COMPANY RESEARCH AND ANALYSIS REPORT

SUSMED, Inc.

4263

Tokyo Stock Exchange Growth Market

25-Nov.-2026

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Summary

Significant revenue growth expected in FY6/27 on the launch of "SUSMED DTx for insomnia Medcle"

SUSMED, Inc. <4263> (hereafter, also "the Company") is an R&D-oriented 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. Operating in DTx Product segment and DTx Platform segment

The Company's business segments are the DTx Product segment and the DTx Platform segment. In the DTx Product segment, it develops DTx apps used by patients and medical professionals. DTx apps are a new digital treatment option other than pharmaceutical or medical device-based therapies, which provide treatment via apps downloaded by patients onto their smartphones. In the DTx Platform segment, the Company mainly helps pharmaceutical/medical device companies conduct clinical trials more efficiently with its clinical trial system. The Company provides the clinical trial system "SUSMED SourceDataSync®" (hereafter, "SUSMED SDS"), which leverages blockchain technology to support pharmaceutical/medical device companies in streamlining clinical trials, and the business is now in full-scale operation.

2. Launched "SUSMED DTx for insomnia Medcle"; termination of the exclusive sales agreement has little impact

"SUSMED DTx for insomnia Medcle" became eligible for insurance coverage on June 1, 2026, and the Company launched the app. The app provides treatment content based on cognitive behavioral therapy for insomnia as SaMD (Software as a Medical Device). It is the first Class II medical device covered by public health insurance as a treatment for insomnia in Japan. Through nine weeks of treatment per prescription, it is expected to deliver insomnia treatment close to face-to-face cognitive behavioral therapy. The Company has terminated its exclusive sales agreement with Shionogi & Co., Ltd. Going forward, the Company will conduct sales activities on its own, and instead of royalty income, it will recognize the full amount of revenue earned as its own product sales. The Company considers the impact of terminating the agreement as minimal. This is because the Company has already established a system to handle the entire supply chain on its own, has been conducting sales activities under that system since becoming eligible for insurance coverage, and has set the business target figures based on this situation. We at FISCO believe that, for the Company's results, the benefit of recognizing the full amount of revenue earned as its own sales could in fact outweigh disadvantages such as higher sales costs resulting from the termination of the agreement.

3. Revenue increased in FY6/26 due to recognition of milestone income

In the Company's results (non-consolidated) for FY6/26, operating revenue increased by 7.4% year on year (YoY) to ¥497mn, operating loss was ¥330mn (compared to a loss of ¥299mn in the previous fiscal year), ordinary loss was ¥325mn (compared to a loss of ¥294mn), and net loss was ¥382mn (compared to a loss of ¥298mn). Revenue increased due to firm performance in the DTx Platform segment, as well as the contribution of milestone income in the DTx Product segment. On the profit side, operating loss widened, because selling, general and administrative (SG&A) expenses increased due to higher personnel and promotion expenses incurred with the launch of "SUSMED DTx for insomnia Medcle."

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4. Significant revenue growth expected in FY6/27

For FY6/27, the Company forecasts (non-consolidated) a significant increase in revenue, with operating revenue up 68.7% YoY to ¥838mn, operating loss of ¥461mn (compared to a loss of ¥330mn in the previous fiscal year), ordinary loss of ¥474mn (compared to a loss of ¥325mn), and net loss of ¥541mn (compared to a loss of ¥382mn). In the DTx Product segment, the Company has launched "SUSMED DTx for insomnia Medcle," targeting 1,000 medical institutions adopting the app and 2,000 monthly prescriptions as of June 2027. Additionally, milestone income associated with pipeline development will also contribute. In the DTx Platform segment, operations of SUSMED SDS and other services are expected to remain firm. On the profit side, operating loss is expected to widen. Costs will increase due to higher R&D expenses as development pipelines progress, promotion expenses for "SUSMED DTx for insomnia Medcle," personnel expenses from active hiring, and expenses related to the head office relocation.

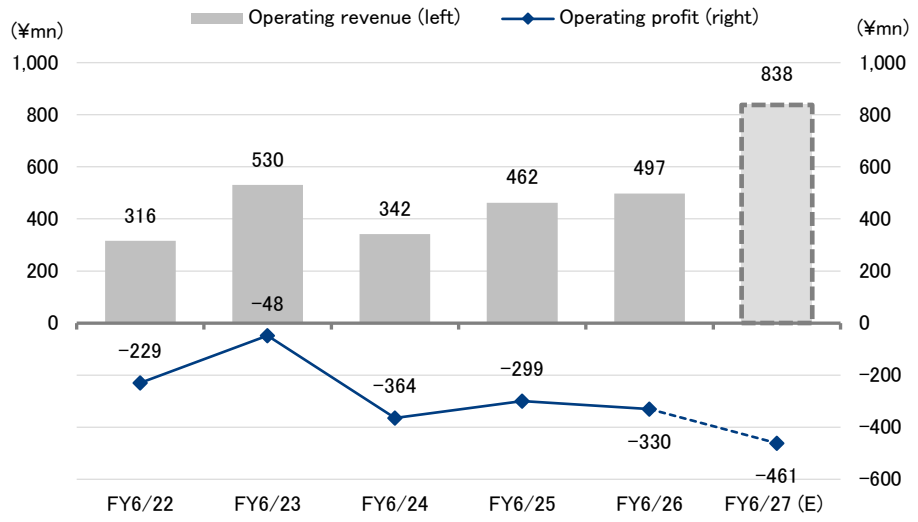
5. Promoting development pipeline expansion in the DTx Product segment and contracts increase in the DTx Platform segment

