support through DTx apps even when they are not in examination room. As a result, DTx apps are also expected to solve problems in chronic disease treatment, such as a high rate of treatment discontinuation, and longer-than-normal treatment periods due to the inability to provide proper, timely and ample therapy intervention.

In terms of examples of DTx app approvals, progress has been made from a relatively early stage overseas. In 2010, U.S.-based WellDoc's DTx app for diabetes became the first such app to be approved by the U.S. Food & Drug Administration (FDA). More recent approvals include OVIVA UK LIMITED's DTx app for type II diabetes in the U.K. in June 2020, mementor DE GmBH's DTx app for insomnia in Germany in October 2020, NightWare, Inc.'s DTx app for insomnia related to nightmares from post-traumatic stress disorder (PTSD) in the U.S. in November 2020, and an app for migraines in Germany in December 2020. In addition, the National Institute for Health and Care Excellence (NICE) in the U.K. recommends treating insomnia with DTx apps rather than sleeping medications.

In Japan, the development and approval of DTx apps have been slower than overseas. The MHLW has developed guidelines that encompass perspectives such as reducing medical expenditures, efforts to develop, introduce, and industrialize cutting-edge medical devices, and work style reforms for medical professionals. It has outlined a policy aimed at promoting the development of an approval environment to encourage widespread adoption of Software as a Medical Device (SaMD) (including software only) via apps and AI. Furthermore, Allm Inc.'s app to support stroke therapy was approved as Japan's first software-only DTx app (not for treatment, but for treatment support) in 2014. More recently, CureApp, Inc.'s DTx app for nicotine addiction and CO checker, which were Japan's first DTx apps for treatment, became eligible for coverage under National Health Insurance in December 2020. Additionally, in September 2022, CureApp's hypertension therapy support app became eligible for coverage under National Health Insurance.

The development process of DTx, research and development of the DTx app → proof-of-concept trial → pivotal trial → filing for approval → insurance coverage, is almost the same as the process for developing a new pharmaceutical (basic research → non-clinical trial → clinical trial → filing for approval → insurance coverage). However, the general development lead time for a DTx app is around 5 or 6 years (approximately six months for app development, 36 months for proof-of-concept trials and pivotal trials, and 24 months to file for approval), whereas it is very different from a pharmaceutical requiring more than 10 years. A DTx app's development lead time is around half that of a new pharmaceutical and development costs are low, resulting in a relatively low level of risk compared to pharmaceutical development.

DTx app development costs and schedule



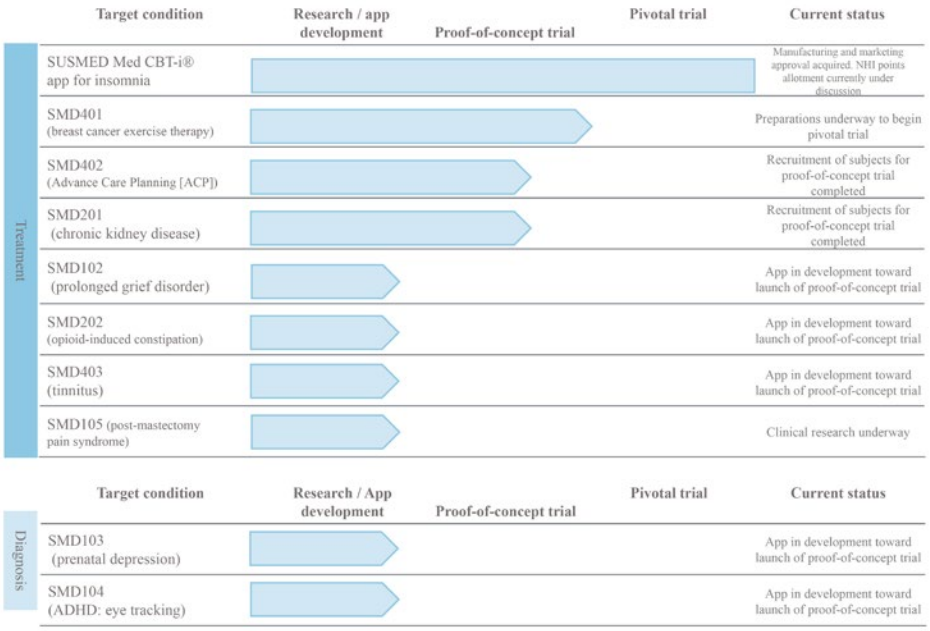
Source: Republished from Material for Business Plan and Growth Potential

Obtained medical device manufacturing and marketing approval for the DTx app for insomnia

3. Pipelines for DTx apps and the domestic market size

The Company's pipelines for DTx apps contain 10 products as of August 10, 2023.

