COMPANY RESEARCH AND ANALYSIS REPORT

SUSMED, Inc.

4263

Tokyo Stock Exchange Growth Market

9-Nov.-2022

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

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Summary

Losses decreased in FY6/22 mainly due to revenue recognized from a milestone income. Development of digital therapeutics, which is attracting interest as a third treatment option, is underway

SUSMED, Inc. <4263> (hereinafter "the Company") is a research and development (R&D)-stage startup conducting business with a focus on the development of digital therapeutics (hereinafter, "DTx"), which is attracting interest as a third treatment option other than pharmaceuticals and medical devices. The Company aims to propose DTx 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." The Company's shares were newly listed on the Mothers Market in December 2021, and it transitioned to a listing on the Growth Market of the Tokyo Stock Exchange (hereinafter, "TSE") in connection with the TSE's market restructuring in April 2022. The Company has two segments: the DTx Product and the DTx Platform.

1. Summary of FY6/22 results

In the FY6/22 results (non-consolidated; although the Accounting Standard for Revenue Recognition, etc. was adopted, it had a negligible impact on profit and loss), operating revenue increased 174.4% year on year (YoY) to ¥316mn, operating loss was ¥229mn (compared to a loss of ¥333mn in FY6/21), ordinary loss was ¥217mn (compared to a loss of ¥271mn in FY6/21), and net loss was ¥233mn (compared to a loss of ¥277mn in FY6/21). Losses at each profit level decreased, helped partly by lower-than-anticipated R&D expenses, in addition to revenue recognized from a milestone income in the DTx Product and profitability improvements in the DTx Platform. R&D expenses decreased by 9.1% YoY to ¥226mn. This decrease reflected lower-than-anticipated expenses due to changes in schedules and cost reduction of clinical trials, in addition to lower-than-planned recruitment. We at FISCO do not believe there are any financial concerns at present because the Company has secured R&D funds through funds raised from its new share listing.

2. FY6/23 results outlook

For the FY6/23 results (non-consolidated), the Company is forecasting operating revenue of ¥522mn, an increase of 64.9% YoY, operating loss of ¥442mn (compared to a loss of ¥229mn in FY6/22), ordinary loss of ¥442mn (compared to a loss of ¥217mn in FY6/22), and net loss of ¥454mn (compared to a loss of ¥233mn in FY6/22). Operating revenue is expected to increase based on projected milestone revenue in accordance with a commercialization agreement with Shionogi & Co., Ltd. <4507>. However, on the cost front, the Company expects increased costs due to a recovery in progress on recruitment plans, and an increase in R&D expenses (an increase of ¥402mn, or 77.9% YoY) due to the acquisition of new pipelines and recruitment of R&D personnel. For this reason, the Company is forecasting increases in losses overall in FY6/23.

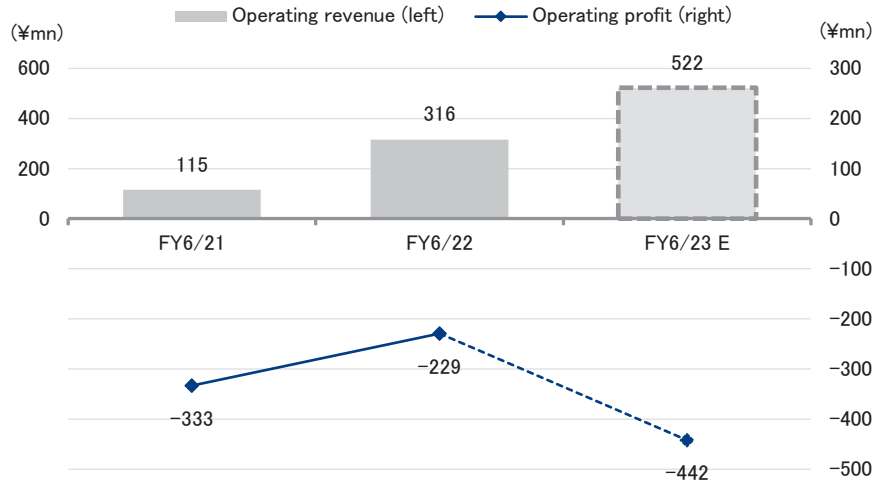
3. Outlook for medium- to long-term growth

