COMPANY RESEARCH AND ANALYSIS REPORT

Kubota Pharmaceutical Holdings Co., Ltd.

4596

Tokyo Stock Exchange Growth Market

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FISCO Ltd. Analyst
Yuzuru Sato

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

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Summary

Focus placed on Kubota Glass product improvement and service enhancement as well as cost control in 2024

Kubota Pharmaceutical Holdings Co., Ltd. <4596> (hereinafter "the Company") develops innovative medical devices and therapeutic drugs to preserve and restore vision while specializing in the field of ophthalmology to promote the digitalization of medical care, in keeping with its vision of "World Without Blindness." The Company has three main projects in its development pipeline: Kubota Glass, which is a wearable myopia control device that aims to treat and control the progression of myopia; eyeMO, which is a home-based remote retinal monitoring device for patients with retinal diseases such as age-related macular degeneration (AMD); and emixustat hydrochloride (HCl), which is a drug candidate indicated for Stargardt disease.

1. Trends of wearable myopia control device

Sales of Kubota Glass, launched in Japan as a spectacle-type augmented reality (AR) device in August 2022 (priced at ¥770,000 tax inclusive), amounted to ¥39mn in FY12/23 (up ¥31mn YoY). The product is available on a made-to-order basis for which it initially took around three months' time from order placement to delivery due to issues involving component shortages. However, with lead times having recently been shortened to a duration of one to two months, the Company has apparently managed to achieve consistent sales of the product, but at low unit volume. In FY12/24, the Company placed its focus on efforts that involved holding seminars and other means of heightening customer satisfaction, while seeking to achieve product improvement and service enhancement with its sights set on greater customer satisfaction. Overseas, the Company has been engaging in negotiations with sales partner candidates in China, which has a substantial myopic population, but its primary focus has been on perfecting its products. The Company also aims to make the product available as a medical device in the future and has accordingly been engaging in joint research with academia to amass evidence on the device's effectiveness in controlling myopia progression. Developments going forward warrant close attention given the potentially sizable market for the product amid a scenario where the global market for myopia control lenses is poised to rise from US$24.4bn in 2021 to US$27.3bn in 2025 as the myopic population increases.

2. Trends of development of other major pipeline projects

In December 2023, the Company concluded a letter of intent with Indian ophthalmic medical product manufacturer AUROLAB for co-development of the eyeMO remote retinal monitoring device. With the aim of introducing the low-cost eyeMO device to medical institutions and public facilities, the Company has granted AUROLAB exclusive rights for development, manufacture, and sales of eyeMO in India and its neighboring countries, along with certain countries in the Middle East and Africa. Although negotiations are pending with respect to terms of the contract, it is likely to include provisions stipulating that the Company is to receive royalties based on sales. Also in December 2023, the Company concluded a vendor agreement with IQVIA Services Japan G.K. domestically in Japan, whereby eyeMO is to be provided for the purpose of carrying out a specified clinical study* to be funded by Chugai Pharmaceutical Co., Ltd. <4519>. Although both arrangements will have a negligible effect on short-term financial results, they warrant close attention given that such initiatives are poised to contribute to revenue over the medium- to long-term. Meanwhile, although no significant difference was observed from results of a phase 3 clinical trial of emixustat hydrochloride (HCl) for use in treating Stargardt disease, subsequent data analysis confirmed a significant difference with respect to inhibiting progression of macular atrophy regarding the patient group of participants in the early stages of the disease. As such, the Company is now considering options that include turning to accelerated approval programs in Japan and other countries enlisting such data.

> * The clinical study is carried out with aims that include verifying whether patients with diabetic macular edema (DME) are able to use the device at home, and having medical professionals evaluate measurement validity. A feasibility study will be conducted prior to the clinical study.