Development Pipeline



Source: Republished from Material for Business Plan and Growth Potential

For the DTx app for insomnia (product name: SUSMED Med CBT-i; development partner: Kurume University), in December 2021 the Company entered into a commercialization agreement with Shionogi & Co., Ltd. The agreement grants exclusive sales rights in Japan to Shionogi & Co. in exchange for up to ¥4.7bn in upfront payments and milestone income. Moreover, once the product has been launched, the Company will receive royalties from Shionogi & Co. based on sales results. As of February 15, 2023, the Company received medical device manufacturing and marketing approval for the app from the MHLW. It is currently discussing National Health Insurance coverage with the MHLW, and working with Shionogi & Co. on a market launch program (expected within 2023). Additionally, in February 2023, the patents for the app's technologies which the Company has already acquired in Japan, the USA, South Korea, and Indonesia received a patent evaluation from the European Patent Office too.

For SMD402 (development partner: National Cancer Center Japan), a DTx app for ACP which provides decision-making support for progressive cancer patients, the recruitment of subjects for a proof-of-concept trial was completed in February 2023. SMD402 would provide clinical effects to subjects easing of psychological distress and improvements in anxiety and depression, and it would bring the cessation of unsuitable treatments.

For the renal rehabilitation app SMD201 (development partners: Tohoku University, Japanese Society of Renal Rehabilitation), the recruitment of subjects for a proof-of-concept trial was also completed in February 2023. Face-to-face renal rehabilitation has already been proven to be effective in improving or slowing down the deterioration of kidney functions, and it iscovered by National Health Insurance. The Company believes that SMD201 would provide the same clinical effects as face-to-face rehabilitation to subjects while saving limited medical resources.

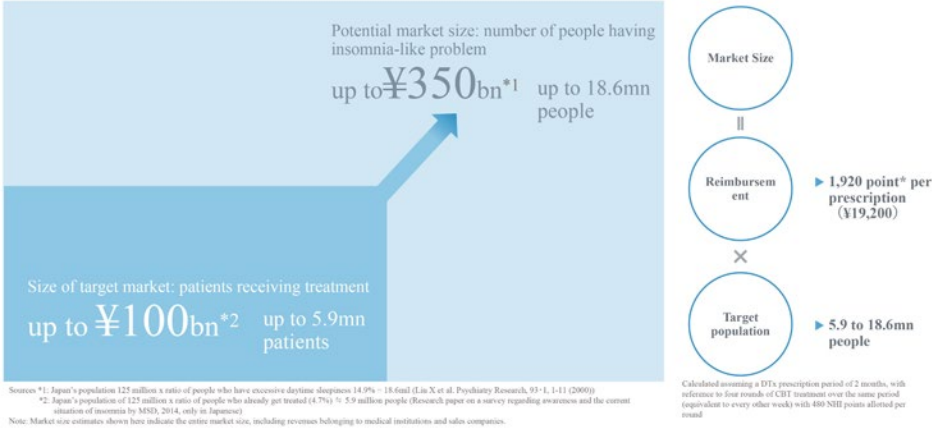
For SMD403, a DTx app for tinnitus, in November 2022 the Company concluded a joint research, development, and marketing agreement with KYORIN Pharmaceutical Co., Ltd., which has expertise in otolaryngology area. The Company has already received an upfront payment (¥100mn) and going forward, it is due to receive milestone income (revealed at the time of agreement, to be ¥600mn) in accordance with development progress, as well as royalties based on sales results once the product has been launched. Currently the app is in the development stage before a proof-of-concept trial.

Regarding the status of other products, SMD401 (development partner: National Cancer Center Japan), a breast cancer patient exercise therapy app, is in preparation for a pivotal trial. SMD102, which targets prolonged grief disorder, and SMD202, which targets opioid-induced constipation, are in development toward the launch of proof-of-concept trials. SMD105 (development partner: Nagoya City University), an acceptance & commitment therapy (ACT) app targeting post-mastectomy pain syndrome (PMPS), is in the clinical research process.