As it incurs large upfront R&D expenses, the Company may face a continuation of periodic operating loss for the foreseeable future. However, if the Company's filing for marketing authorization for its DTx app for insomnia is once approved, its revenue could grow significantly from FY6/24, and if other pipelines continue to progress steadily, this could fuel heightened expectations for obtaining a second or third marketing authorization. Another tailwind for the Company is that the Ministry of Health, Labour and Welfare (MHLW) is developing an authorization environment to promote widespread adoption of Software as a Medical Device (SaMD) as part of national policy. As a result, there could be accelerated growth in pipelines development. Growth in the DTx Platform is expected through the use of blockchain technology, as are synergies between the DTx Product and DTx Platform. Considering these factors, we at FISCO believe that the Company is able to achieve medium- to long-term growth.

Key Points

- An R&D-stage startup conducting business with a focus on the development of DTx, which is attracting interest as a third treatment option
- Losses at each profit level are expected to grow in FY6/23 due to increased R&D expenses
- Medium- to long-term growth can be expected based on factors such as the acquisition of marketing authorization for the DTx app for insomnia and pipeline expansions

Results trends



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

Company profile

An R&D-stage startup conducting business with a focus on the development of digital therapeutics (DTx)

1. Company profile

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

The Company is headquartered in the Nihonbashi Honcho district of Chuo-ku, Tokyo. As of the end of FY6/22, the Company had total assets of ¥4,943mn, net assets of ¥4,850mn, share capital of ¥1,853mn, and an equity ratio of 98.1%. The number of shares issued by the Company was 16,201,100 (no treasury shares) as of the same date.

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 TSE in December 2021, and it transitioned to a listing on the Growth Market of the TSE in connection with the TSE's market restructuring in April 2022.

In terms of business development, the Company initiated clinical trials of its DTx app for insomnia in September 2016. In June 2018, it initiated a verification test of its clinical development support system using blockchain technology. In February 2019, the Company began providing DTx development support services, and in May 2019, it began providing a machine learning automated analytics system. In December 2021, the Company entered into a commercialization agreement with Shionogi & Co., Ltd. regarding the DTx app for insomnia. In February 2022, the Company filed for marketing authorization approval of the DTx app for insomnia.

SUSMED, Inc.

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Company profile

History

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

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

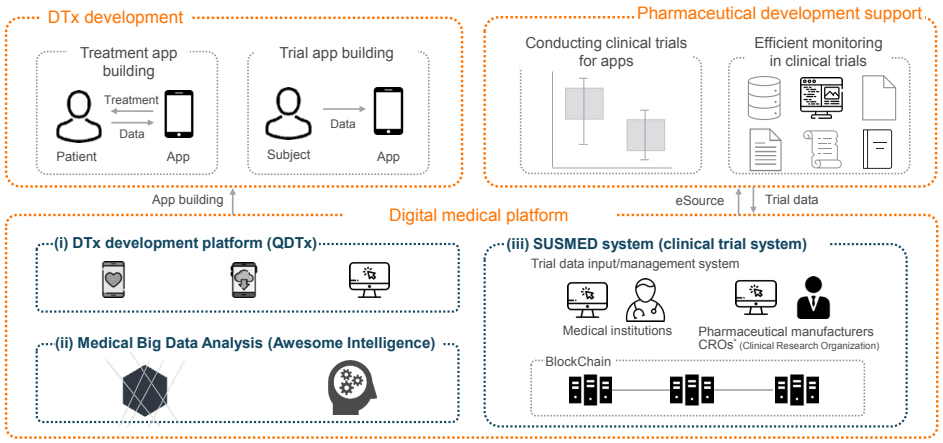
Business Overview

DTx Product, which develops DTx apps and DTx Platform, which supports more efficient clinical trials