As part of its growth strategy, the Company is promoting the expansion of development pipelines and the progress of clinical trials in the DTx Product segment for maximizing revenue from a long-term perspective, and increase in the number of contracts and enhancements of new services in the DTx Platform segment in order to achieve continuous and cumulative revenue growth. To enhance these growth strategies, 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 segment overseas and it is currently selecting countries to enter based on a mix of factors, including the presence of regulatory laws, insurance reimbursement frameworks, market size, and competitive situation.

Key Points

- Operating in DTx Product segment and DTx Platform segment
- Launched "SUSMED DTx for insomnia Medcle"
- Revenue increased in FY6/26 due to recognition of milestone income
- Significant revenue growth expected in FY6/27
- Promoting development pipeline expansion and contracts increase in the DTx Platform segment

Results trends



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

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Company profile

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

1. Company profile

The Company is an R&D-oriented startup that is developing DTx apps, which are 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 to "Continuously provide society with sustainable medicine services by leveraging ICT." Its name is derived from the phrase "SUStainable MEDicine." The Company is headquartered in 1-chome, Nihonbashi Honcho, Chuo-ku, Tokyo (relocated on September 14, 2026). As of the end of FY6/26, the Company had total assets of ¥4,218mn, net assets of ¥4,070mn, and an equity ratio of 94.2%. The number of shares issued by the Company was 16,868,100 (including 6,244 treasury shares) as of the same date. As of August 2026, it had 51 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 (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, initiated a verification test of its clinical development support system using blockchain technology in June 2018, began providing DTx development support services in February 2019, and began providing a machine learning automated analytics system in May 2019. Then, in June 2026, it launched "SUSMED DTx for insomnia Medcle."

History

Date	Item
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 Labour Sciences Research Grants (comprehensive research project to fight cancer)

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Company profile

Date	Item
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
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 (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
October 2025	Signed a memorandum of understanding with KYORIN Pharmaceutical to add the Company's roles regarding the DTx app for tinnitus Started providing SUSMED SDS, a clinical trial system utilizing blockchain technology, for a company-sponsored clinical trial conducted by Heartseed
February 2026	Achieved a milestone under the joint R&D and marketing agreement with ASKA Pharmaceutical for the DTx app in the field of obstetrics and gynecology (efficacy confirmed in the proof-of-concept trial)
May 2026	Started a pivotal trial of KRP-DT123, a DTx app for tinnitus Obtained acknowledgement for insurance coverage of "SUSMED DTx for insomnia Medcle"
June 2026	Launched "SUSMED DTx for insomnia Medcle" Achieved a milestone under the joint R&D and marketing agreement with KYORIN Pharmaceutical for the DTx app in the ENT field (start of DTx app use in the pivotal trial)

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

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Business overview

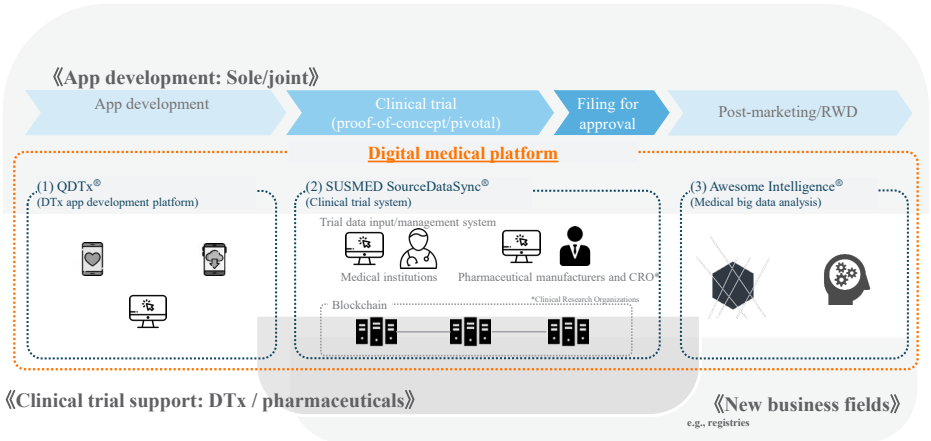
Operating in DTx Product segment and DTx Platform segment

1. Business overview

The Company's business segments are the DTx Product segment and the DTx Platform segment. In the DTx Product segment, it develops DTx apps used by patients and medical professionals. In June 2026, it launched "SUSMED DTx for insomnia Medcle," an app intended to support the treatment of insomnia, as its first product to be brought to market. In the DTx Platform segment, it mainly helps pharmaceutical/medical device companies conduct clinical trials more efficiently with its clinical trial system utilizing blockchain technology and recognizes service usage fees from business customers as revenue. The Company also aims to expand into new fields such as medical big data analytics.