Moreover, SMD103 (development partner: Nagoya University), which targets prenatal depression, is in development toward the launch of a proof-of-concept trial. Its patent for the algorithm and device have already been obtained. SMD104, which carries out eye tracking analysis related to ADHD, is in development toward the launch of a proof-of-concept trial.

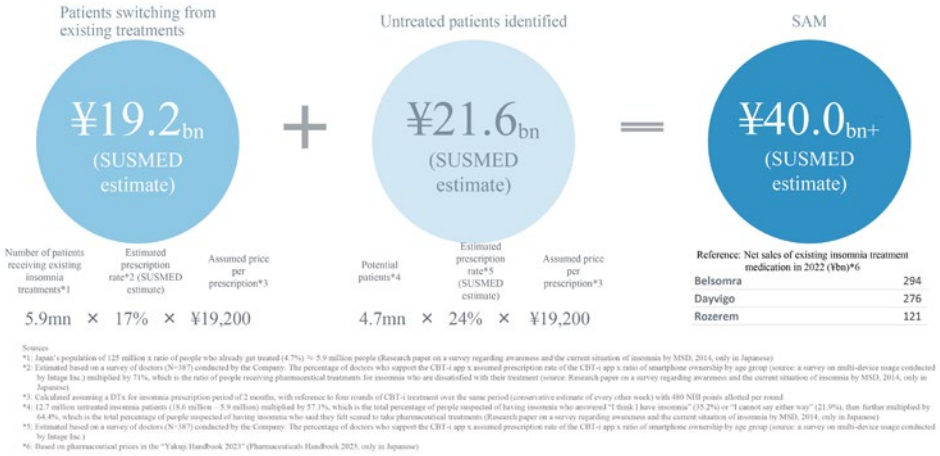
According to the Company's disclosure materials, the market size of SUSMED Med CBT-i in Japan is estimated at ¥100.0bn, and expandable to ¥350.0bn if potential patients are included. Furthermore, the Serviceable Available Market (SAM), which represents targeted demand, is estimated at more than ¥40.0bn in total (¥19.2bn by switching from existing sleep medication therapy + ¥21.6bn by reaching out to untreated patients who are aware of their insomnia symptoms but are hesitant to take sleeping pills). The estimated domestic market sizes of other pipelines are ¥7.2bn for SMD401, ¥30.9bn for SMD402, and ¥66.0bn for SMD201.

Market size of DTx app for insomnia in Japan (estimate)



Source: Reprinted from the Company's results briefing materials

Serviceable Available Market (SAM) for the DTx app for insomnia



Source: Reprinted from the Company's results briefing materials

The DTx Platform segment, supporting more efficient clinical trials by using blockchain technology

4. DTx Platform segment

In the DTx Platform, the Company mainly provides three services, 1) DTx development support services using DTx app development platform "QDTx®" based on expertise gained in the development process for the DTx app for insomnia; 2) Awesome Intelligence®, a machine learning automated analytics service that analyzes medical big data; and 3) the SUSMED SourceDataSync, which is a general-purpose clinical trial system that supports streamlining clinical trials for pharmaceutical/medical device companies.

In particular, the SUSMED SourceDataSync, with a monitoring system leveraged by blockchain technology, realizes the high level of security and data tampering resistance required in clinical trials, while drastically reducing the man-hours and costs related to monitoring. The Awesome Intelligence is provided as a cloud service and is used to analyze real world data and other medical big data.