1. Business Overview

The Company has two segments: (1) the DTx Product, which develops DTx apps, and (2) the DTx Platform, which supports more efficient clinical trials with its proprietary system, machine learning automated analytics system (medical big data analysis), and DTx app development platform system. In FY6/22, operating revenue was ¥200mn in the DTx Product and ¥116mn in the DTx Platform. In the DTx Product, any products are not yet sold because the segment is still in the development stage, but revenue was recognized from a milestone income based on a commercialization agreement with Shionogi & Co., Ltd. In the DTx Platform, revenue was recognized from service usage fees, primarily from contracting companies (14 companies, mainly pharmaceutical manufacturers, as of the end of FY6/22).

Overview of business fields



Source: Reprinted from the Company's results briefing materials

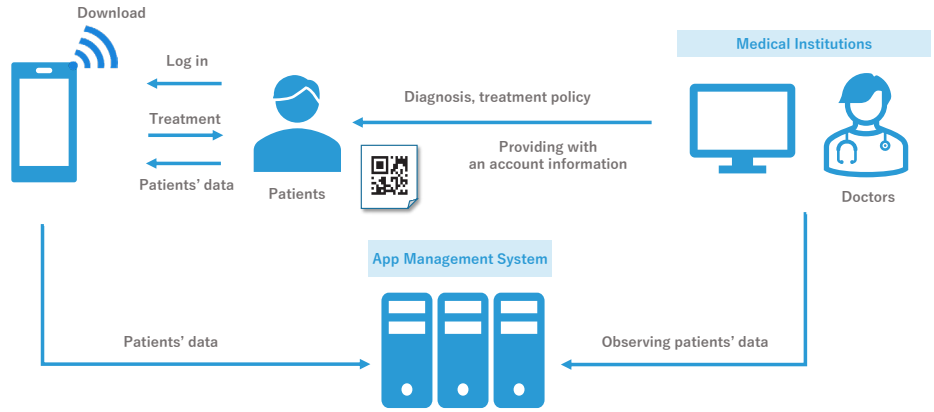
The DTx Product develops DTx apps, which are attracting interest as a third treatment option

2. DTx Product

The DTx Product develops DTx apps and clinical trial apps. DTx apps are a new option that provides treatment via apps downloaded by patients onto their smartphones, other than pharmaceutical or medical device-based therapies (drug therapy, chemical therapy, surgery, etc.) 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, can reshape patients' daily life habits and thus generate a superior therapeutic effect. To illustrate how treatment is provided, the app does not involve a physician as opposed to remote or telemedicine therapy. 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 examinations 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 Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, based on medical evidence related to efficacy and safety confirmed through clinical trials. For this reason, there are certain difficulties that must be overcome in order to develop DTx apps. Another distinction between DTx apps and 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 are doctors and medical institutions. According to the revenue model, the Company is paid based on the number of prescriptions written by medical institutions that have received medical fees (The medical fee for approved DTx apps consists of a 70% national insurance payment and a 30% co-payment.)

Flow for providing DTx apps



Source: Reprinted from the Company's results briefing materials

For example, in the field of insomnia, Japanese patients are typically treated with drug therapy using sleeping medications and other drugs. However, drug therapy is known to create complications such as side effects and addiction issues, as well as patients' hesitation to take sleeping medications. 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. According to reports, the National Institutes of Health in the United States have recommended cognitive behavioral therapy as the first line of treatment for insomnia. In Japan, however, there is a lack of medical resources to provide cognitive behavioral therapy, and the current reality is that drug therapy remains the predominant treatment.

In addressing these issues, DTx apps pose very little risk of complications such as side effects and addiction issues, which are common concerns in drug therapy. DTx apps could become a treatment option for providing patients with cognitive behavioral therapy, the first line of treatment, without being constrained by the availability of medical resources.

