COMPANY RESEARCH AND ANALYSIS REPORT

SUSMED, Inc.

4263

Tokyo Stock Exchange Growth Market

7-Nov.-2024

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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. Developing DTx apps and supporting efficient drug discovery processes

The Company does business in two segments: the DTx Product segment, in which it develops DTx apps, and the DTx Platform segment, in which it helps to increase the efficiency of clinical development of both pharmaceutical and medical device companies. 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, 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. In the DTx Platform segment, the Company mainly provides three services, 1) DTx development support services using DTx app development platform "QDTx®"; 2) Awesome Intelligence®, a machine learning automated analytics service that analyzes medical big data; and 3) SUSMED SourceDataSync®, which is a general-purpose clinical trial system that supports streamlining clinical trials for pharmaceutical/medical device companies. SUSMED SourceDataSync in particular helps significantly reduce man-hours and expenses related to monitoring by leveraging the features of blockchain technology.

2. Regarding the DTx app for insomnia, filed an application for partial changes and made progress toward insurance coverage

For SUSMED Med CBT-i® app, the DTx for insomnia, the Company acquired manufacturing and marketing approval as a medical device from the Ministry of Health, Labour and Welfare on February 15, 2023 and was processing procedures for insurance coverage, but thereafter in the fiscal 2024 discussions on revising medical fees, the decision was made to put off insurance coverage, so the Company temporarily withdrew the request for insurance coverage on January 29, 2024. Thereafter, on August 30, 2024, the Company filed an application for partial changes (an application to change a portion of items related to already approved pharmaceuticals and medical devices, etc.). This filing was made after multiple discussions with the regulatory authorities based on the new insurance system, revised in the fiscal 2024 medical fee revisions, which says that the overall therapeutic programs such as the apps developed by the Company are to be evaluated as special treatment materials. As for the future outlook, if the application for partial changes is approved, generally, there are deliberations by a specialized organization for medical treatment materials, etc. and following approval by the Central Social Insurance Medical Council, insurance coverage is obtained. While a specific timeline is yet to be determined, the Company has made progress toward insurance coverage.

3. In FY 6/24, expanded losses due to increased R&D expenses

In the Company's results (non-consolidated) for FY6/24, operating revenue decreased by 35.4% (YoY) to ¥342mn, operating loss was ¥364mn (compared to a loss of ¥48mn in FY6/23), ordinary loss was ¥357mn (compared to a loss of ¥44mn in FY6/23), and net loss of ¥357mn (compared to a loss of ¥50mn in FY6/23). The DTx Platform segment generated stable revenue, but the DTx Product segment saw a decrease in upfront contractual payments and milestone income. These factors led to a decrease in Company-wide revenue. Also, the increase in R&D expenses (by 38.0% YoY to ¥243mn) had an impact as losses expanded. The operating loss expanded YoY but was smaller than the latest forecast on February 14, 2024.

4. For FY6/25, expanded losses expected due to increased R&D expenses but significant increase in revenue

For FY6/25 results (non-consolidated), the Company is expecting operating revenue to increase by 39.9% to ¥479mn, operating loss of ¥583mn (compared to a loss of ¥364mn in FY6/24), ordinary loss of ¥583mn (compared to a ¥357mn loss in FY6/24) and net loss of ¥589mn (compared to a loss of ¥357mn in FY6/24). The increase in R&D expenses associated with progress in pipeline development (planned increase of 68.3% YoY to ¥409mn) and an increase in personnel expenses with increased hiring for business expansion are mainly expected to increase the operating loss. The Company is expecting upfront contractual payments and some milestone income in the DTx Product segment, with stable sales expansion in the DTx Platform segment to result in a major gain in revenue. Key measures in the DTx Product segment are to obtain insurance coverage for SUSMED Med CBT-i®, an app for insomnia, and promote further pipeline development. The key measures in the DTx Platform segment are to promote SUSMED SourceDataSync a clinical trial system, to be used in multiple trials and to start operation of a venous disease registry system.

5. Promoting development pipeline expansion in the DTx Product segment and increased contracts in the DTx Platform segment

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, 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.