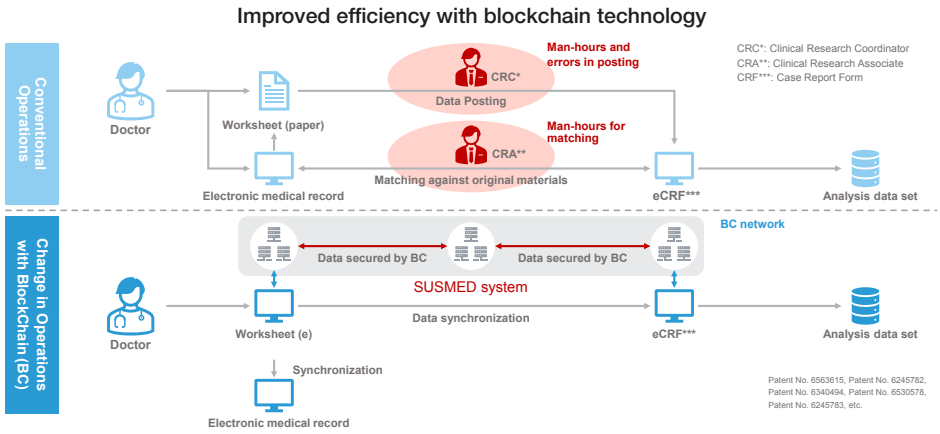
Since 2017, the Company has been undertaking R&D in the application of blockchain technology, in order to replace the monitoring data matching tasks required in clinical trials with its system, currently named as "SUSMED SourceDataSync." As a result, the Company has acquired numerous patents. In December 2020 the Minister of Health, Labour and Welfare officially approved the system as fulfilling the monitoring requirements required by Good Clinical Practice (GCP)*1 ordinances, through adoption of the Cabinet Office's regulatory sandbox system*2 and the use of the Grey Zone Elimination system*3.

*1 Good Clinical Practice (GCP): Ministerial ordinance for implementing clinical trials of pharmaceuticals.
*2 A system in which verification approved by regulatory authorities is carried out and the results are used to revise regulations, in order to implement new technologies and business models in society. IoT, blockchain, robotics are examples of new technologies, while platform businesses and the sharing economy are examples of business models.
*3 A system that allows a business to confirm in advance whether regulations will be applied in accordance with a specific business plan, enabling it to conduct business activities with confidence even when the scope of current regulations is unclear.

Following that, the Company has promoted further improvement in reliability and expanded fields of blockchain technology application through joint research and alliances with partners such as medical institutions, academic research institutions, and pharmaceutical companies. In June 2021, it entered into a business alliance with EPS Holdings, Inc. to achieve efficient clinical trials using blockchain technology. In May 2022, it began joint research with the NCNP on improving the reliability of registry data using blockchain technology.

In June 2022, it entered into a contract with Aculys Pharma, Inc., a Japanese bio-venture company engaged in new drug development in the neurology and psychiatry fields, to conduct the world's first corporate clinical trial utilizing blockchain technology. The Company is providing SUSMED SourceDataSync in collaboration with business alliance partner CMIC Co., Ltd. (a subsidiary of CMIC HOLDINGS Co., Ltd. <2309>), which is a pioneering contract research organization (CRO) for pharmaceutical development. In November 2022, Aculys Pharma started to use SUSMED SourceDataSync in its Phase 3 clinical trial in Japan for pitolisant, a histamine 3 receptor antagonist/inverse agonist targeting narcolepsy patients. Furthermore, in January 2023, SUSMED SourceDataSync began operating in a second clinical trial when Aculys Pharma started a Phase 3 clinical trial in Japan for pitolisant as a treatment for excessive daytime sleepiness accompanying obstructive sleep apnea syndrome.

Also in January 2023, the Company entered into a business alliance with Linical Co., Ltd. and ClinChoice K.K. to build a full support service for efficient and effective clinical trials using SUSMED SourceDataSync.



Source: Reprinted from the Company's results briefing materials

Upfront R&D expenses will be incurred for the foreseeable future

5. Risk factors

The Company's general risk factors include, as with new drug development, the risk of uncertainty in R&D concerning DTx apps, side effects, product liability, legal regulations, and intellectual property litigation. In addition, how fast SUSMED Med CBT-i, which has already acquired medical device manufacturing and marketing approval, becomes widely used is being considered as a risk. The Company may face a continuation of periodic operating loss for the foreseeable future as it is going to incur upfront R&D expenses for other pipelines.

In response to these risk factors, the Company will continue seeds acquisition and pipeline advancement for DTx apps, to drive earnings growth in the future. At the same time, it intends to consider measures that will allow it to generate revenue sooner, such as licensing out its pipelines to other companies or earning milestone revenue. In addition, as an R&D-intensive firm, the Company will continue to incur large R&D expenses over the long term. Therefore, the Company plans to strengthen its financial foundation by raising funds at appropriate times as necessary, until it is able to record stable revenue from SUSMED Med CBT-i.