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

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

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

Currently filing for marketing authorization for the DTx app for insomnia

3. Pipelines for DTx apps and the domestic market size

The pipelines for the Company's DTx apps and their current status can be divided into DTx apps for treatment and those for diagnosis. As of the end of FY6/22, the Company was developing eight apps on its proprietary DTx app development platform (QDTx®). The DTx apps for treatment include the DTx app for insomnia (currently under review for marketing authorization), SMD401 for breast cancer patient exercise therapy (preparations currently underway for the start of a pivotal trial), SMD402 for Advance Care Planning (hereinafter, "ACP")* (proof-of-concept trial currently underway), SMD201 for chronic kidney disease (preparations currently underway for start of proof-of-concept trial), SMD102 for prolonged grief disorder (app development stage), and SMD202 for opioid-induced constipation (app development stage). In DTx apps for diagnosis include SMD103 for maternal symptoms of depression (app development stage / patent related to algorithm and device approved) and SMD104 for ADHD: Eye Tracking (app development stage).

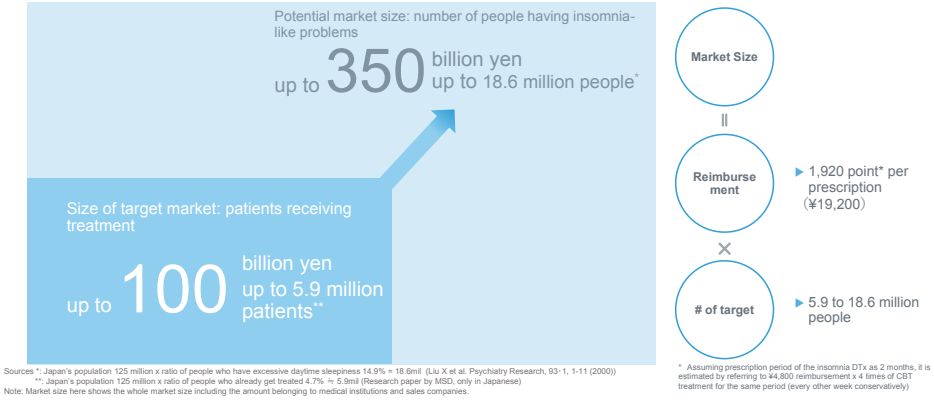
* Refers to efforts to provide decision-making support for care planning for progressive cancer patients.

Among these DTx apps, the Company began clinical trials of the DTx app for insomnia in September 2016 and conducted a pivotal trial of this app from May to November 2021 (equivalent to a phase 3 clinical trial in new drug development), achieving the primary endpoints of the trials. Based on this successful trial outcome, the Company entered into a commercialization agreement with Shionogi & Co., Ltd. in December 2021, and filed for marketing authorization in February 2022. In June 2022, the Company announced detailed clinical trial results at a meeting of the Japanese Society of Sleep Research. If the review proceeds smoothly, the Company expects to obtain approval sometime in spring 2023, marking the first approval in Japan of a DTx app for insomnia. Under the commercialization agreement with Shionogi, the Company will grant Shionogi exclusive marketing rights for the app in Japan. In return, the Company plans to receive milestone income up to ¥4.7bn. In addition, the Company will receive royalties on product sales after the app is launched.

The development process of DTx, research and development of the DTx app → proof-of-concept trial → pivotal trial → filing for approval → insurance coverage, is almost the same as the process for developing a new pharmaceutical (basic research → non-clinical trial → clinical trial → filing for approval → insurance coverage). However, the general development lead time for a DTx app is around 5 or 6 years, whereas it is very different from for a pharmaceutical requiring more than 10 years. A DTx app's development lead time is around half that of a new pharmaceutical, providing the benefit of lower development costs.