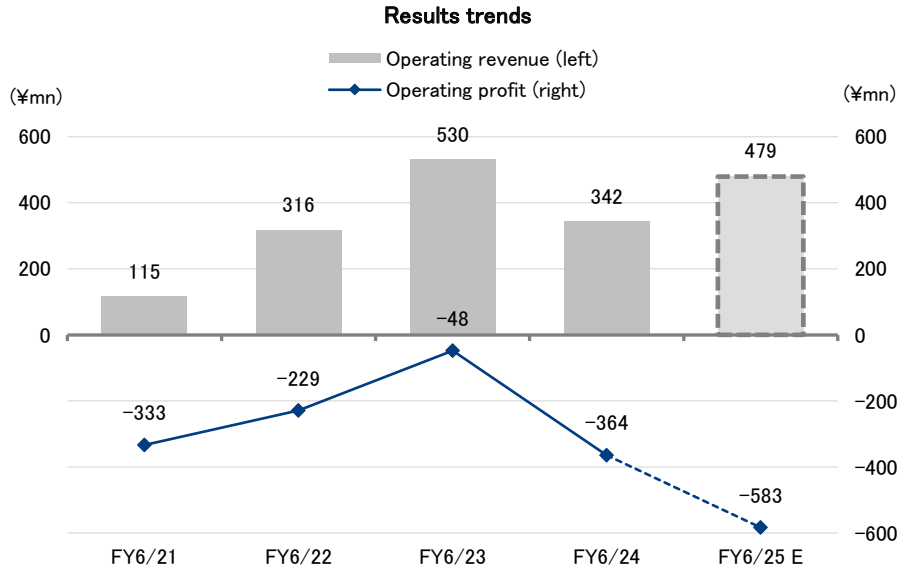
6. Evaluation of medium- to long-term growth potential

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, the DTx app for insomnia, SUSMED Med CBT-i® made progress toward insurance coverage as a result of filing an application for partial changes. As for government policy, the Ministry of Health, Labour and Welfare is paving the way for the approval environment of SaMD so that SaMD products can spread widely in the market. This situation is a tailwind for the Company and pipeline developments are expected to gain momentum in the near future. Together with expansion in the DTx Platform segment driven by the application of blockchain technology, FISCO believes the Company has medium- to long-term growth potential.

Summary

Key Points

- Startup venture doing business in the DTx Product segment, where it develops DTx apps, and in the DTx Platform segment where it helps increase the efficiency of the drug discovery and development process
- For the DTx app for insomnia, filed an application for partial changes and making progress toward insurance coverage
- Expanded losses in FY6/24. Expecting bigger losses in FY6/25 due to increased R&D expenses but revenue will increase significantly
- Expanding development pipeline in the DTx Product segment and increasing business contracts in the DTx Platform segment
- Positive assessment of medium- to long-term growth potential



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 FY6/24, the Company had total assets of ¥4,932mn, net assets of ¥4,604mn, share capital of ¥4,584mn, and an equity ratio of 92.9%. The number of shares issued by the Company was 16,759,300 (including 11 treasury shares) as of the same date. As of the end of August 2024, 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. <4507>. 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 (subsequently in August 2024 it filed an application for partial changes). Also, in November 2022, the Company entered into an agreement with KYORIN Pharmaceutical Co., Ltd. <4569> for joint R&D and post-launch marketing of a DTx app for tinnitus, and in September 2023 it entered into an agreement with ASKA Pharmaceutical Co., Ltd. (a subsidiary of ASKA Pharmaceutical Holdings Co., Ltd. <4886>) for joint R&D and post-launch marketing of a DTx app in the obstetrics and gynecology field.

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 Ministers of Health, Labour and Welfare (MHLW) and METI
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. and started joint development
October 2020	Entered into a 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

Company profile

Date	Description
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	Business alliance with Linical Co., Ltd. <2183> and ClinChoice K.K. to build a system for providing full support services 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
September 2023	Signed a memorandum of understanding with Tohoku University to promote real world data utilization from medical devices through blockchain technology Entered into an agreement with ASKA Pharmaceutical Co., Ltd. for joint R&D and post-launch marketing of a DTx app in the obstetrics and gynecology field
August 2024	Started clinical trials on a cognitive behavioral therapy app under joint research and development with Niigata University Filed an application for partial changes of SUSMED Med CBT-i®, a DTx for insomnia

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

Business overview

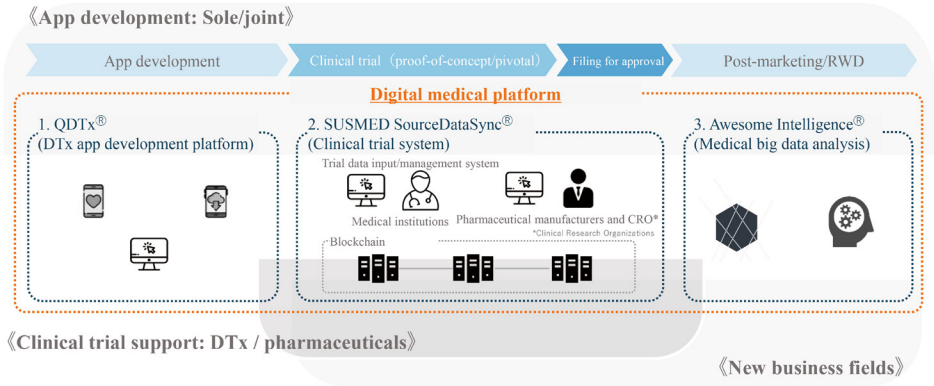
Operating in two business segments: DTx Product, which develops DTx apps, and DTx Platform, which supports efficiency gains in clinical development