Results trends

Losses decreased considerably in FY6/23, with increased revenue exceeding forecasts

1. Summary of FY6/23 results

In the FY6/23 results (non-consolidated), operating revenue increased 67.5% YoY to ¥530mn, operating loss was ¥48mn (compared to a loss of ¥229mn in FY6/22), ordinary loss was ¥44mn (compared to a loss of ¥217mn in FY6/22), and net loss was ¥50mn (compared to a loss of ¥233mn in FY6/22). In the DTx Product segment, the Company recorded milestone income and there was also smooth growth in the DTx Platform segment. As a result, overall losses decreased from the previous period considerably. Each result exceeded the revised forecast released on February 10, 2023, with operating revenue exceeding the forecast by ¥8mn, operating profit by ¥84mn, ordinary profit by ¥87mn, and net profit by ¥89mn. Sales were roughly in line with targets while efforts including the curbing of recruitment expenses (due to an increase in direct applications and progress on recruitment through referrals) contributed to profits. Also, during FY6/23, there were periods where no clinical trials were being held, leading to R&D expenses decreasing by 22.1% YoY to ¥176mn. Although this was ¥50mn lower than the previous fiscal year, it was ¥25mn higher than forecast.

Summary of FY6/23 results (non-consolidated)

(¥mn)

	FY6/22	FY6/23	YoY change
Operating revenue	316	530	67.5%
Business expenses	546	578	6.0%
(R&D expenses)	226	176	-22.1%
(Selling, general and administrative expenses)	309	394	27.6%
Operating profit	-229	-48	-
Ordinary profit	-217	-44	-
Net profit	-233	-50	-
Segment operating revenue			
DTx Product	200	400	100.0%
DTx Platform	116	130	11.8%
Segment profit			
DTx Product	11	256	2112.4%
DTx Platform	57	66	14.6%
Corporate expenses	-298	-371	-

Source: Prepared by FISCO from the Company's financial results

2. Trends by business segment

In the DTx Product segment, operating revenue increased 100.0% YoY to ¥400mn while segment profit (operating profit before adjustments for corporate expenses, etc.) was ¥256mn (compared to ¥11mn in FY6/22). Milestone income of ¥400mn from Shionogi & Co. was recognized in accordance with the acquisition of medical device manufacturing and marketing approval for SUSMED Med CBT-i. In the DTx Platform segment, operating revenue increased 11.8% YoY to ¥130mn while segment profit increased 14.6% to ¥66mn. Although the number of contracting companies decreased by two from the end of FY6/22, dropping to 12, the increase in contracted unit prices contributed to exceeding targets.

The Company has secured R&D funds by raising through its new share listing

3. Financial position

Looking at the Company's financial position, total assets increased ¥157mn from the end of FY6/22 to ¥5,101mn as of the end of FY6/23. This was primarily due to a ¥144mn increase in cash and cash equivalents, including ¥100mn of upfront income on a contract. Total liabilities increased ¥136mn from the end of FY6/22 to ¥230mn, mainly due to a ¥121mn increase in contract liabilities. Total net assets rose ¥20mn from the end of FY6/22 to ¥4,870mn, and the equity ratio decreased 2.8 percentage points YoY to 95.3%. There are no particularly significant changes in line items. In regard to cash flows, the Company achieved a positive cash flow from operating activities.

Because the Company is a startup in the R&D stage, it may continue to generate negative operating cash flows as it incurs upfront R&D expenses. However, the Company secured R&D funds by raising from its new share listing in December 2021. The Company might need to raise additional funds depending on how things go with future R&D and development pipelines. Still, we at FISCO do not believe there are any financial concerns at present.

Balance Sheets and Cash Flow Statements (Simplified)

(¥mn)

	End-FY6/21	End-FY6/22	End-FY6/23	Change
Total assets	1,674	4,943	5,101	157
Current assets	1,674	4,935	5,085	149
Non-current assets	0	8	15	7
Total liabilities	97	93	230	136
Current liabilities	96	87	224	136
Non-current liabilities	0	5	5	-
Total net assets	1,577	4,850	4,870	20
Shareholders' equity	1,577	4,850	4,861	11
Equity ratio	94.2%	98.1%	95.3%	-2.8%

	FY6/21	FY6/22	FY6/23
Cash flow from operating activities	-235	-165	100
Cash flow from investing activities	-4	-20	-18
Cash flow from financing activities	1,500	3,463	62
Cash and cash equivalent at end of year	1,626	4,904	5,048

Note: The Company newly listed its shares in December 2021.
Source: Prepared by FISCO from the Company's financial results

Business outlook

FY6/24 results forecast

● FY6/24 results outlook

The Company's FY6/24 results (non-consolidated) forecast has yet to be finalized. The Company is anticipating smooth growth of revenue in the DTx Platform segment, but in the DTx Product segment, it thinks that it is difficult to reasonably estimate revenue from SUSMED Med CBT-i at the start of the fiscal year. It states that it will disclose forecasts as soon as it is feasible to do so. Also, the Company received an upfront payment from KYORIN Pharmaceutical Co., Ltd. related to SMD403, but it has not yet been determined when the revenue will be recognized.

