COMPANY RESEARCH AND ANALYSIS REPORT

SUSMED, Inc.

4263

Tokyo Stock Exchange Growth Market

6-Nov.-2025

FISCO Ltd. Analyst
Masanobu Mizuta

FISCO Ltd.
https://www.fisco.co.jp

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Contents

Summary

Obtained approval for partial changes of manufacturing and marketing of the DTx app for insomnia and submitted a request for insurance coverage

SUSMED, Inc. <4263> (hereafter, also "the Company") is a research and development (R&D)-stage startup conducting business with a focus on the development of digital therapeutics (hereafter, also "DTx"), which is attracting interest as a third treatment option other than pharmaceuticals and medical devices.

1. Pipeline developments are on track; the DTx Platform business is now fully operational

The Company does business in two segments: 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/medical device companies conduct clinical trials more efficiently with its proprietary platform on which a general-purpose clinical trial management system and machine learning automated analytics system are implemented. 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. The Company obtained approval for partial changes of manufacturing and marketing of the DTx app "SUSMED DTx for insomnia Medcle" on September 2, 2025, and submitted a request for insurance coverage to the Ministry of Health, Labour and Welfare (WHLW) on September 4 of the same year. The other projects in the development pipeline are also progressing well, including achieving milestones in February 2025 under the agreement with ASKA Pharmaceutical Co., Ltd.. In the DTx Platform, 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) A clinical trial system "SUSMED SourceDataSync®" (hereafter, "SUSMED SDS"), which leverages blockchain technology to support pharmaceutical/medical device companies in streamlining clinical trials.

2. Loss reduction in FY6/25 due to increased revenue

In the Company's results (non-consolidated) for FY6/25, operating revenue increased by 35.1% year on year (YoY) to ¥462mn, operating loss was ¥299mn (compared to a loss of ¥364mn in the previous fiscal year), ordinary loss was ¥294mn (compared to a loss of ¥357mn in the previous fiscal year), and net loss was ¥298mn (compared to a loss of ¥357mn in the previous fiscal year), with increased revenue contributing to loss reduction. R&D expenses were ¥273mn, a ¥30mn increase from the previous fiscal year due to progress in pipeline developments, but ¥28mn lower than the initial plan due to efficiency efforts. In the DTx Product segment, operating revenue increased by 50.0% to ¥300mn, and segment profit (operating profit before adjustments for corporate expenses, etc.) increased by 112.3% to ¥118mn. Upfront contractual payments of ¥200mn and milestone income of ¥100mn received from ASKA Pharmaceutical were recognized. In the DTx Platform segment, operating revenue increased by 14.3% to ¥162mn, and segment profit was ¥33mn (compared to a loss of ¥11mn in the previous fiscal year). SUSMED SDS, for which additional functions had been developed, began generating revenue and the business returned to profitability.

3. Disclosure of FY6/26 earnings forecast is undecided

The disclosure of performance forecasts (non-consolidated) for FY6/26 remains undecided. Regarding the DTx app “SUSMED DTx for insomnia Medcle,” approval for partial changes was obtained on September 2, 2025, and a request for insurance coverage was submitted to the MHLW on September 4 of the same year. However, the insurance reimbursement amount and the timing of insurance coverage have not yet been determined at this time, making it difficult to reasonably estimate its revenue. The forecasts will be disclosed promptly once the reimbursement amount is fixed and earnings can be estimated. For the DTx Platform segment, revenue contribution is expected from expansion of adoption of SUSMED SDS. Key initiatives include the launch of “SUSMED DTx for insomnia Medcle,” progress in pipeline developments for the DTx Product segment, and the accumulation of track records of clinical trial system in the DTx Platform segment.