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 helps pharmaceutical and medical device companies conduct clinical development more efficiently with its proprietary platform on which a general-purpose clinical trial management system and machine learning automated analytics system are implemented. As of the end of FY6/24, 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 (KOLs) 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 2024, it has 21 projects adopted by governmental agencies such as AMED and the Japan Science and Technology Agency (hereinafter, JST), it is conducting 23 joint research projects, it holds 24 patents (including overseas patents and joint filings), and it has 12 pipelines of DTx apps.

Overview of business fields



Source: Reprinted from Material for Business Plan and Growth Potential

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

2. DTx Product segment

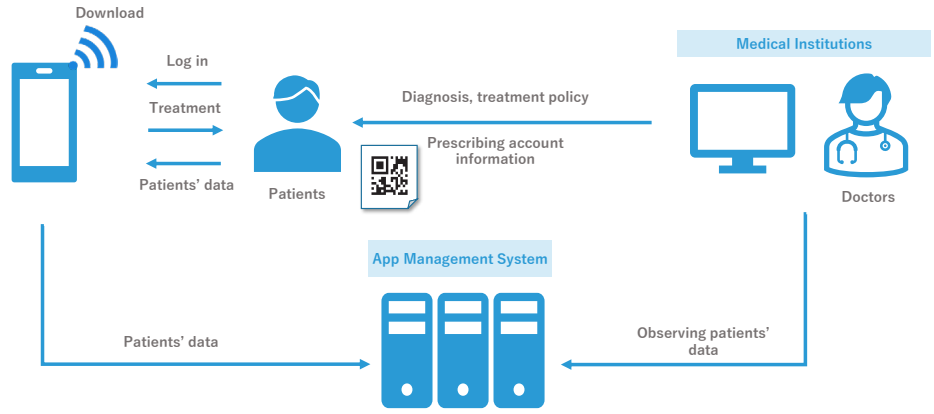
In the DTx Product segment, the Company develops DTx apps and clinical trial apps. DTx apps are a new digital treatment option other than pharmaceutical or medical device-based therapies (drug therapy, chemical therapy, surgery, etc.), which provides treatment via apps downloaded by patients onto their 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.) In the Company's case, it has basically adopted the strategy of entering into an agreement with pharmaceutical/ medical device companies for joint development and post-launch marketing, so the partner in the contract conducts sales and marketing to medical institutions, collects medical fees based on the number of prescriptions. Based on the contract, the Company shall receive an upfront contractual payment, milestone income according to the stage of development, and royalty income depending on post-launch sales amounts.

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. Furthermore, research teams from the University of Tokyo and other institutions have announced that cognitive behavioral therapy is the most effective approach in early stage treatment of 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.

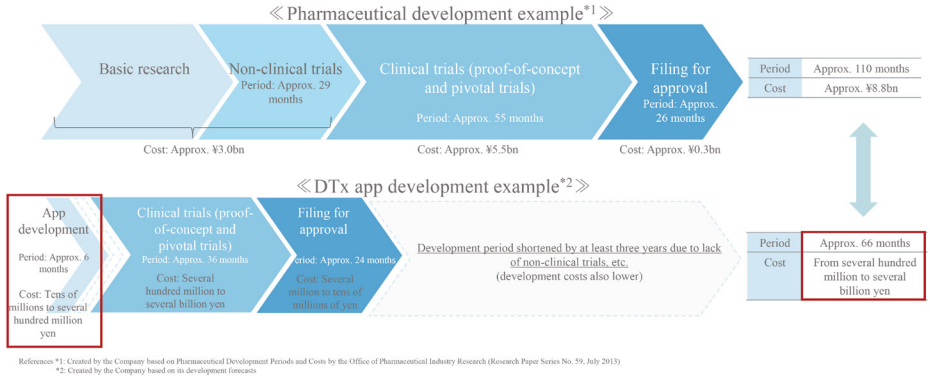
For doctors, the use of DTx apps eliminates the need for their direct involvement. This has benefits such as significantly increasing the number of patients a doctor can treat and enabling a doctor to present proper treatment to patients based on accumulated real-world data. Patients will be able to 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, Inc.'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, in the field of insomnia, where the Company is developing the DTx app, the U.K.'s National Institute for Health and Care Excellence (NICE) recommends treating insomnia with DTx apps rather than sleeping medications, and the European treatment guidelines have also been revised to include cognitive behavioral therapy using digital technology as a first choice alongside face-to-face interventions.