Additionally, the Company has a strong track record 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 expanding its development pipelines. As of the end of FY6/26, it has a total of 21 projects adopted by government 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"), and also has a total of 24 joint research projects. The Company holds 32 patents (including overseas patents and joint filings) and has 11 development pipelines of DTx apps.

Overview of business fields



Source: The Company's results briefing materials

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Developing DTx apps, which are attracting attention as a third treatment option

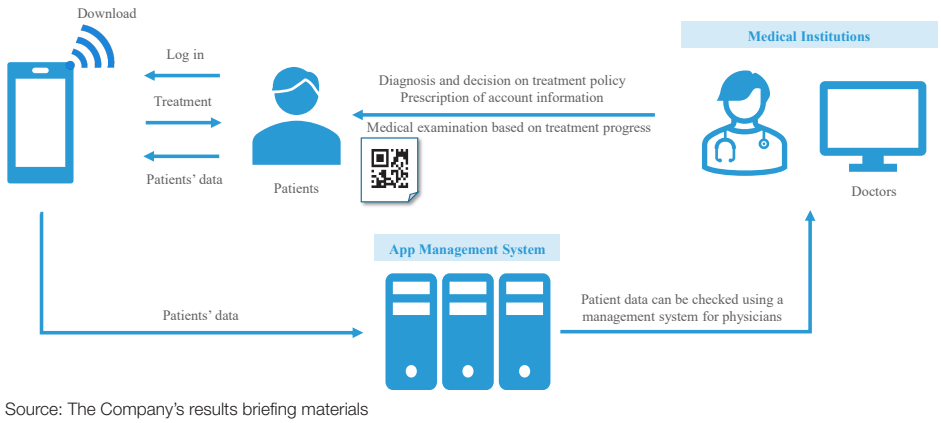
2. DTx Product segment

In the DTx Product segment, the Company develops DTx apps (including diagnostic apps). DTx apps are a new digital treatment option other than pharmaceutical or medical device-based therapies (drug therapy, chemical therapy, surgery, etc.), which provide 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 conducting 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 provides 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 is targeted at doctors and medical institutions, rather than general consumers.

Revenue is earned based on the number of prescriptions written by medical institutions that have received medical fees (for DTx apps covered by insurance, 70% of the medical fee is covered by National Health Insurance and 30% by the patient.) In the Company's case, in addition to developing and marketing products on its own, it also has the option of entering into agreements with pharmaceutical/medical device companies for joint development and post-launch marketing; in the latter case, the partner in the contract conducts sales and marketing to medical institutions and collects medical fees based on the number of prescriptions. The Company receives from the partner 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

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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 also announced that cognitive behavioral therapy is the most effective approach in early stage treatment of insomnia. Furthermore, face-to-face cognitive behavioral therapy became eligible for insurance coverage from June 2026. In Japan, however, a lack of medical resources to provide cognitive behavioral therapy is still an issue, and 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 sufficient therapy intervention.

Overseas, DTx app approvals are making progress. 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 in 2014. More recently, CureApp's therapeutic app for nicotine addiction with CO checker, which was Japan's first DTx app 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's app for reducing alcohol consumption was added to the insurance coverage. The treatment support app for pediatric ADHD also became eligible for insurance coverage in June 2026.

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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 → insurance coverage). However, the general development lead time for a DTx app is around 5 or 6 years (approximately 6 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 its development costs are low, resulting in a relatively low level of risk compared to pharmaceutical development.

Launched "SUSMED DTx for insomnia Medcle" in June 2026

3. "SUSMED DTx for insomnia Medcle"

For the DTx app for insomnia, the Company entered into an exclusive sales partnership agreement with Shionogi & Co., Ltd. <4507> in December 2021 and obtained manufacturing and marketing approval for medical devices from the MHLW on February 15, 2023. Subsequently, on August 30, 2024, the Company applied for partial changes to the approved items (an application to make partial changes to the items already approved for drugs, medical devices, etc.), and on September 2, 2025, it obtained approval for this application from the MHLW under the name "SUSMED DTx for insomnia Medcle." Then, at the general assembly of the Central Social Insurance Medical Council, an advisory body to the Minister of Health, Labour and Welfare, held on May 13, 2026, it obtained acknowledgement for insurance coverage. It became eligible for insurance coverage on June 1, 2026, and the Company launched the app. The insurance reimbursement amount is set at ¥24,100 per prescription (with technical fees also calculated separately), approximately 20% higher than the ¥19,200 per prescription the Company initially expected.

"SUSMED DTx for insomnia Medcle" provides treatment content based on cognitive behavioral therapy for insomnia as SaMD. It is the first Class II medical device covered by public health insurance as a treatment for insomnia in Japan. It adopts an intervention by chat-based program, and through nine weeks of treatment per prescription (one week of sleep hygiene education and sleep diary entries, followed by eight weeks of treatment with content based on cognitive behavioral therapy principles), it is expected to deliver insomnia treatment close to face-to-face cognitive behavioral therapy. The Company's technologies for the DTx app for insomnia have been patented in Japan, the US, South Korea, and Indonesia, and received a decision to grant a patent from the European Patent Office in February 2023. The Company has also opened two websites on its corporate homepage: one is for healthcare professionals, and the other is for consumers as disease awareness website, "Nemuri no Michishirube" (Guide to Sleep).