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

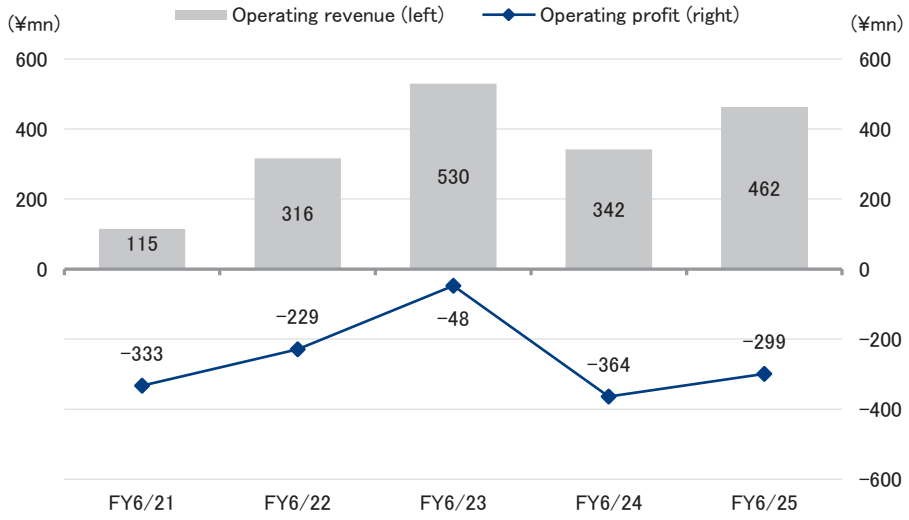
As part of its growth strategy, the Company has identified the increase in the number of development pipelines and the progress of clinical trials as key management indicators in the DTx Product segment for maximizing revenue from a long-term perspective. In the DTx Platform segment, it has identified items such as expansions to the number of contracts and enhancements of new services as key management indicators in order to achieve continuous and accumulative revenue growth. 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/medical device companies. Furthermore, it plans to develop its DTx Product business overseas, and to select target countries to entry based on a mix of factors, including the presence of regulatory laws, insurance reimbursement frameworks, market size, and competition.

Key Points

- Pipeline development is on track; the DTx Platform business is now fully operational
- FY6/25 loss reduction due to increased revenue
- Obtained approval for partial changes of the DTx app for insomnia and submitted a request for insurance coverage
- Disclosure of FY6/26 earnings forecast is undecided
- Expanding development pipelines in the DTx Product segment and increasing business contracts in the DTx Platform segment

Summary

Results trends



Note: Disclosure of FY6/26 earnings forecast is undecided
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 3-chome, Nihonbashi Honcho, Chuo-ku, Tokyo. As of the end of FY6/25, the Company had total assets of ¥4,502mn, net assets of ¥4,370mn, share capital of ¥4,322mn, and an equity ratio of 96.0%. The number of shares issued by the Company was 16,822,700 (including 6,148 treasury shares) as of the same date. As of the end of August 2025, it has 41 employees. The Company is scheduled to relocate its headquarters to 1-chome, Nihonbashi Honcho, Chuo-ku, Tokyo in September 2026 (planned).

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 (hereafter, also "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. In September 2025, it obtained approval for partial changes of it, and submitted a request for insurance coverage.

Other than the insomnia DTx app, in November 2022 the Company entered into a joint R&D and marketing agreement with KYORIN Pharmaceutical Co., Ltd. <4569> for a DTx app in the ENT field, and in September 2023 entered into a joint R&D and post-launch marketing agreement with ASKA Pharmaceutical for a DTx app in the field of obstetrics and gynecology. In December 2024, the construction of the integrated venous disease registry system developed with Tohoku University was completed and made available to medical device companies; in the same month, the clinical trial system SUSMED SDS started operations in an investigator-initiated clinical trial conducted by the National Center of Neurology and Psychiatry (NCNP); and in February 2025, the Company achieved a milestone under the joint R&D and sales agreement with ASKA Pharmaceutical.

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

Company profile

Date	Description
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 (hereafter, “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 specialized 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 (hereafter, “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 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
December 2024	Completed the construction of the integrated venous disease registry developed with Tohoku University and made available to medical device companies Started the operation of the clinical trial system SUSMED SDS in investigator-initiated clinical trials conducted by the NCNP
February 2025	Achieved a milestone under the joint R&D and sales agreement with Aska Pharmaceutical Co., Ltd.
April 2025	Started clinical trials for SMD402, a DTx app for patients with depression and advanced or recurrent cancer
July 2025	Obtained acknowledgment for partial changes of manufacturing and marketing of “SUSMED DTx for insomnia Medcle”
September 2025	Obtained approval for partial changes of “SUSMED DTx for insomnia Medcle” and submitted a request for insurance coverage