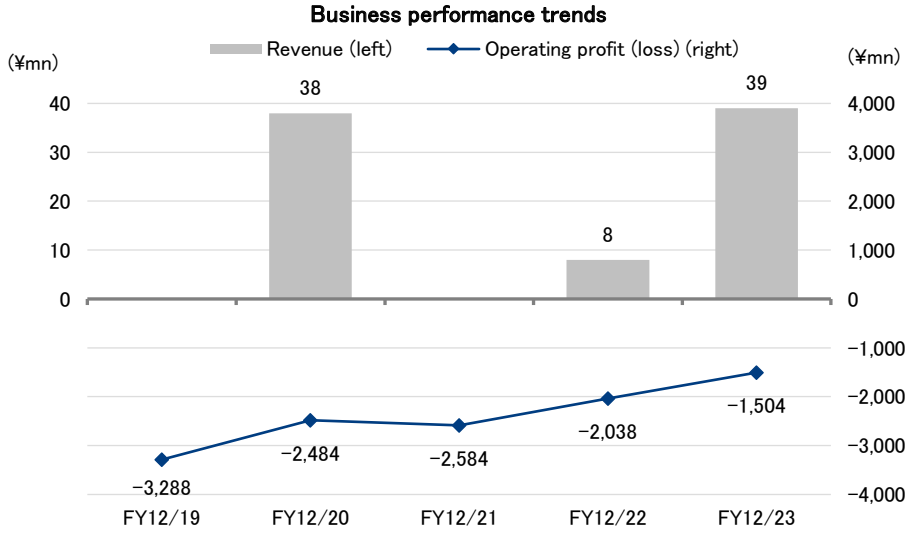
3. Business performance trends

Looking at consolidated results for FY12/23, the Company posted revenue of ¥39mn (up ¥31mn year on year (YoY)) given an increase in revenue from sales of Kubota Glass, and operating loss of ¥1,504mn (contracted by ¥534mn), mainly as a result of a ¥724mn decrease in research and development (R&D) expenses. The Company has not disclosed consolidated results forecasts for FY12/24 upon having determined that such estimates are difficult to calculate rationally at this point in time due to challenges in projecting sales trends for Kubota Glass and also because R&D expenses are subject to change depending on circumstances. However, the Company will persist with its efforts to optimize costs. Although cash on hand stood at ¥2,767mn as of the end of FY12/23 and around two years' worth of funds have been secured for operating activities, the Company has opted to procure funds by exercising share acquisition rights given that products are still in the development stage.

Key Points

- Key focus for 2024 on heightening customer satisfaction through Kubota Glass product improvement and service enhancement
- eyeMO likely to be used in specified clinical study of patients with diabetic macular edema (DME) in Japan as well upon conclusion of agreement for eyeMO co-development with major Indian corporation
- Considering the option of launching emixustat hydrochloride (HCl) indicated for Stargardt disease enlisting the accelerated approval program in Japan
- FY12/24 results forecasts not disclosed, but Company intends to control costs in operations other than those of Kubota Glass

Summary



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

Company profile

A biotech company that seeks to develop innovative pharmaceuticals and medical devices focused on the ophthalmology field

1. Company history

In 2002, Dr. Ryo Kubota, a researcher and ophthalmologist, founded the former Acucela Inc. in Seattle, Washington, in the U.S., for the purpose of developing pharmaceuticals and medical devices focused on the ophthalmology field. In February 2014, shares of the former Acucela Inc. were listed as foreign shares on the Tokyo Stock Exchange Mothers Board. Subsequently, in December 2016, Acucela Japan KK, a Japanese subsidiary, was turned into a holding company named Kubota Pharmaceutical Holdings Co., Ltd. through a triangular merger, and Kubota Pharmaceutical Holdings Co., Ltd. was relisted on the Tokyo Stock Exchange Mothers Board as a domestic stock. (The former Acucela Inc. was delisted at the end of November 2016.) The Company is currently listed on the Tokyo Stock Exchange Growth Market.