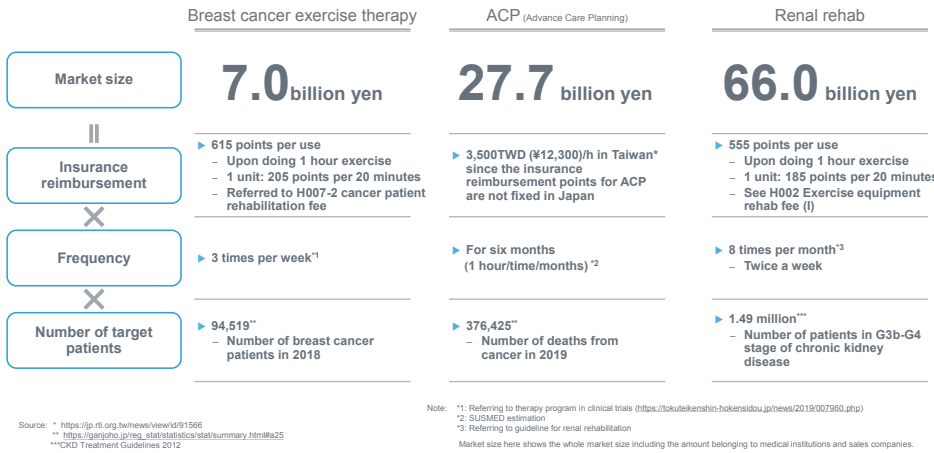
According to the Company's disclosure materials, the market size of the DTx app for insomnia in Japan is estimated at ¥100.0bn and ¥350.0bn if potential patients are included. Furthermore, the Serviceable Available Market (SAM), which represents targeted demand, is estimated at more than ¥40.0bn in total (¥19.2bn from switchover needs from existing sleep medication therapy + ¥21.6bn from finding untreated patients who realize they have insomnia but are hesitant to receive sleep medication therapy). The estimated domestic market sizes of other pipelines are ¥7.0bn for SMD401 for breast cancer patient exercise therapy, ¥27.7bn for SMD402 for ACP, and ¥66.0bn for SMD201 for chronic kidney disease rehabilitation.

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



Source: Reprinted from the Company's results briefing materials

Domestic market size of other pipelines (estimate)

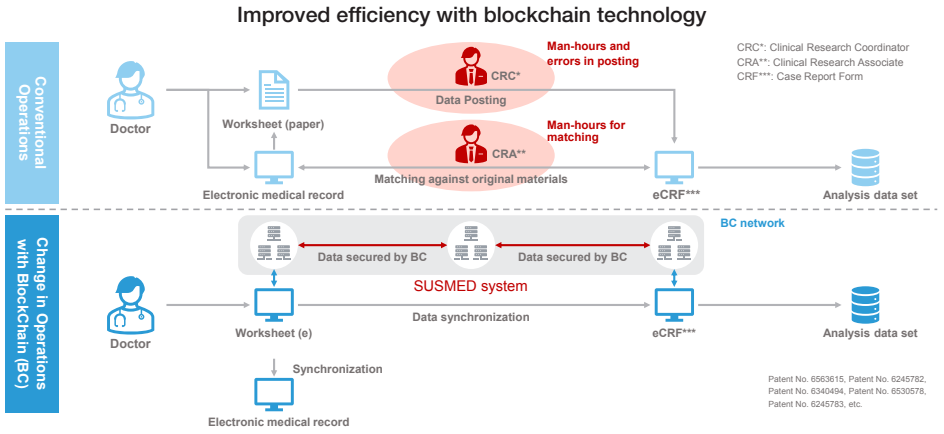


Source: Reprinted from the Company's results briefing materials

The DTx Platform supports more efficient clinical trials by using blockchain technology and other innovations

4. DTx Platform

In the DTx Platform, the Company mainly provides three services, 1) DTx development support services using its proprietary DTx app development platform “QDTx®” based on expertise gained in the development process for the DTx app for insomnia; 2) Awesome Intelligence, a machine learning automated analytics service that analyzes medical big data; and 3) the SUSMED system, which is a general-purpose clinical trial system. The SUSMED system employs a monitoring system fitted with blockchain technology to simultaneously realize the high level of security and data tampering resistance required in clinical trials, while drastically reducing the man-hours and costs related to clinical trial monitoring. The Awesome Intelligence is provided as a cloud service and is used to analyze medical big data, including real world data.