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

Business overview

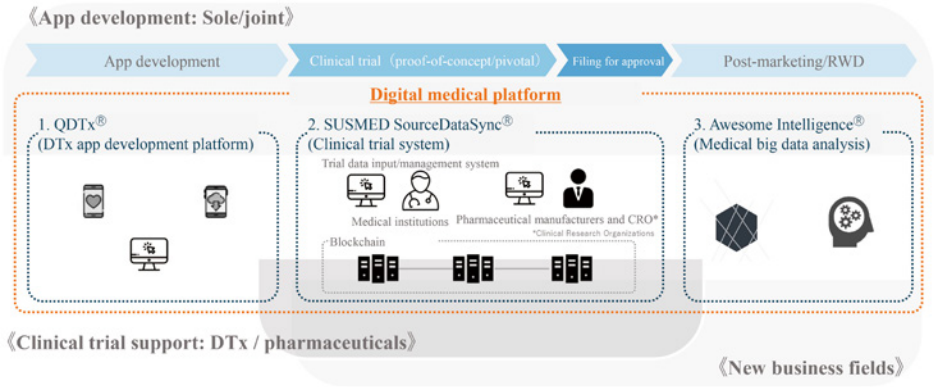
Operating in DTx Product segment and DTx Platform segment

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/medical device companies conduct clinical trials 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 FY6/25, 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 the end of FY6/25, it has a total of 21 projects adopted by governmental agencies such as the Japan Agency for Medical Research and Development (hereafter, also "AMED") and the New Energy and Industrial Technology Development Organization (hereafter, also "NEDO"), it is conducting 23 joint research projects, it holds 30 patents (including overseas patents and joint filings), and has 12 pipelines of DTx apps.

Overview of business fields



Source: The Company's results briefing materials

Developing DTx apps as a third treatment option

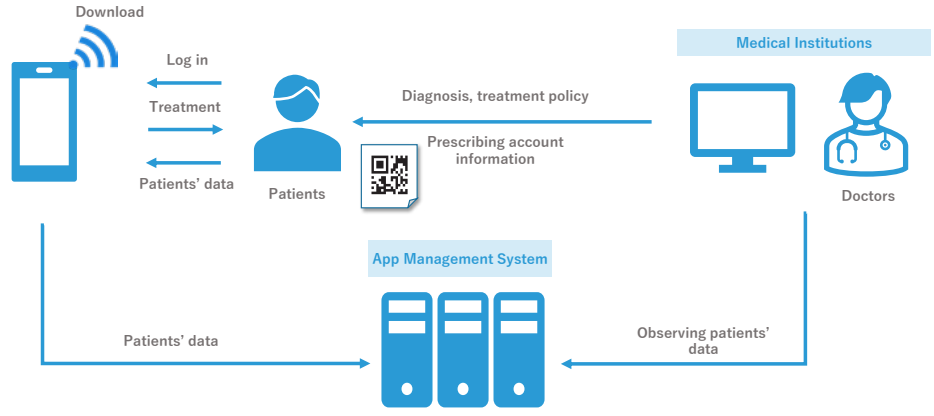
2. DTx Product segment

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. Another distinction between DTx apps and healthcare 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 adopted a basic 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 and collects medical fees based on the number of prescriptions. Based on the contract, the Company receives 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: 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. 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 an 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 overseas. In 2010, US-based Welldoc, Inc.'s DTx app for diabetes became the first such app to be approved by the US Food & Drug Administration (FDA). More recent approvals include OVIVA UK LIMITED's DTx app for type II diabetes in the UK 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 US 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 UK'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'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. In September 2022, CureApp's hypertension treatment support app was added to the insurance coverage; in February 2025, Shionogi's pediatric attention deficit hyperactivity disorder (ADHD) treatment support app obtained manufacturing and marketing approval, and in September 2025, CureApp, Inc.'s app for reducing alcohol consumption was added to the insurance coverage.

The development process of DTx, research and development of the DTx app → proof-of-concept trial → pivotal trial → filing for approval → 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 → 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.