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As “SUSMED DTx for insomnia Medcle” became eligible for insurance coverage at or above the reimbursement amount set under the agreement with Shionogi, the milestone payment to be received from Shionogi was fixed at ¥200mn. It will be recognized as operating revenue in Q1 FY6/27. In addition, following discussions with Shionogi, the Company concluded to terminate the agreement. Going forward, the Company will conduct sales activities on its own, and instead of royalty income, it will recognize the full amount of revenue earned as its own product sales. For sales activities, rather than substantially increasing its sales staff, the Company will curb increases in sales costs by securing contracts through exhibitions at academic conferences, its own webinars, and other initiatives. It will also consider collaboration with new partners. As a roadmap for increasing the number of medical institutions adopting the app and the number of prescriptions, the Company envisions continuing efficient promotion activities, and, for example, sharing the prescription experience of medical institutions that adopted the app early. The Company considers the impact of terminating the agreement with Shionogi as minimal. This is because the Company has already established a system to handle the entire supply chain on its own, has been conducting sales activities under that system since becoming eligible for insurance coverage, and has set the business target figures based on this situation. We at FISCO believe that, for the Company’s results, the benefit of recognizing the full amount of revenue earned as its own sales could in fact outweigh disadvantages such as higher sales costs resulting from the termination of the agreement.

11 items in the development pipeline as of August 2026

4. Pipelines for DTx apps

The Company has 11 pipelines (excluding “SUSMED DTx for insomnia Medcle”) for therapeutic and diagnostic apps as of August 7, 2026.

Development Pipeline

	Target condition	Research/ App development	Proof-of-concept trial	Pivotal trial	Current status
Treatment	SMD401 (breast cancer exercise therapy)				Preparing for the next trial
	SMD402 (ACP* *: Advance Care Planning)				Company-sponsored clinical trial in progress
	SMD201 (chronic kidney disease)				Preparing for the next trial
	SMD102 (prolonged grief disorder)				App in development Research paper announced
	SMD202 (opioid-induced constipation)				App in development toward launch of proof-of-concept trial
	SMD403 (tinnitus)				Pivotal trial started

	Target condition	Research/ App development	Proof-of-concept trial	Pivotal trial	Current status
Treatment	SMD105 (post-mastectomy pain syndrome)				Proof-of-concept trial in progress
	SMD106 (premenstrual syndrome / premenstrual dysphoric disorder)				Preparing for the next trial
	SMD107 (persistent postural-perceptual dizziness)				Completed clinical research Research results presented at academic conference
Diagnosis	SMD103 (prenatal depression)				App in development Research paper announced
	SMD104 (ADHD: eye tracking)				App in development Selected for AMED project

Source: The Company’s results briefing materials

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Regarding SMD401, a breast cancer patient exercise therapy app (development partner: National Cancer Center Japan), 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), the company-sponsored clinical trial initiated in April 2025 is in progress. 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 lead to 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.

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. In addition, for SMD202, which targets opioid-induced constipation, an app is being developed toward the launch of proof-of-concept trials.

For KRP-DT123/SMD403, a DTx app for tinnitus (development partner: KYORIN Pharmaceutical <4569>*), an investigator-initiated specified clinical research study (Tokai University Hospital) produced promising results for future development, which were reported by the principal investigator, Professor Koichiro Wasano (Department of Otorhinolaryngology, Head and Neck Surgery, Tokai University School of Medicine), at the 70th Annual Meeting of the Japan Audiological Society in October 2025. SUSMED and KYORIN Pharmaceutical then started a pivotal trial in May 2026. This is a multicenter, randomized, double-blind, controlled trial evaluating the efficacy and safety of 16 weeks of use of the app in patients with distressing chronic tinnitus, and after completion of the trial, KYORIN Pharmaceutical plans to file for approval in Japan.

> * In November 2022, the Company entered into a joint R&D and marketing agreement with KYORIN Pharmaceutical for a DTx app in the ENT field. The Company receives an upfront contractual payment (¥100mn), milestone income according to development progress (¥600mn as known at the time of the agreement), and royalty income depending on post-launch sales. In addition, as the specified clinical research was completed and significant improvement was confirmed, in October 2025 the Company signed a memorandum of understanding to add its roles in the R&D and post-launch marketing of the app (a favorable revision increasing milestone income and royalty income). Then, in June 2026, the Company received ¥240mn as a development milestone upon the start of use of the DTx app in the pivotal trial and recognized it as operating revenue in Q4 FY6/26.

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 conducting a proof-of-concept trial.

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Regarding SMD106 (development partner: ASKA Pharmaceutical*), in January 2025, a specified clinical research study 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. As efficacy was confirmed in the above specified clinical research in February 2026, the Company is now preparing for the next trial.