Source: Reprinted from the Company’s results briefing materials

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, the Ministry of Health, Labour and Welfare (MHLW) officially approved the system as fulfilling the monitoring requirements required by Good Clinical Practice (GCP) ordinances, through adoption of the Cabinet Office’s regulatory sandbox system*1 and the use of the Grey Zone Elimination system.*2 Following that, the Company has promoted further improvement in reliability and expanded fields of blockchain technology application through joint research and alliances with partners such as medical institutions, academic research institutions, and pharmaceutical companies.

*1 A system in which verification approved by regulatory authorities is carried out and the results are used to revise regulations, in order to implement new technologies and business models in society. IoT, blockchain, robotics are examples of new technologies, while platform businesses and the sharing economy are examples of business models.

*2 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.

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

5. Risk factors

The Company's general risk factors include, as with new drug development, the risk of uncertainty in R&D concerning DTx apps, side effects, product liability, legal regulations, and intellectual property litigation. Furthermore, as it incurs large upfront R&D expenses, the Company may face a continuation of periodic operating loss for the foreseeable future.

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 acquiring 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 secures a stable source of revenue.

Results trends

In FY6/22, losses at each profit level decreased mainly due to revenue recognized from a milestone income

1. Summary of FY6/22 results

In the FY6/22 results (non-consolidated; (non-consolidated; although the Accounting Standard for Revenue Recognition, etc. was adopted, it had a negligible impact on profit and loss), operating revenue increased 174.4% YoY to ¥316mn, operating loss was ¥229mn (compared to a loss of ¥333mn in FY6/21), ordinary loss was ¥217mn (compared to a loss of ¥271mn in FY6/21), and net loss was ¥233mn (compared to a loss of ¥277mn in FY6/21). Losses at each profit level decreased, helped partly by lower-than-anticipated R&D expenses, in addition to revenue recognized from a milestone income in the DTx Product and profitability improvements in the DTx Platform. R&D expenses decreased by 9.1% to ¥226mn. This decrease reflected lower-than-anticipated expenses due to changes in schedule and cost reductions of clinical trials, in addition to lower-than-planned recruitment.

By segment, in the DTx Product, operating revenue was ¥200mn (compared to ¥0mn in FY6/21) and profit (operating profit before adjustments for corporate expenses, etc.) was ¥11mn. Any products are not yet sold because the segment is still in the development stage, but revenue was recognized from a milestone income based on a commercialization agreement with Shionogi & Co., Ltd., leading to positive profitability. In the DTx Platform, operating revenue was ¥116mn (¥115mn in FY6/21) and profit was ¥57mn (¥8mn in FY6/21). Revenue was recognized from service usage fees from contracting companies, and profitability improved due to a rebound from special factors in FY6/21 and the effect of concentrating the customer base.

Summary of FY6/22 results (non-consolidated)

(¥mn)

	FY6/21 Result	FY6/22 Result	YoY change
Operating revenue	115	316	174.4%
Operating loss	-333	-229	-
Ordinary loss	-271	-217	-
Net loss	-277	-233	-
(R&D expenses)	249	226	-9.1%
Segment operating revenue			
DTx Product	-	200	-
DTx Platform	115	116	1.2%
Segment profit (loss) (before adjustments)			
DTx Product	-160	11	-
DTx Platform	8	57	552.1%
Corporate expenses	-182	-298	-

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

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

2. Financial position

Looking at the Company's financial position, total assets increased ¥3,268mn from the end of FY6/21 to ¥4,943mn as of the end of FY6/22, and total liabilities decreased ¥3mn from the end of FY6/21 to ¥93mn. Total net assets rose ¥3,272mn from the end of FY6/21 to ¥4,850mn, and the equity ratio increased 3.9 points YoY to 98.1%. Cash and cash equivalents increased by ¥3,277mn to ¥4,904mn as a result of funds raised from the new share listing in December 2021 (¥2,967mn) and funds raised from over-allotment (¥496mn).