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 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: Reprinted from Material for Business Plan and Growth Potential

Filed an application for partial changes of the DTx app for insomnia

3. Regarding the DTx app for insomnia, filed an application for partial changes in August 2024

For SUSMED Med CBT-i®, the DTx app for insomnia, the Company entered into a commercialization agreement with Shionogi & Co., Ltd in December 2021. The agreement grants exclusive sales rights in Japan to Shionogi & Co. in exchange for up to ¥4,700mn in total as an upfront contractual payment and milestone income. On February 15, 2023, medical device manufacturing and marketing approval was obtained from MHLW. Since then, the Company had submitted a request for insurance coverage to MHLW and had been making preparations for launch on the market. However, on January 29, 2024, the Company temporarily withdrew the request. This was due to the decision made during discussions of the fiscal 2024 medical fee revisions to postpone insurance coverage of SUSMED Med CBT-i® in connection with the delay in approving insurance coverage for its additional indication — face-to-face cognitive behavioral therapy for insomnia provided by physicians—which had also been proposed for insurance coverage.

Thereafter, on August 30, 2024, the Company filed an application for partial changes (an application to change a portion of items related to already approved pharmaceuticals and medical devices, etc.). This filing was made after multiple discussions with the regulatory authorities based on the new insurance system, revised in the fiscal 2024 medical fee revisions, which says that the overall therapeutic programs such as the apps developed by the Company are to be evaluated as special treatment materials. As for the future outlook, if the application for partial changes is approved, generally, there are deliberations by a specialized organization for insured medical materials, etc. and following approval by the Central Social Insurance Medical Council, insurance coverage is obtained. The Company has not yet announced any specific timeline.

Additionally, 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 in February 2023, too. With a view to approval of partial changes and obtaining insurance coverage, the Company is continuing preparations with Shionogi to start marketing the product.

12 items in the pipeline as of August 2024

4. Pipelines for DTx apps

The Company's development pipelines for therapeutic and diagnostic apps consist of 12 items (including the insomnia DTx app SUSMED Med CBT-i®) as of August 9, 2024.

Development Pipeline

	Target condition	Research/ App development	Proof-of-concept trial	Pivotal trial	Current status
Treatment	SUSMED Med CBT-i® app for insomnia				Filed an application for partial changes
	SMD401 (breast cancer exercise therapy)				Preparing for the next trial
	SMD402 (ACP* *: Advance Care Planning)				Preparing for the next trial Announced at ASCO*
	SMD201 (chronic kidney disease)				Preparing for the next trial
	SMD102 (prolonged grief disorder)				App in development Announced research paper
	SMD202 (opioid-induced constipation)				App in development toward launch of proof-of-concept trial
	SMD403 (tinnitus)				Clinical research underway

	Target condition	Research/ App development	Proof-of-concept trial	Pivotal trial	Current status
Treatment	SMD105 (post-mastectomy pain syndrome)				Completed clinical research Preparing for proof-of-concept trial
	SMD106 (obstetrics and gynecology)				App in development toward launch of proof-of-concept trial
	SMD107 (persistent postural-perceptual dizziness)				Clinical research underway
Diagnosis	SMD103 (prenatal depression)				App currently in development Research paper announced
	SMD104 (ADHD: eye tracking)				App currently in development Selected for AMED project

Source: Reprinted from Material for Business Plan and Growth Potential

Regarding SMD401 (development partner: National Cancer Center Japan), a breast cancer patient exercise therapy app, and SMD402 (development partner: Jikei University School of Medicine), a DTx app for ACP that provides decision-making support for progressive cancer patients, proof-of-concept trials are completed and preparations for the next trials are underway. It is expected that SMD402 would provide clinical effects to subjects such as easing of psychological distress and improvements in anxiety and depression, and it would bring the cessation of unsuitable treatments. In June 2024, the results of the proof-of-concept trial were presented in an oral session at the annual meeting of the American Society of Clinical Oncology (ASCO).

SMD201, a rehabilitation app for chronic kidney disease (development partners: Tohoku University, The Japanese Society of Renal Rehabilitation), also completed a proof-of-concept trial and is preparing for the next trial. The expected benefits are improving or suppressing the deterioration of kidney function, and preventing shifts to dialysis treatment. Face-to-face renal rehabilitation, including exercise therapy, has already been recommended for patients with advanced chronic kidney diseases due to the effectiveness for improving or slowing down the deterioration of kidney function. The Company believes that this DTx meets medical needs in terms of improvement of both medical quality and efficiency. For SMD102, which targets prolonged grief disorder (development partner: University of Zurich), and for SMD202, which targets opioid-induced constipation, apps are being developed toward the launch of proof-of-concept trials.