> * In September 2023, the Company entered into an agreement with ASKA Pharmaceutical for the joint development and post-launch marketing of SMD106 (under which, 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). Then, in February 2025, ¥100mn was received upon achievement of the milestone (start of use of the proof-of-concept trial app), and together with the already received ¥200mn upfront contractual payment, was recognized as operating revenue for FY6/25. Furthermore, as efficacy was confirmed in the proof-of-concept trial in February 2026, ¥100mn was received as a milestone and recognized as operating revenue for FY6/26.

For SMD107, which targets persistent postural-perceptual dizziness (PPPD) (development partner: Niigata University), the clinical trial started at Niigata University in August 2024 has been completed, and its results were reported at the 127th Annual Meeting of the Japanese Society of Otorhinolaryngology-Head and Neck Surgery in May 2026 by Dr. Takashi Kimura, a member of the research group of Professor Arata Horii (Department of Otolaryngology-Head and Neck Surgery, Niigata University School of Medicine), showing that the therapeutic effect was maintained at week 10, after the end of the 8-week treatment period.

For SMD103 for patients with perinatal depression (development partner: Nagoya University), patents have been acquired for the algorithm and device, and the app is being developed toward the launch of a proof-of-concept trial, with a joint research paper published in April 2024. In addition, for SMD104, which diagnoses ADHD by eye-tracking analysis, an app is under development for a proof-of-concept trial and has been adopted for the AMED project.

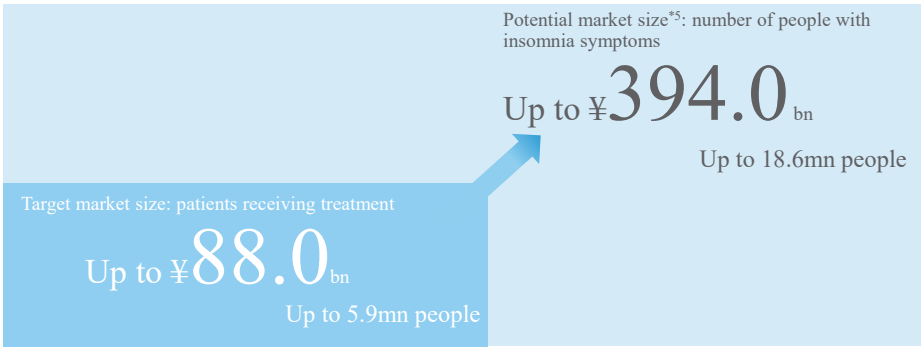
Domestic market size for DTx apps for insomnia estimated at ¥394.0bn

5. Domestic market size

The Company estimates that the market size (insurance reimbursement amount × number of patients × monotherapy rate × ratio of mild to moderate patients) of “SUSMED DTx for insomnia Medcle” in Japan is ¥88.0bn, and ¥394.0bn if potential patients are included. Of this, the Serviceable Available Market (SAM), which represents targeted demand, is estimated at more than ¥42.0bn in total (¥15.0bn by switching from existing sleep medication therapy + ¥27.0bn 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 the main pipelines under development 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.

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

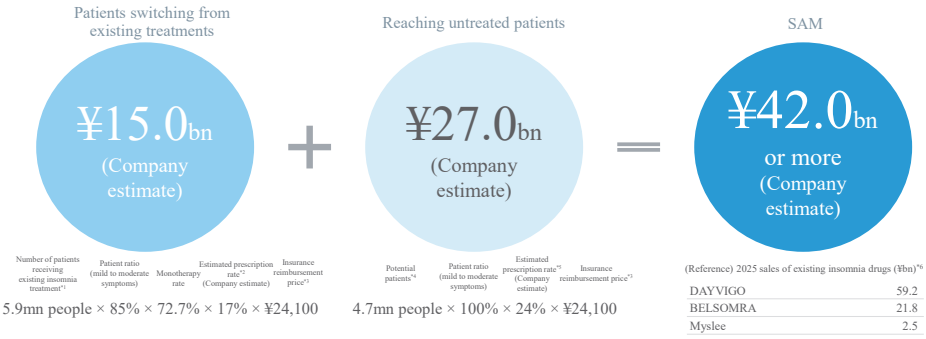


	Number of patients*1, *2	× Insurance reimbursement price	× Monotherapy rate*3	× Ratio of patients with mild to moderate symptoms*4
Potential market	18.6mn people	¥24,100	-	100%
Target market	5.9mn people		72.7%	85%