Obtained approval for partial changes of the DTx app for insomnia

3. DTx app for insomnia

For SUSMED Med CBT-i®, the Company's first DTx app obtaining manufacturing and marketing approval, a sales partnership agreement* was concluded with Shionogi in December 2021, and manufacturing and marketing approval for medical devices was obtained from the MHLW on February 15, 2023. Subsequently, on August 30, 2024, the Company applied for partial changes to the approved items of "SUSMED DTx for insomnia Medcle" (an application to make partial changes to the items already approved for drugs, medical devices, etc.), and at the SaMD Research Committee of the Pharmaceutical Affairs Council of the MHLW held on July 28, 2025, acknowledgement for the partial changes was granted. Official approval for this application was obtained from the MHLW on September 2, 2025. Accordingly, the Company submitted a request for insurance coverage to the Ministry of Health, Labour and Welfare on September 4 of the same year. As for the future outlook, generally, there are deliberations by a specialized organization for insuring medical materials, etc., followed by approval from the Central Social Insurance Medical Council before insurance coverage is obtained. The Company has not yet announced any specific timeline.

> * The agreement grants exclusive sales rights in Japan to Shionogi in exchange for up to ¥4,700mn in total as an upfront contractual payment and milestone income.

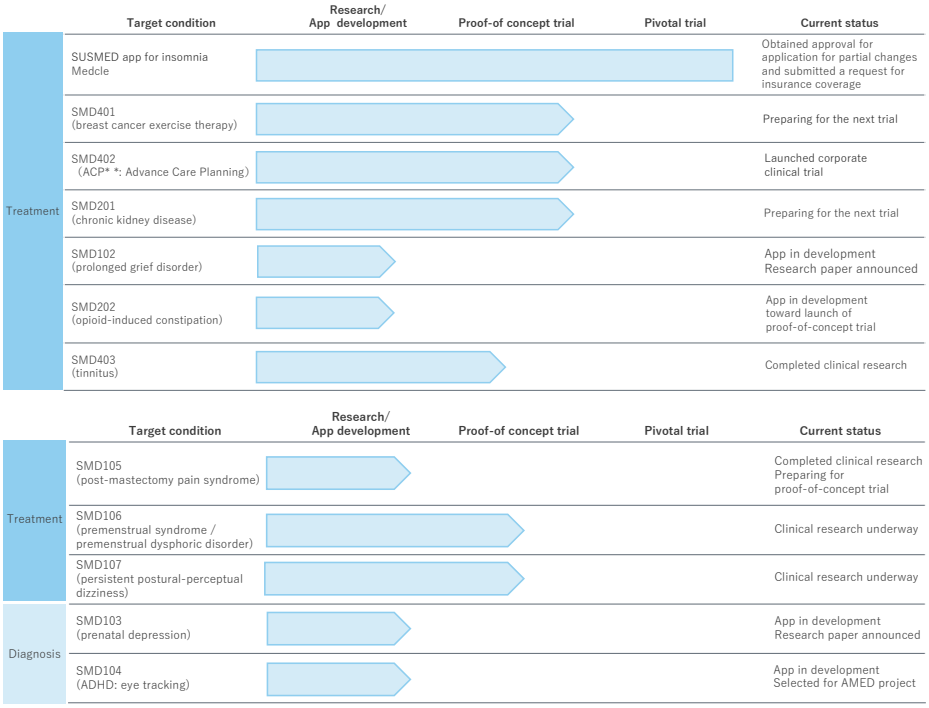
Additionally, the patents for the app's technologies which the Company has already acquired in Japan, the USA, South Korea, and Indonesia received a patent evaluation from the European Patent Office in February 2023, too. With a view to obtaining insurance coverage, the Company is continuing preparations with Shionogi for the commercialization of the product.

12 items in the pipeline as of August 2025

4. Pipelines for DTx apps

The Company's development pipelines for therapeutic and diagnostic apps consist of 12 items (including "SUSMED DTx for insomnia Medcle") as of August 8, 2025.

Development Pipeline



Source: The Company's material on Business Plan and Growth Potential

Regarding SMD401 (development partner: National Cancer Center Japan), a breast cancer patient exercise therapy app, proof-of-concept trials are completed and preparations for the next trials are underway.

For SMD402, an advance care planning (ACP) app for patients with depression and advanced or recurrent cancer (development partner: The Jikei University School of Medicine), company-sponsored clinical trials were initiated in April 2025. 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), 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. The next trial is targeted to begin within FY6/26.