Regarding SMD403 for patients with tinnitus (development partner: KYORIN Pharmaceutical), specified clinical research is now ongoing. SMD105, an acceptance and commitment therapy (ACT) app for patients with post-mastectomy pain syndrome (PMPS) (development partner: Nagoya City University), has completed clinical research and is preparing for a proof-of-concept trial. For SMD106, which is for obstetrics and gynecology disease areas (development partner: ASKA Pharmaceutical), an app is currently being developed for the start of a proof-of-concept trial. For SMD107 for patients with persistent postural perceptual dizziness (PPPD) (development partner: Niigata University), the joint development with the university was presented at the 125th Annual Meeting of the Japanese Society of Otorhinolaryngology Head and Neck Surgery in May 2024 and a clinical trial has started in August.

In the area of diagnostics, particularly SMD103 for the disease area of prenatal depression (development partner; Nagoya University), patents have already been acquired for the algorithm and device and a joint research paper was published in April 2024. The app is currently being developed, aiming to start a proof-of-concept trial. In addition, for SMD104, which carries out eye tracking analysis related to ADHD, the app is in development toward the launch of a proof-of-concept trial.

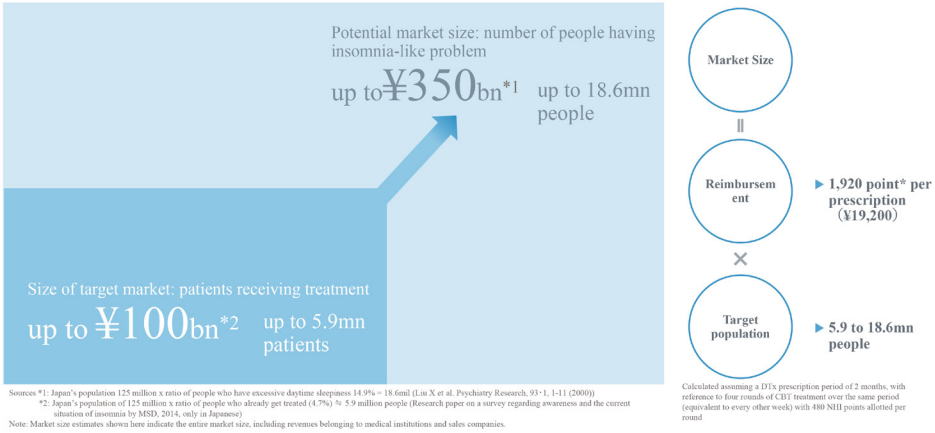
Based on a contract entered into with KYORIN Pharmaceutical in November 2022 related to the joint research and development and post-launch marketing of SMD403, an upfront payment of ¥100mn and milestone income of ¥100mn related to the start of a clinical trial of SMD403 were received, and this ¥200mn in total was recognized as revenue for FY6/24. Furthermore, in September 2023, the Company entered into an agreement with ASKA Pharmaceutical, a specialty pharma in obstetrics and gynecology, related to joint research and development and post-launch marketing for SMD106, a DTx app in the area of obstetrics and gynecology, and an upfront contractual payment of ¥200mn has been received (not yet recognized as revenue.). In addition to this amount, the Company is to receive milestone income of ¥2,500mn in total according to development stages, and royalties based on post-launch sales amounts.