*1: Japan's population of approx. 125mn × 14.9% share of people suffering from excessive daytime sleepiness = 18.6mn people (Liu X et al. Psychiatry Research, 93·1, 1-11 (2000))
*2: Japan's population of approx. 125mn × 4.7% share of people receiving treatment ≈ 5.9mn people ("Survey on Awareness and Actual Conditions of Insomnia," MSD, 2014)
*3: Share of people prescribed a single sleeping medication among those in the general population aged 20–74 who were prescribed psychotropic drugs over a three-month period (Source: MHLW, "Report on the Actual Conditions of Prescriptions of Anxiolytics and Hypnotics")
*4: Share of people with possible mild or moderate insomnia (40.9%) among those with possible insomnia (48.1%), based on a 2025 survey using the Athens Insomnia Scale questions (N=10,000) (Source: NISHIKAWA Co., Ltd., "Nishikawa White Paper on Sleep 2025"). For untreated patients (12.7mn people), the patient ratio (mild to moderate symptoms) is set at 100%, assuming that patients with severe symptoms are already receiving treatment
*5: Calculated by multiplying the number of untreated people with insomnia, 12.7mn (18.6mn − 5.9mn), by the insurance reimbursement price and adding the target market size (12.7mn people × ¥24,100 + ¥88.0bn ≈ ¥394.0bn)
Note: The market size (estimate) represents the size of the entire market targeted by the Company's app and includes revenue attributable to medical institutions and sales partners.

Source: The Company's results briefing materials

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



Number of patients receiving existing insomnia treatment*1 | Patient ratio (mild to moderate symptoms) | Monotherapy rate | Estimated prescription rate*2 (Company estimate) | Insurance reimbursement price*3

5.9mn people × 85% × 72.7% × 17% × ¥24,100

Potential patients*4 | Patient ratio (mild to moderate symptoms) | Estimated prescription rate*5 (Company estimate) | Insurance reimbursement price*3

4.7mn people × 100% × 24% × ¥24,100

(Reference) 2025 sales of existing insomnia drugs (¥bn)*6

DAYVIGO	59.2
BELSOMRA	21.8
Myslee	2.5

*1: Japan's population of approx. 125mn × 4.7% share of people receiving treatment = 5.9mn people ("Survey on Awareness and Actual Conditions of Insomnia," MSD, 2014)
*2: Estimated from the Company's survey of physicians (N=387) as the share of physicians supportive of CBT-I apps × assumed prescription rate of CBT-I apps × smartphone ownership rate by age group (Source: INTAGE, "Multi-Device Survey"), multiplied by the 71% share of people taking insomnia drugs who are dissatisfied with their current drug ("Survey on Awareness and Actual Conditions of Insomnia," MSD, 2014)
*3: Reimbursement price of the DTx app for insomnia
*4: Estimated by multiplying the 12.7mn untreated people with insomnia symptoms (18.6mn − 5.9mn) by 57.1%, the combined share of those with suspected insomnia who answered "I think I have insomnia" (35.2%) or "Neither" (21.9%), and further by 64.4%, the share of those with suspected insomnia who feel afraid to take insomnia drugs ("Survey on Awareness and Actual Conditions of Insomnia," MSD, 2014)
*5: Estimated from the Company's survey of physicians (N=387) as the share of physicians supportive of CBT-I apps × assumed prescription rate of CBT-I apps × smartphone ownership rate (Source: INTAGE, "Multi-Device Survey")
*6: Yakuji Handbook 2026, on an NHI drug price basis

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 segment, based on expertise gained in the development process for the DTx app for insomnia, the Company provides services such as DTx development support services using the DTx app development platform QDTx®, Awesome Intelligence® (hereafter, Awesome Intelligence), a machine learning automated analytics service that analyzes medical big data, and SUSMED SDS, a clinical trial system utilizing blockchain technology.

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In particular, SUSMED SDS with a monitoring system that incorporates 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 conducting R&D on the application of blockchain technology 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/medical device companies. In May 2022, the Company began joint research with the National Center of Neurology and Psychiatry (hereafter, also "NCNP") on improving the reliability of registry data using blockchain technology. In June 2022, it entered into a service contract with Aculys Pharma, Inc. (now Viatris Pharmaceuticals Japan G.K.), 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 targeting excessive daytime sleepiness associated with obstructive sleep apnea syndrome. Based on the results of these trials, it has been announced that manufacturing and marketing approval was obtained in September 2026.

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 (now Institute of Science Tokyo), 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 October 2025, the Company started providing SUSMED SDS for the Phase 1/2 company-sponsored clinical trial of HS-005 (catheter administration), a cardiac regenerative medicine for severe heart failure due to ischemic heart disease and dilated cardiomyopathy, conducted by Heartseed. This was the first time the system had been provided for a clinical trial of a regenerative medicine product, and in June 2026, the first patient was dosed in this trial.

SUSMED SDS has also been adopted in the specified clinical research for the DTx app for tinnitus SMD403, the specified clinical research for SMD106 for PMS/PMDD, and the company-sponsored trial for the ACP app SMD402, and in May 2026 it was adopted in the pivotal trial for the DTx app for tinnitus KRP-DT123/SMD403.