In regard to key measures, in the DTx Product segment, the Company aims to start selling SUSMED Med CBT-i (via MR of Shionogi & Co.) and it plans to make progress on its development pipelines (starting pivotal trial preparations for SMD402 and SMD201, launching clinical research on SMD403, and starting a proof-of-concept trial for SMD105). In the DTx Platform segment, it plans to acquire new projects for SUSMED SourceDataSync and to start building registries based on blockchain technology.

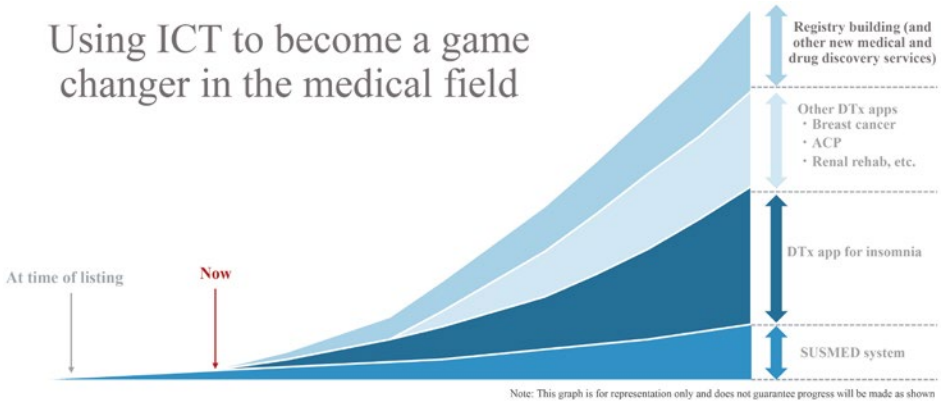
Growth strategy

Advance joint research to enhance pipelines and apply blockchain technology

1. Outlook for medium- to long-term growth

Because it is still in the R&D stage, the Company has not established management indicators that would serve as numerical targets. As part of its growth strategy for the foreseeable future, the Company has identified the increase in the number of pipelines and the progress of clinical trials as key management indicators in the DTx Product segment for maximizing revenue from a long-term perspective. In the DTx Platform segment, it has identified items such as expansions to the number of contracts and enhancements of new services to achieve continuous and accumulative revenue growth as key management indicators. To enhance its performance in these management indicators, the Company is also promoting joint research and alliances with partners such as medical institutions, academic research institutions, and pharmaceutical companies. Furthermore, it plans to develop its DTx Product business overseas and it is currently selecting countries to expand into based on a mix of factors, including the presence of regulatory laws, insurance reimbursement frameworks, market size, and competitive situation.

Image of medium- to long-term strategy



Source: Republished from Material for Business Plan and Growth Potential

Overseas expansion: DTx Product segment

■ Countries are being selected based on a mix of factors, including the presence of regulatory laws, insurance reimbursement frameworks, market size, and competitive situation

*HC: Health Care **: Evaluation by SUSMED taking into consideration population, medical expenditure per person, etc.

	Country/region	DTx regulation	Insurance framework: DTx eligible for insurance	Comments	Category	Market size***	Competitor	Entry method
Large markets	USA	510K	Mainly private sector insurance: Depends on DTx product	DTx for private sector insurance companies	DTx/HC*	Large	Pear	Licensing / self-entry
	China	Regulated	Mainly national insurance: DTx not eligible	Excessive competition from healthcare apps	DTx	Large	Asleep	Licensing
	EU	MDR since May 2021	Depends on country: Eligible in France and Germany		DTx	Large	Somnio	Licensing / self-entry
Recognized as equivalent	South Korea	Regulated	Mainly national insurance: DTx may become eligible in future	Recognized as similar to Japan	DTx	Medium		Licensing / self-entry
	Mexico	Unregulated	Mainly national insurance	Recognized as similar to Japan	HC*	Small	HC app only	Under consideration
Other	Taiwan	Regulated	Mainly national insurance: DTx may become eligible in future		DTx	Medium	HC app only	Licensing / self-entry
	Australia	Regulated	Mainly national insurance: DTx may become eligible in future		Undetermined	Large	Pear/Bighe alth	Under consideration
	Thailand	Regulated	Mainly national insurance: DTx not eligible	No regulatory laws in Malaysia		Extremely small		