Domestic market size for DTx apps for insomnia estimated at ¥350.0bn

5. Domestic market size

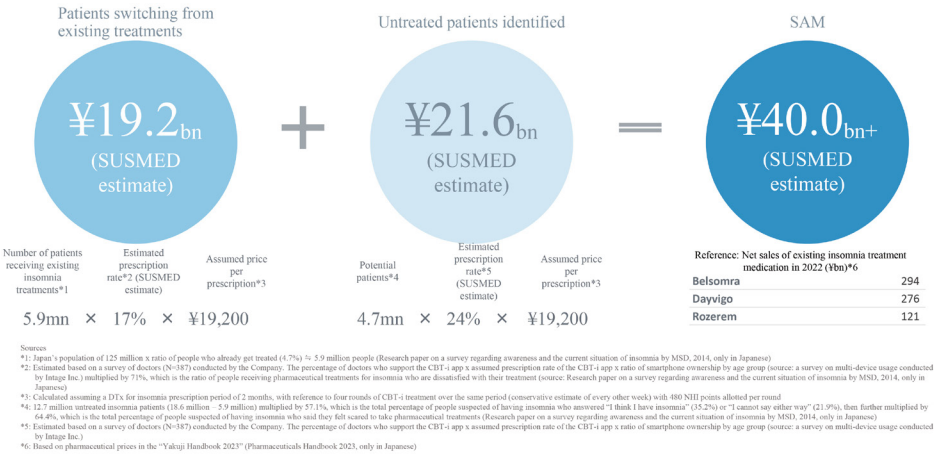
According to the Company's disclosure materials, the market size of SUSMED Med CBT-i® in Japan (insurance reimbursement amounts × number of target patients) is estimated at ¥100.0bn, and expandable to ¥350.0bn if potential patients are included. Furthermore, the Serviceable Available Market (SAM), which 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 main pipelines are ¥7.2bn for SMD401, a breast cancer patient exercise therapy app, ¥30.9bn for SMD402, a DTx app for ACP, and ¥66.0bn for SMD201, a rehabilitation app for chronic kidney disease.

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

6. 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) SUSMED SourceDataSync, which is a general-purpose clinical trial system that supports streamlining clinical trials for pharmaceutical/medical device companies.

In particular, 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 "SUSMED SourceDataSync." As a result, the Company has acquired numerous patents. In December 2020 MHLW 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.

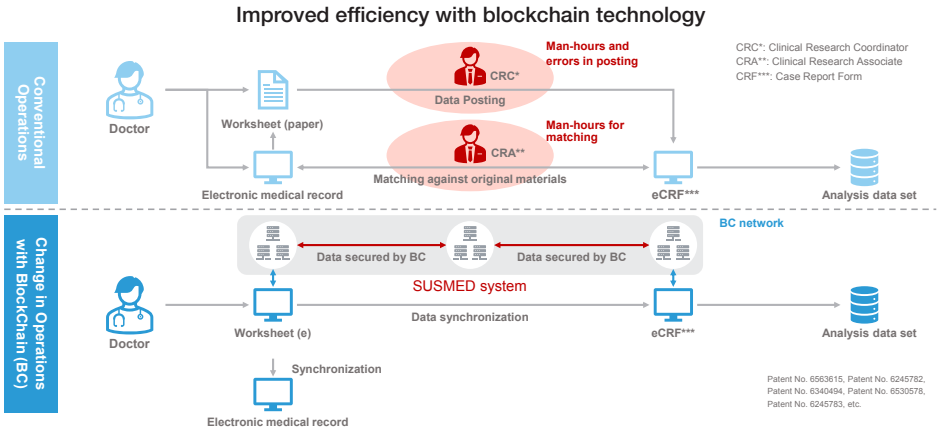
*1 Good Clinical Practice (GCP): Ministerial ordinance for implementing clinical trials of pharmaceuticals.
*2 A system in which verification approved by regulatory authorities is carried out and the results are used to revise regulations, in order to implement new technologies and business models in 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, the Company began joint research with NCNP on improving the reliability of registry data using blockchain technology. In June 2022, it entered into a service 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. 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.

In January 2023, SUSMED SourceDataSync began operating in its second corporate 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, the Company entered into a business alliance with Linical Co., Ltd. <2183> and ClinChoice K.K. to build a full support service for efficient and effective clinical trials using SUSMED SourceDataSync. In September 2023, a memorandum of understanding was signed with Tohoku University for building a venous disease registry, administered by the Japanese Association of Cardiovascular Intervention and Therapeutics and related academic societies, using SUSMED SourceDataSync. This project is expected to promote real world data utilization from medical devices by leveraging the features of blockchain technology. In addition, SUSMED SourceDataSync started working in specified clinical research for SMD403, an app for tinnitus. In October 2023, the results of joint research with Tokyo Medical and Dental University, adopted as AMED's R&D promotion network project in 2021, were published and showed that utilizing blockchain technology makes monitoring tasks required in clinical trials more efficient.

Business overview



Source: Reprinted from Material for Business Plan and Growth Potential

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

7. 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, the progress of the application for partial changes of SUSMED Med CBT-i®, and its subsequent spread in the market 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 secure a stable source of revenue.

Results trends

In FY6/24 loss expanded due to a decrease in revenue

1. Overview of FY6/24 non-consolidated results

In the Company's FY6/24 results (non-consolidated), operating revenue decreased by 35.4% YoY to ¥342mn, operating loss was ¥364mn (compared to a loss of ¥48mn in FY6/23), ordinary loss was ¥357mn (compared to a loss of ¥44mn in FY6/23) and net loss was ¥357mn (compared to a loss of ¥50mn in FY6/23). The DTx Platform segment recorded steady revenue, but the DTx Product segment saw a decrease in upfront contractual payments and milestone income. These factors led to a decline in Company-wide revenue. R&D expenses also rose (by 38.0% YoY to ¥243mn), and resulted in the loss increase. The operating loss increased from the previous fiscal year, but was smaller than the latest forecast (¥459mn) on February 14, 2024.