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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. Although the Company launched "SUSMED DTx for insomnia Medcle" in June 2026, its results may continue to show periodic losses, as substantial R&D expenses will continue to be incurred until the market launch of pipelines still under development. In response to these risk factors, in addition to earning profits from "SUSMED DTx for insomnia Medcle," the Company is also considering measures that will allow it to generate revenue sooner, such as licensing out its development pipelines to other companies or earning milestone income. In addition, as an R&D-oriented firm, the Company will continue to incur large R&D expenses over the long term, which are needed to acquire seeds for DTx apps and advance pipeline development with the aim of maximizing future profits. 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

Revenue increased in FY6/26 due to recognition of milestone income

1. Overview of FY6/26 results

In the Company's results (non-consolidated) for FY6/26, operating revenue increased by 7.4% YoY to ¥497mn, operating loss was ¥330mn (compared to a loss of ¥299mn in the previous fiscal year), ordinary loss was ¥325mn (compared to a loss of ¥294mn), and net loss was ¥382mn (compared to a loss of ¥298mn). Revenue increased due to firm performance in the DTx Platform segment, as well as the contribution of milestone income in the DTx Product segment. On the profit side, operating loss widened, because SG&A expenses increased due to higher personnel and promotion expenses incurred with the launch of "SUSMED DTx for insomnia Medcle." R&D expenses decreased (down ¥26mn YoY to ¥247mn) as a portion was capitalized. An impairment loss of ¥67mn was recorded as an extraordinary loss.

In the DTx Product segment, operating revenue was ¥340mn (¥300mn in the previous fiscal year), and segment profit (operating profit before adjustments for corporate expenses, etc.) was ¥103mn (¥118mn). Milestone income of ¥100mn received from ASKA Pharmaceutical and milestone income of ¥240mn received from KYORIN Pharmaceutical were recognized. In the DTx Platform segment, operating revenue was ¥156mn (¥162mn), and segment profit was ¥76mn (¥33mn). SUSMED SDS contributed. The number of development pipeline projects in the DTx Product segment was 11, as "SUSMED DTx for insomnia Medcle," was excluded following its launch, and the number of contractual projects in the DTx Platform segment decreased by 1 YoY to 15.

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Summary of FY6/26 results (non-consolidated)

(¥mn)

	FY6/25 Results	FY6/26 Results	YoY	
			Difference	YoY change
Operating revenue	462	497	34	7.4%
Business expenses	762	827	64	8.5%
Business costs	12	17	5	41.8%
R&D expenses	273	247	-26	-9.6%
Selling, general and administrative expenses	476	562	85	18.0%
Operating profit	-299	-330	-30	-
Ordinary profit	-294	-325	-30	-
Net profit	-298	-382	-84	-
Segment operating revenue				
DTx Product	300	340	40	13.4%
DTx Platform	162	156	-6	-3.7%
Segment profit				
DTx Product	118	103	-14	-12.4%
DTx Platform	33	76	43	132.3%
Corporate expenses	-450	-510	-	-

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 FY6/26 were down ¥284mn from the end of the previous fiscal year to ¥4,218mn. This was mainly because, while accounts receivable and contract assets increased by ¥258mn, intangible assets by ¥72mn, and investments and other assets by ¥71mn, cash and deposits decreased by ¥699mn. Total liabilities increased by ¥15mn to ¥147mn. Total net assets decreased by ¥300mn to ¥4,070mn. While share capital and capital surplus each increased by ¥17mn due to the issuance of new shares as restricted stock compensation and other factors, and share acquisition rights increased by ¥46mn, retained earnings decreased by ¥382mn due to the recognition of a net loss. The equity ratio declined 1.8 percentage points to 94.2%. The Company also carried out a capital reduction on May 25, 2026, to secure flexibility and agility in its capital policy. However, this was a transfer between accounts and did not change the amount of net assets.

Because the Company is an R&D-oriented startup, it has continued to generate negative operating cash flow, but it has 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.

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Balance Sheets and Cash Flow Statements (Simplified)

(¥mn)

	End-FY6/22	End-FY6/23	End-FY6/24	End-FY6/25	End-FY6/26	Change
Total assets	4,943	5,101	4,932	4,502	4,218	-284
Current assets	4,935	5,085	4,898	4,462	4,027	-435
Non-current assets	8	15	33	40	190	150
Total liabilities	93	230	327	132	147	15
Current liabilities	87	224	321	125	147	22
Non-current liabilities	5	5	6	6	-	-6
Total net assets	4,850	4,870	4,604	4,370	4,070	-300
Shareholders' equity	4,850	4,861	4,584	4,322	3,975	-347
Equity ratio	98.1%	95.3%	92.9%	96.0%	94.2%	-1.8pp

	FY6/22	FY6/23	FY6/24	FY6/25	FY6/26
Cash flow from operating activities	-165	100	-230	-432	-474
Cash flow from investing activities	-20	-18	-8	-19	-228
Cash flow from financing activities	3,463	62	37	3	2
Cash and cash equivalent at end of year	4,904	5,048	4,846	4,398	3,698

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

Outlook

Significant revenue growth expected in FY6/27

● FY6/27 forecasts

For FY6/27, the Company forecasts (non-consolidated) a significant increase in revenue, with operating revenue up 68.7% YoY to ¥838mn, operating loss of ¥461mn (compared to a loss of ¥330mn in the previous fiscal year), ordinary loss of ¥474mn (compared to a loss of ¥325mn), and net loss of ¥541mn (compared to a loss of ¥382mn). In the DTx Product segment, in addition to the launch of "SUSMED DTx for insomnia Medcle," milestone income accompanying progress in pipeline development will also contribute. As for milestones, it has been fixed that ¥200mn to be received from Shionogi will be recognized in Q1. In the DTx Platform segment, operations of SUSMED SDS and other services are expected to remain firm. On the profit side, operating loss is expected to widen. Costs will increase due to higher R&D expenses (up 76.1% YoY to ¥435mn) as development pipelines progress, promotion expenses for "SUSMED DTx for insomnia Medcle," personnel expenses from active hiring, and expenses related to the head office relocation.