The Company will reduce its share capital of ¥1,853mn by ¥1,843mn and transfer the entire reduction to legal capital surplus, resulting in a share capital of ¥10mn after the reduction, with an effective date of November 30, 2022. There will be no effect on the amount of net assets because this is a transfer within the accounts of the net assets section of the balance sheet.

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

Balance Sheets and Cash Flow Statements (Simplified)

(¥mn)

	FY6/21	FY6/22
Total assets	1,674	4,943
(Current assets)	1,674	4,935
(Non-current assets)	0	8
Total liabilities	97	93
(Current liabilities)	96	87
(Non-current liabilities)	0	5
Total net assets	1,577	4,850
(Shareholders' equity)	1,577	4,850
(Share capital)	100	1,853
Equity ratio (%)	94.2%	98.1%
Number of issued shares at end of year	13,256,600	16,201,100
Cash flow from operating activities	-235	-165
Cash flow from investing activities	-4	-20
Cash flow from financing activities	1,500	3,463
Cash and cash equivalent at end of year	1,626	4,904

Note1: The Company newly listed its shares in December 2021.
Note2: The Company plans to reduce its share capital to ¥10mn, with an effective date of November 30, 2022.
Source: Prepared by FISCO from the Company's financial results

Business Outlook

Losses at each profit level are expected to grow in FY6/23 due to increased R&D expenses

For the FY6/23 results (non-consolidated), the Company is forecasting operating revenue of ¥522mn, an increase of 64.9% YoY, operating loss of ¥442mn (compared with a loss of ¥229mn in FY6/22), ordinary loss of ¥442mn (compared to a loss of ¥217mn in FY6/22), and a net loss of ¥454mn (compared to a loss of ¥233mn in FY6/22).

Summary of forecasts for FY6/23 results (non-consolidated)

(¥mn)

	FY6/22 Results	FY6/23 Forecasts	YoY change
Operating revenue	316	522	64.9%
Operating loss	-229	-442	-
Ordinary loss	-217	-442	-
Net loss	-233	-454	-
(R&D expenses)	226	402	77.9%

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

Operating revenue will increase in line with expectations of milestone revenue based on the commercialization agreement with Shionogi & Co., Ltd. However, the Company anticipates increased costs as a result of a recovery in progress on recruitment plans, as well as increased R&D expenses (a 77.9% YoY increase to ¥402mn) due to the acquisition of new pipelines and securing R&D personnel. Consequently, overall losses are expected to rise. The number of development pipelines in the DTx Product is expected to increase by 1 to 9 compared to the end of the previous fiscal year. The number of contracting companies in the DTx Platform is scheduled to remain unchanged from the end of FY6/22, at 14. The Company plans to move forward with the following key measures: obtaining marketing authorization for its DTx app for insomnia, making progress on pipeline development (complete subject recruitment for SMD402 for ACP and SMD201 for chronic kidney disease rehabilitation), launching a clinical trial system in clinical trials sponsored by a pharmaceutical company, and expanding the application fields of blockchain technology (registry fields etc.).

Growth strategy

Advance joint research to enhance pipelines and apply blockchain technology

1. Advance joint research to enhance pipelines and apply blockchain technology

Because it is still in the R&D stage, the Company has not established management indicators that would serve as numerical targets. As part of its growth strategy for the foreseeable future, the DTx Product has identified its key management indicators as the number of pipelines and the progress rate on clinical trials for maximizing revenue from a long-term perspective, while the DTx Platform has identified the number of contracts to achieve continuous and accumulative revenue growth as its key management indicator. Furthermore, as of August 2022, the number of patents acquired (including overseas patents and joint applications) was 21, the number of DTx pipelines was 8, the number of project adoptions was 16, the number of joint research partners was 14 companies and institutions, and the number of contracting companies in the DTx Platform was 14.