For SMD102, which targets prolonged grief disorder (development partner: University of Zurich), an app is being developed toward the launch of proof-of-concept trials, and a research paper was published. For SMD202, which targets opioid-induced constipation, an app is being developed toward the launch of proof-of-concept trials.

SMD403 for patients with tinnitus (development partner: KYORIN Pharmaceutical) has completed specified clinical research. Results are promising for future development, and they are scheduled to be presented by the principal investigator at the Annual Meeting of the Japan Audiological Society in October 2025. Preparations for the next trial have also begun.

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. The next trial is targeted to begin within FY6/26.

Regarding SMD106 (development partner: ASKA Pharmaceutical), in January 2025, a specified clinical trial targeting patients with premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD) was initiated in collaboration with Mariko Ogawa, specially appointed professor at the Fukushima Medical Center for Children and Women of Fukushima Medical University, with the first subject enrolled and app usage started on February 12, 2025. In relation to the joint development and post-launch marketing agreement* for SMD106 entered into with ASKA Pharmaceutical in September 2023, ¥100mn was received upon achievement of the milestone (start of use of the exploratory clinical trial app) in February 2025, and together with the already received ¥200mn upfront contractual payment, was recognized as operating revenue for FY6/25.

* In addition to an upfront contractual payment of ¥200mn, the Company is to receive milestone income of ¥2,500mn in total according to development stages, and royalties based on post-launch sales amounts.

For SMD107, an app for patients with persistent postural-perceptual dizziness (PPPD) (development partner: Niigata University), it 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.

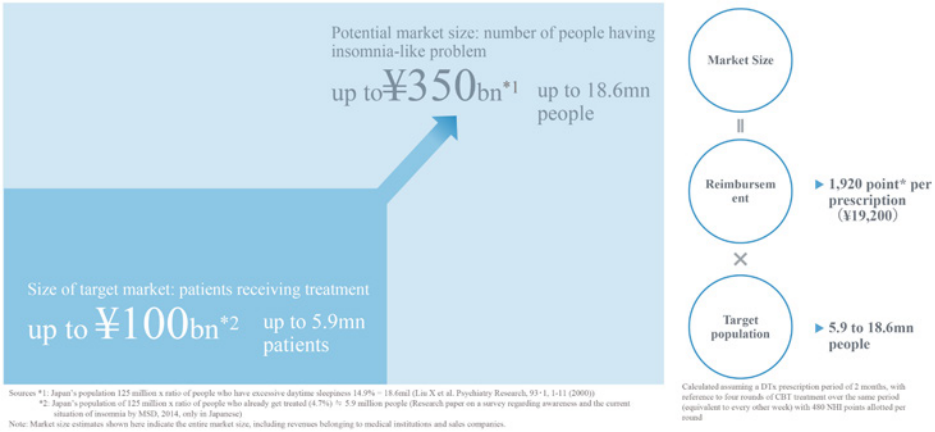
For SMD103 for patients with prenatal depression (development partner; Nagoya University), patents have already been acquired for the algorithm and device, and a joint research paper was published in April 2024. For SMD104, which diagnoses ADHD by eye-tracking analysis, it is under development for an exploratory clinical trial and has been adopted for the AMED project.

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

5. Domestic market size

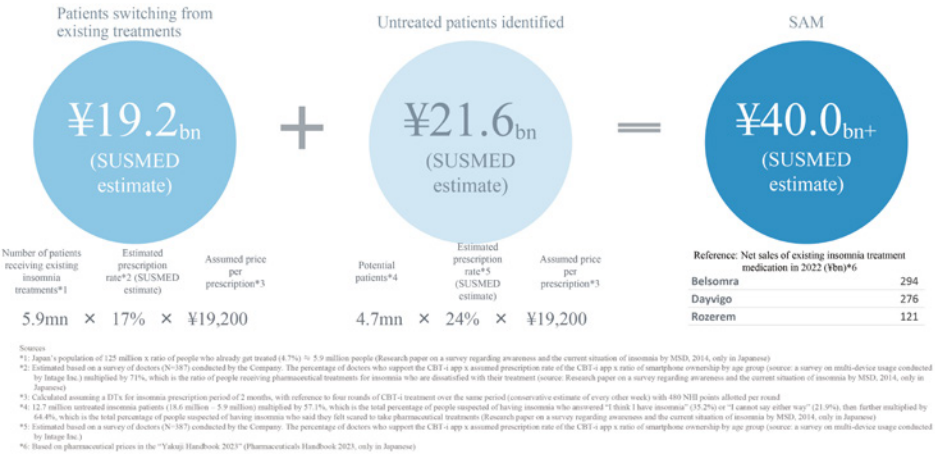
The Company estimates that the market size (insurance reimbursement amounts × number of target patients) of “SUSMED DTx for insomnia Medcle” in Japan is at ¥100.0bn, and ¥350.0bn if potential patients are included. Furthermore, the Serviceable Available Market (SAM), which represents targeted demand, 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: The Company's results briefing materials