Summary of FY6/24 results (non-consolidated)

(¥mn)

	FY6/23 Results	FY6/24 Results	YoY	
			Difference	YoY change
Operating revenue	530	342	-188	-35.4%
Business expenses	578	707	128	22.2%
(Business costs)	7	11	3	46.8%
(R&D expenses)	176	243	67	38.0%
(Selling, general and administrative expenses)	394	452	57	14.6%
Operating profit	-48	-364	-316	-
Ordinary profit	-44	-357	-312	-
Net profit	-50	-357	-306	-
Segment operating revenue				
DTx Product	400	200	-200	-
DTx Platform	130	142	11	9.1%
Segment profit				
DTx Product	256	55	-201	-
DTx Platform	66	-11	-77	-
Corporate expenses	-371	-409	-37	-

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

2. Trends by business segment

In the DTx Product segment, operating revenue was ¥200mn (¥400mn for the previous fiscal year), while segment profit (operating profit before adjustments for corporate expenses, etc.) was ¥55mn (compared to ¥256mn in FY6/23). In the previous fiscal year, ¥400mn of milestone income related to SUSMED Med CBT-i®, received from Shionogi for obtaining manufacturing and marketing approval as a medical device, was recognized, but in FY6/24, an upfront contractual payment of ¥100mn and milestone income of ¥100mn related to SMD403 for tinnitus, received from KYORIN Pharmaceutical, was recognized. In the DTx Platform segment, operating revenue increased by 9.1% YoY to ¥142mn, but segment profit was a loss of ¥11mn (compared to profit of ¥66mn in the previous fiscal year). The number of contracts as of the end of FY6/24 increased by 1 YoY to 13, lifting revenue, but in terms of profits, R&D expenses for additional development on SUSMED SourceDataSync increased and led to the loss.

Securing R&D funds through fund procurement at listing

3. Financial position

In terms of financial position, total assets as of the end of FY6/24 were down ¥169mn from the end of the previous fiscal year to ¥4,932mn. This was mainly because cash and deposits decreased by ¥201mn. Total liabilities increased ¥97mn to ¥327mn, mainly because contract liabilities increased by ¥111mn. Total net assets decreased by ¥266mn to ¥4,604mn. By recording a net loss, retained earnings decreased by ¥357mn. There are no particularly significant changes in line items, but the equity ratio dropped 2.4pp to 92.9%.

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)

	FY6/21	FY6/22	FY6/23	FY6/24	Change
Total assets	1,674	4,943	5,101	4,932	-169
Current assets	1,674	4,935	5,085	4,898	-187
Non-current assets	0	8	15	33	18
Total liabilities	97	93	230	327	97
Current liabilities	96	87	224	321	96
Non-current liabilities	0	5	5	6	0
Total net assets	1,577	4,850	4,870	4,604	-266
Shareholders' equity	1,577	4,850	4,861	4,584	-277
Equity ratio	94.2%	98.1%	95.3%	92.9%	-2.4pt

	FY6/21	FY6/22	FY6/23	FY6/24
Cash flow from operating activities	-235	-165	100	-230
Cash flow from investing activities	-4	-20	-18	-8
Cash flow from financing activities	1,500	3,463	62	37
Cash and cash equivalent at end of year	1,626	4,904	5,048	4,846

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

Business outlook

Expecting expanded loss due to increased R&D expense but much higher revenue in FY6/25

● Overview of FY6/25 non-consolidated results outlook

For its FY6/25 results (non-consolidated), the Company is forecasting operating revenue to increase by 39.9% to ¥479mn, operating loss of ¥583mn (compared to a loss of ¥364mn in FY6/24), ordinary loss of ¥583mn (compared to a loss of ¥357mn in FY6/24) and net loss of ¥589mn (compared to a loss of ¥357mn in FY6/24). An increase in R&D expenses related to pipeline development progress (projected increase of 68.3% YoY to ¥409mn) and an increase in personnel expenses associated with increased hiring for business expansion are expected to increase the operating loss. However, on the sales side, the DTx Product segment's upfront contractual payments (¥200mn already received from ASKA Pharmaceutical) and some milestone income, and steady sales expansion in the DTx Platform segment (planning to increase contracts by 2 to 15) are expected to lead to a significant increase in revenue.