As its main KPIs, the Company targets 1,000 medical institutions adopting "SUSMED DTx for insomnia Medcle" and 2,000 monthly prescriptions as of June 2027, the fiscal year-end, with 11 development pipelines and 17 project contracts, up 2 YoY. Key initiatives include, in the DTx Product segment, sales promotion of "SUSMED DTx for insomnia Medcle" and development progress in pipelines (start of the next trial for SMD105, completion of the pivotal trial for SMD403, start of the pivotal trial for SMD106, and start of the next trial for SMD107), and in the DTx Platform segment, building up a track record of the clinical trial system.

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For “SUSMED DTx for insomnia Medcle,” the Company expects prescriptions to build up gradually toward the fiscal year-end, rather than ramping up sharply. Regarding the termination of the exclusive sales agreement with Shionogi, the Company considers the impact on its results as minimal. This takes into account the fact that it has established a system to handle the entire supply chain on its own; as well as that it has already conducted sales activities under that system since becoming eligible for insurance coverage; that its targets have been set based on this situation; that the revenue per prescription it recognizes will increase; and that it will make additional management efforts going forward such as strengthening sales activities.

Growth strategy

Expansion of development pipeline, promotion of increase in contracts in DTx Platform segment

1. Growth strategy

Although the Company has not established management indicators that would serve as numerical targets as part of its growth strategy, it is promoting the expansion of development pipelines and the progress of clinical trials in the DTx Product segment for maximizing revenue from a long-term perspective, and an increase in the number of contracts and enhancements of new services in the DTx Platform segment in order to achieve continuous and cumulative revenue growth. To enhance these growth strategies, 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 segment overseas and it is currently selecting countries to enter based on a mix of factors, including the presence of regulatory laws, insurance reimbursement frameworks, market size, and competitive situation.

As one example of its joint research initiatives, the Company started joint research and development with NCNP in May 2022. This project involved the 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, the Company signed a joint research agreement with Shiga University related to fundamental technology for causal discovery titled “Establishment and Application of Fundamental Technology for Causal Discovery to Realize Reliable AI Systems,” and this research was selected by the Japan Science and Technology Agency (JST) as an FY2022 Strategic Basic Research Program (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 Program on Open Innovation Platforms for Industry-academia Co-creation (COI-NEXT). In addition, in April 2024, the Company started an initiative with Nagoya University related to the 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 for AMED’s FY2023 Funding for Research to Expedite Effective Drug Discovery by Government, Academia and Private Partnership (GAPFREE6).

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Contributing to solutions for social issues through business

2. Sustainability management

For sustainability management, the mission of the Company is 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 engages 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, as DTx apps inherently have none of the environmental impact that typically occurs in the manufacturing of pharmaceuticals or medical devices (such as greenhouse gas emissions from factory operations, use/pollution of water resources, and generation of industrial waste), they help to reduce 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 they are software products, DTx apps do 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 helps 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, the Company has established five action guidelines—"Always consider social significance," "Focus on essential outcomes," "Respect each other as professionals," "Enjoy growth," and "Think objectively and act proactively"—and it 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 rose from 71.5% in FY6/25 to 76.1% in FY6/26, while the share of employees using remote work three or more days a week fell from 66.7% to 60.9%.

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. The status of these areas is measured and evaluated with multiple quantitative and qualitative indicators. In addition, in order to enhance corporate governance, the Company established a Governance Committee in July 2023 as an advisory body for matters related to the nomination and remuneration of directors, and in September 2024, it changed from a company with a board of corporate auditors to a company with an audit and supervisory committee.

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. By effectively utilizing this public research aid, the Company is strengthening R&D activities that contribute to the sustainability of medicine, such as providing new treatment methods, addressing unmet medical needs to increase the efficiency of clinical settings, and appropriately allocating medical resources.

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Positive evaluation of medium- to long-term growth potential

3. FISCO's view

The Company is an R&D-oriented 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, in the DTx Product segment, in addition to launching "SUSMED DTx for insomnia Medcle," the Company has recently started preparing for the next trial of SMD106, a DTx app in the field of obstetrics and gynecology, based on the results of the proof-of-concept trial, and has started a pivotal trial of KRP-DT123/SMD403, a DTx app for tinnitus, making steady progress in development toward the launch of subsequent products. In the DTx Platform segment as well, business is entering full swing, evidenced by the regulatory approval of a pharmaceutical product based on the results of a clinical trial using SUSMED SDS. Given these circumstances, FISCO is positively evaluating the Company's medium- to long-term growth potential and will closely monitor future development progress.

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