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



Source: 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 SDS, which is a clinical trial system that supports streamlining clinical trials for pharmaceutical/ medical device companies.

In particular, SUSMED SDS, with a monitoring system leveraged by blockchain technology, realizes a high level of security and data tampering resistance required in clinical trials, while drastically reducing the man-hours and costs related to monitoring. 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. As a result, the Company has acquired numerous patents. In December 2020, MHLW officially approved SUSMED SDS as the system fulfilling the monitoring requirements in 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, and 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 is promoting 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 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-sponsored clinical trial utilizing blockchain technology. Aculys Pharma conducted two domestic Phase 3 clinical trials using SUSMED SDS: one for Pitolisant (a histamine H3 receptor antagonist/inverse agonist) targeting narcolepsy patients, and the other for also Pitolisant targeting daytime excessive sleepiness associated with obstructive sleep apnea syndrome. Both trials showed favorable analysis results, and it has been announced that application for manufacturing and marketing approval is planned in the future.

In September 2023, a memorandum of understanding was signed with Tohoku University to build a venous disease registry administered by the Japanese Association of Cardiovascular Intervention and Therapeutics and related academic societies using SUSMED SDS, and its construction was completed in December 2024, commencing provision to medical device companies.

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. In December 2024, SUSMED SDS began operations for an investigator-initiated trial conducted by NCNP (exploring the efficacy and safety of rituximab for myalgic encephalomyelitis/chronic fatigue syndrome). In addition, SUSMED SDS has been adopted in specified clinical trials for the DTx app for tinnitus SMD403, and for SMD106 for PMS/PMDD, also in a company-sponsored trial for the ACP app SMD402.

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. Regarding "SUSMED DTx for insomnia Medcle," approval was obtained for partial changes of manufacturing and marketing on September 2, 2025, and a request for insurance coverage was submitted to the MHLW on September 4 of the same year. However, as market penetration remains a risk, it is possible that operating loss will continue for the time being due to substantial R&D expenses. 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

Loss narrowed due to increased revenue effect in FY6/25

1. Overview of FY6/25 results

In the Company's results (non-consolidated) for FY6/25, operating revenue increased by 35.1% YoY to ¥462mn, operating loss was ¥299mn (compared to a loss of ¥364mn in the previous fiscal year), ordinary loss was ¥294mn (compared to a loss of ¥357mn in the previous fiscal year), and net loss was ¥298mn (compared to a loss of ¥357mn in the previous fiscal year), with increased revenue contributing to loss reduction. R&D expenses were ¥273mn, up ¥30mn from the previous fiscal year due to progress in pipeline developments, but they were ¥28mn below the initial plan (¥302mn) due to improved efficiency.

By segment, operating revenue increased by 50.0% YoY to ¥300mn, and segment profit (operating profit before adjustments for corporate expenses, etc.) increased by 112.3% to ¥118mn in the DTx Product segment. Upfront contractual payments of ¥200mn and milestone income of ¥100mn received from ASKA Pharmaceutical were recognized. In the DTx Platform segment, operating revenue increased by 14.3% to ¥162mn, and segment profit was ¥33mn (compared to a loss of ¥11mn in the previous fiscal year). SUSMED SDS, for which additional functions had been developed, began generating revenue and the business returned to profitability. The number of development pipeline projects in the DTx Product segment remained at 12 as of the end of the previous fiscal year, and the total number of contractual projects in the overall business increased by 3, reaching 16.