Key measures in the DTx Product segment are acquiring insurance coverage for SUSMED Med CBT-i®, a DTx app for insomnia, and promoting progress in pipeline developments (the starting of a confirmatory trial for SMD402, beginning preparations for a proof-of-concept trial for SMD403, the starting of a proof-of-concept trial for SMD105, start of specified clinical research for SMD106, and the start of clinical research for SMD107). In the DTx Platform segment, the Company's key measures are to promote SUSMED SourceDataSync to be used in multiple trials and to start operation of a registry system for venous disease.

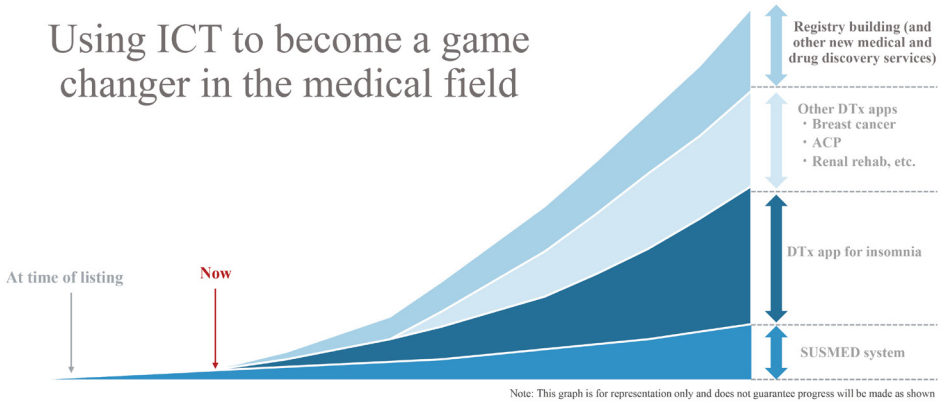
Growth strategy

Expand development pipeline, promote increase in contracts in DTx Platform segment

1. Growth strategy

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, 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: Reprinted from Material for Business Plan and Growth Potential

Growth strategy

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	Nox Health	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	Bighealth	Under consideration
	Thailand	Regulated	Mainly national insurance: DTx not eligible	No regulatory laws in Malaysia		Extremely small		

Source: Reprinted from Material for Business Plan and Growth Potential

As one of the examples of joint research initiatives, the Company started joint research and development with NCNP in May 2022. This project was regarding development of a personal information anonymization method and establishment of data processing technology for accumulating and utilizing data collected from diverse sources while ensuring its quality. It was selected 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, with Shiga University, the Company signed a joint research agreement related to 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 JST as an FY 2022 strategic and creative research promotion project (CREST). In October 2022, the Company commenced an initiative with NCNP for 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).

In addition, in April 2024, the Company started an initiative with Nagoya University related to utilization of model systems based on risk variants for mental disorders and development of drug discovery seeds and stratified biomarkers through multi-modality industry-academia collaboration. This initiative was selected as a Joint Industry-Academia-Government Mission-Oriented-type Drug Discovery Technology Research Project (GAPFREE6).

Contributing to solutions for social issues through business

2. Sustainability management

The Company has not disclosed its materiality issues in relation to its initiatives to address sustainability 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 established a Governance Committee in May 2023, as an advisory body for matters related to the nomination and remuneration of directors, to enhance corporate governance. In February 2024, the Company's Clinical Development Department was designated by the Ministry of Education, Culture, Sports, Science and Technology as a research institution stipulated under the Regulations for Handling Grants-in-Aid for Scientific Research. Effectively utilizing this public research aid, the Company is going to strengthen R&D activities, such as providing new treatment methods, increasing the efficiency of clinical settings, and appropriately allocating medical resources, in order to contribute to SUStainable MEDicine. Subject to an approval at the 9th General Meeting of Shareholders held on September 27, 2024, the Company will change from a company with a board of corporate auditors to a company with an audit and supervisory committee.

Positive evaluation of medium- to long-term growth potential

3. Analyst viewpoint

The Company is a startup in the R&D stage, and as it incurs upfront R&D expenses, it is expected to face a continuation of periodic operating loss for the foreseeable future. However, regarding SUSMED Med CBT-i®, the DTx app for insomnia, the Company filed an application for partial changes, taking a big step forward toward insurance coverage after the withdrawal of the request in January 2024. In terms of government policy, MHLW is paving the way for the approval environment of SaMD so that SaMD products can spread widely in the market. This situation is a tailwind for the Company and pipeline developments are expected to gain momentum in the near future. Together with expansion of the DTx platform segment driven by the application of blockchain technology, FISCO believes the Company's medium- to long-term growth potential is worthy of a positive evaluation.

FISCO

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