Source: Republished from Material for Business Plan and Growth Potential

Looking at examples of joint research and alliances, the Company made a 0.8% investment in March 2022 in Collabo Create Co., Ltd. (a consolidated subsidiary of SUZUKEN CO., LTD.; established in March 2022 to plan and propose healthcare platforms). Through Collabo Create, the Company will promote services related to DTx development support and general-purpose clinical trial systems, among other activities. Additionally, in March 2022, the Company entered into a joint research agreement with Kyushu University concerning the development of an AI model to propose expert treatment for percutaneous catheter ablation for atrial fibrillation. This research was adopted as a "Practical Research Project for Life-Style related Diseases including Cardiovascular Diseases and Diabetes Mellitus" in collaboration with the FY2021 Medical Arts Research Project of AMED.

In May 2022, the Company, together with NCNP, began research and development concerning the development of a personal information anonymization method and establishment of data processing technology for accumulating and utilizing data collected from diverse sources, and guaranteeing data quality. This research was adopted as "Research and Development Concerning Processing Methods and Assuring the Quality of Clinical Data to Promote Data Utilization," for the FY2022 "Research and Development Grants for Comprehensive Research for Persons with Disabilities" of AMED. In September 2022, it concluded an agreement with Shiga University regarding joint research on fundamental technology for causal discovery titled Establishment and Application of Fundamental Technology for Causal Discovery to Realize Reliable AI Systems. This research was selected by the Japan Science and Technology Agency (JST) as an FY2022 strategic and creative research promotion project (CREST). In October 2022, the Company began an initiative with the NCNP regarding the development and social implementation of a mental health platform using a remote mental healthcare system adapted for all generations (KOKOROBO-J). This initiative was selected for the JST's FY2022 co-creation venue building support program (COI-NEXT).

Contributing to solutions for social issues through business, including developing DTx apps and making drug discovery processes more efficient

2. Sustainability management

The Company has not disclosed its materiality issues in relation to its initiatives to address Environmental, Social, and Governance (ESG) management and the Sustainable Development Goals (SDGs). However, it is working to help achieve "Good Health and Well-Being," one of the SDGs, through its business activities, including proposing treatment options through the development of DTx apps, making the drug discovery process more efficient and optimizing development costs by providing a general-purpose clinical trial system, and promoting medical data utilization and increasing the efficiency of the entire pharmaceutical industry's value chain by providing a machine learning automated analytics system.

It has established a Governance Committee as an advisory body for matters related to the nomination and remuneration of directors, to enhance corporate governance.

Expectations regarding medium- to long-term growth potential

3. FISCO's view

The Company is an R&D-stage startup, and as it incurs upfront R&D expenses, it is expected to face a continuation of periodic operating loss for the foreseeable future. However, SUSMED Med CBT-i, its first product to gain medical device manufacturing and marketing approval, is forecast to start fully contributing revenues from FY6/25, so at FISCO, we plan to closely watch the sales situation of this app. Another tailwind for the Company is that MHLW is developing an authorization environment to promote widespread adoption of SaMD as part of national policy. We would also like to focus on the expansion and progress of the development pipeline. Growth in the DTx Platform segment is expected through the use of blockchain technology, as are synergies between the DTx Product and DTx Platform segments. Considering these factors, we at FISCO believe that the Company has growth potential over the medium to long term.

Shareholder return policy

Prioritizing the securing of funds for R&D activities for the time being

Regarding the shareholder return policy, the Company recognizes the return of profits to shareholders as a crucial management issue. In light of its operating results and financial condition, the Company will consider distributing surplus profits to shareholders in the future. However, in order to prioritize securing funds for continuously and systematically conducting R&D activities that require significant upfront investment, the Company does not intend to provide shareholder returns through dividends and other means in the near future.

FISCO

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