Summary of FY6/25 results (non-consolidated)

(¥mn)

	FY6/24 Results	FY6/25 Results	YoY	
			Difference	YoY change
Operating revenue	342	462	120	35.1%
Business expenses	707	762	54	7.8%
Business costs	11	12	0	4.6%
R&D expenses	243	273	30	12.4%
Selling, general and administrative expenses	452	476	24	5.3%
Operating profit	-364	-299	65	-
Ordinary profit	-357	-294	62	-
Net profit	-357	-298	59	-
Segment operating revenue				
DTx Product	200	300	100	50.0%
DTx Platform	142	162	20	14.3%
Segment profit				
DTx Product	55	118	62	112.3%
DTx Platform	-11	33	44	-
Corporate expenses	-409	-450	-	-

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

Securing R&D funds through fund procurement at new listing

2. Financial position

In terms of financial position, total assets as of the end of FY6/25 were down ¥429mn from the end of the previous fiscal year to ¥4,502mn. This was mainly because cash and deposits decreased by ¥448mn. Total liabilities decreased ¥195mn to ¥132mn, mainly because contract liabilities decreased by ¥196mn. Total net assets decreased by ¥233mn to ¥4,370mn. Due to recognizing a net loss, retained earnings decreased by ¥298mn. There are no particularly significant changes in line items, but the equity ratio dropped 3.1pp to 96.0%.

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-FY6/22	End-FY6/23	End-FY6/24	End-FY6/25	Change
Total assets	4,943	5,101	4,932	4,502	-429
Current assets	4,935	5,085	4,898	4,462	-435
Non-current assets	8	15	33	40	6
Total liabilities	93	230	327	132	-195
Current liabilities	87	224	321	125	-195
Non-current liabilities	5	5	6	6	0
Total net assets	4,850	4,870	4,604	4,370	-233
Shareholders' equity	4,850	4,861	4,584	4,322	-261
Equity ratio	98.1%	95.3%	92.9%	96.0%	3.1pp

	FY6/22	FY6/23	FY6/24	FY6/25
Cash flow from operating activities	-165	100	-230	-432
Cash flow from investing activities	-20	-18	-8	-19
Cash flow from financing activities	3,463	62	37	3
Cash and cash equivalent at end of year	4,904	5,048	4,846	4,398

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

Outlook

Outlook disclosure for FY6/26 is undecided

● FY6/26 forecasts

The disclosure of performance forecasts (non-consolidated) for FY6/26 remains undecided. Regarding the DTx app "SUSMED DTx for insomnia Medcle," approval was obtained for partial changes to manufacturing and marketing on September 2, 2025, and a request for insurance coverage was submitted to the Ministry of Health, Labour and Welfare on September 4 of the same year. However, as of now, insurance reimbursement amount and the timing of insurance coverage remain undetermined, so it is difficult to reasonably estimate its revenue. As soon as reimbursement amount is finalized and a performance forecast becomes possible, it will be promptly disclosed. For the DTx Platform segment, revenue contribution is expected from expansion of adoption of SUSMED SDS.

Key measures include the launch of "SUSMED DTx for insomnia Medcle," development progress in several pipelines (start of the next trial for SMD201 and SMD105, publication of specific clinical research results for SMD403, and completion of specific clinical research for SMD106), and increasing the track records of clinical trial system in the DTx Platform segment.