To enhance these management indicators, the Company is also promoting joint research and alliances with partners such as medical institutions, academic research institutions, and pharmaceutical companies. Looking at examples of these initiatives after the new share listing in December 2021, the Company made a 0.8% investment in March 2022 in Collabo Create Co., Ltd. (a consolidated subsidiary of SUZUKEN CO., LTD. <9987>; established in March 2022 to plan and propose healthcare platforms). Through Collabo Create, the Company will undertake systems related to DTx development support and general-purpose clinical trial systems, among other activities. Additionally, in March 2022, the Company entered into a joint research agreement with Kyushu University concerning the development of an AI model to propose expert treatment for percutaneous catheter ablation for atrial fibrillation. This research was adopted as a “Practical Research Project for Life-Style related Diseases including Cardiovascular Diseases and Diabetes Mellitus” in collaboration with the FY2021 Medical Arts Research Project of AMED.

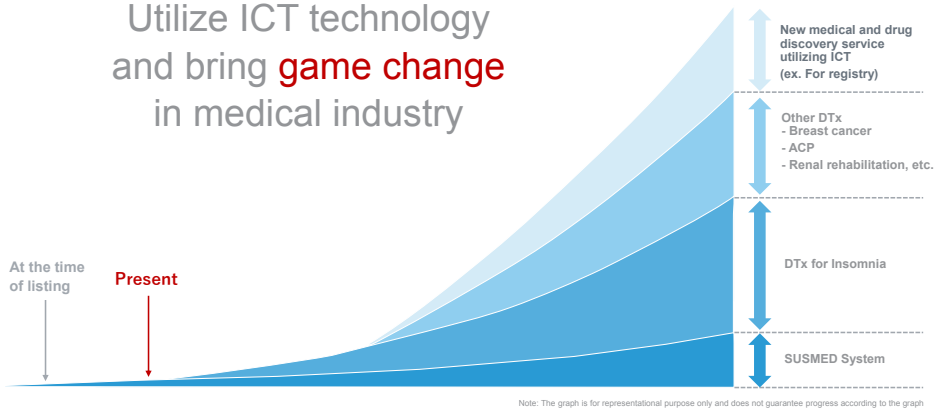
In May 2022, the Company, together with National Center of Neurology and Psychiatry, began research and development concerning the development of a personal information anonymization method and establishment of data processing technology for accumulating and utilizing data collected from diverse sources, and guaranteeing data quality. This research was adopted as "Research and Development Concerning Processing Methods and Assuring the Quality of Clinical Data to Promote Data Utilization," for the FY2022 "Research and Development Grants for Comprehensive Research for Persons with Disabilities" of AMED. The Company intends to expand blockchain technology's application fields (registry fields, etc.), which is one of its key measures for FY6/23.

In June 2022, the Company concluded a contract with Aculys Pharma, Inc. concerning conducting the world's first clinical trial using blockchain technology. The Company will conduct the trial in collaboration with CMIC Co., Ltd., which is a contract research organization, while obtaining the cooperation of medical institutions. This clinical trial is anticipated to have the effect of enhancing the reliability of the clinical data itself, along with significantly reducing time and costs for data entry and other processes at medical institutions.

2. Outlook for medium- to long-term growth

The Company is an R&D-stage startup, and as it incurs large upfront R&D expenses, it may face a continuation of periodic operating loss for the foreseeable future. However, if the Company's filing for marketing authorization for its DTx app for insomnia is once approved, its revenue could grow significantly from FY6/24, and if other pipelines continue to progress steadily, this could fuel heightened expectations for obtaining a second or third marketing authorization. Another tailwind for the Company is that MHLW is developing an authorization environment to promote widespread adoption of Software as a Medical Device (SaMD) as part of national policy. As a result, there could be accelerated growth in pipelines development. Growth in the DTx Platform is expected through the use of blockchain technology, as are synergies between the DTx Product and DTx Platform. Considering these factors, we at FISCO believe that the Company has growth potential over the medium to long term.

Image of medium- to long-term strategy



Source: Republished from matters concerning business plan and growth potential

Shareholder return policy

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

Initiatives to address ESG management and the SDGs

Helping to solve social issues through DX support

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

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