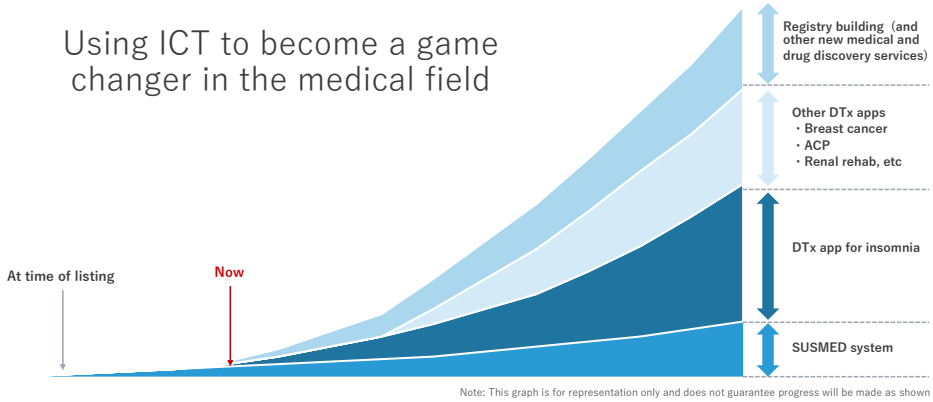
Growth strategy

Expansion of development pipeline, promotion of 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 as key management indicators in order to achieve continuous and accumulative revenue growth. 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/medical device companies. Furthermore, it plans to develop its DTx Product business overseas and it is currently selecting countries to entry 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: The Company's material on 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: The Company's material on 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 government, academia and private partnership mission-oriented drug discovery technology research project (GAPFREE6).

Contributing to solutions for social issues through business

2. Sustainability management

For sustainability management, the mission of the Company states "To continuously provide society with sustainable medicine services by leveraging ICT." Its fundamental policy is to strive to achieve both enhancement of social sustainability and improvement of corporate value through its business activities. The Company identifies key issues related to sustainability, formulates corresponding strategies, and is engaging in various sustainability initiatives.

The identified materiality include: contributing to the environment; providing products and services to address medical challenges; developing human resource and improving the internal work environment; and strengthening

corporate governance. In terms of environmental contribution, DTx apps inherently avoid environmental impacts (such as greenhouse gas emissions from factory operations, use/pollution of water resources, and generation of industrial waste) that typically occur in the manufacturing of pharmaceuticals or medical devices, thus contributing to reducing society's overall environmental burden. For the provision of products and services to address medical challenges, the development of DTx apps not only enables shorter development times and lower development costs compared to general pharmaceuticals and medical devices, but also, as software products, does not require manufacturing facilities after regulatory approval. This reduces various risks throughout the development and manufacturing processes and helps to optimize and control medical expenses. The clinical trial system SUSMED SDS also contributes to reduce development costs and medical expenses by cutting man-hours and labor costs associated with monitoring work.

For human resource development and internal work environment improvement, five action guidelines have been established—"Always consider social significance," "Focus on essential outcomes," "Respect each other as professionals," "Enjoy growth," and "Think objectively and act proactively." These serve as one of hiring criteria, and the Company is working to build an environment and systems based on these values. As an example of achievements from these efforts, the annual paid leave utilization rate for all employees improved from 67.3% in FY6/23 to 81.8% in FY6/24. In addition, the retention rate (target: around 80%) improved from 79.2% to 83.3%. For strengthening corporate governance, the Company focuses on four major areas: corporate governance, compliance (business ethics and anti-corruption), risk management (business continuity planning and information security), and enhancement of environments for the utilization and generation of intellectual property. These status are measured and evaluated with multiple quantitative and qualitative indicators.

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. Through effectively utilizing this public research aid, the Company is going to strengthening R&D activities, such as providing new treatment methods, addressing unmet medical needs to increase the efficiency of clinical settings, and appropriately allocating medical resources, in order to contribute to the SUStainabile MEDicine. It established a Governance Committee in July 2023, as an advisory body for matters related to the nomination and remuneration of directors, to enhance corporate governance. In addition, in September 2024, the Company changed 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. FISCO's view

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, in the DTx Product segment, the launch of "SUSMED DTx for insomnia Medcle" is approaching, and other development pipeline projects, such as SMD106—which is making steady progress by achieving a milestone in February 2025 under a joint research, development, and post-launch marketing agreement with Aska Pharmaceutical—are also on track. The Ministry of Health, Labour and Welfare's efforts to develop an approval environment for SaMD as part of national policy are acting as a tailwind, and are expected to give momentum to future progress in the development pipeline of DTx product businesses. Furthermore, in the DTx Platform segment, there is a full-scale rollout of business centered on SUSMED SDS, which utilizes blockchain technology. Given these circumstances, FISCO is positively evaluating the Company's medium- to long-term growth potential and will closely monitor future developments.

FISCO

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■ For inquiries, please contact: ■
FISCO Ltd.
5-13-3 Minami Aoyama, Minato-ku, Tokyo, Japan 107-0062
Phone: 03-5774-2443 (IR Consulting Business Division)
Email: support@fisco.co.jp