Company profile

Since its founding, the Company has conducted business activities in keeping with its management philosophy of "Contributing to society by creating innovative drugs and medical technologies to preserve and restore vision for millions of people worldwide." In 2006, the Company initiated development of emixustat hydrochloride (HCl), a drug candidate using Visual Cycle Modulation (VCM) technology.* In 2008, the Company concluded a co-development and commercialization agreement with Otsuka Pharmaceutical Co., Ltd. (a group company of Otsuka Holdings Co., Ltd. <4578>) for emixustat HCl for geographic atrophy secondary to dry age-related macular degeneration. However, the agreement was terminated following the announcement in May 2016 of the results of a phase 2b/3 clinical trial of emixustat HCl for geographic atrophy secondary to dry age-related macular degeneration. In addition, the Company carried out a phase 3 clinical study of emixustat HCl for Stargardt disease, which is a genetically inherited retinal disease, but it announced in August 2022 that no significant difference had been found with respect to the primary endpoint. However, further data analysis confirmed the effectiveness of the drug in inhibiting progression of symptoms for the patient group in the early stages of the disease, so the Company is reconsidering its development strategy.

* Visual Cycle Modulation technology: A therapeutic technology that is expected to have the effect of reducing toxic by-products that accumulate in the retina, alleviating retinal disorders caused by oxidative stress, and protecting the retina from light damage, through the visual cycle (the mechanism that converts photons to electrical signals within the retina in the posterior of the eye). The results of clinical studies have confirmed that emixustat HCl has the effect of selectively inhibiting an enzyme called RPE65 that performs a key function in the visual cycle.

Looking at medical devices development pipeline projects besides Kubota Glass, a wearable myopia control device aiming to treat and control the progression of myopia, the Company is pursuing eyeMO, which is a remote retinal monitoring device for retinal diseases such as age-related macular degeneration (AMD). eyeMO allows patients to self-measure the condition of their retina at home. With respect to Kubota Glass, the product was soft launched in the U.S. in June 2022 and in Japan in August 2022 and the Company is undertaking sales activities in Japan. In addition, in March 2019 the Company concluded a development agreement with TRISH,* which is a consortium affiliated with NASA, to develop a compact OCT (Optical Coherence Tomography) device together with NASA. The compact OCT device will allow monitoring of the health of astronauts' retinas during spaceflight. Phase 1 of development was completed in February 2020 and received a good assessment, but since then there has been a change in administration and review of the NASA budget, so the project continues to be under suspension.

* TRISH (Translational Research Institute for Space Health): Partnering with NASA through a cooperative agreement, TRISH is a consortium that funds transformative technologies to protect and preserve astronaut physical and mental health during NASA's Deep Space missions.

Company profile

Utilizing advanced technology to take on the challenge of developing innovative medical devices and therapeutic drugs guided by a vision of “World Without Blindness” in addition to launching its myopia eradication project

2. Growth strategy

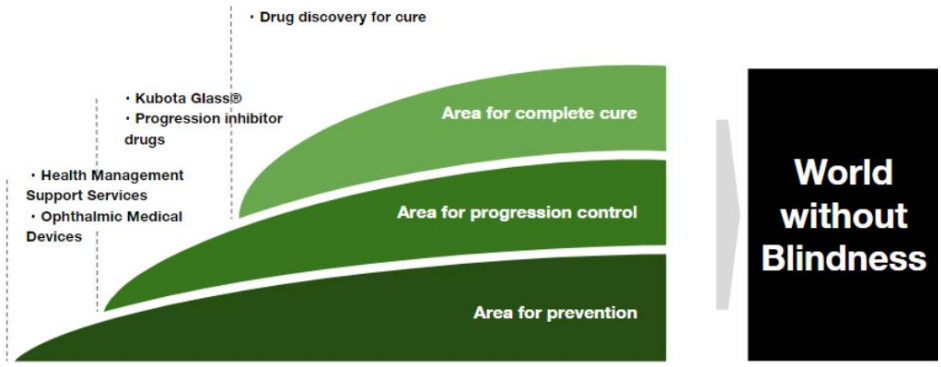
Guided by its vision of “World Without Blindness,” the Company works to develop medical devices using the latest digital technologies as well as therapeutic drugs for eye disorders that lack effective treatments and in 2023 started the ZERO Diopter Project* to eradicate myopia. In its development strategy, the Company is building a portfolio of two businesses of pharmaceuticals and medical devices with different risk-return profiles and is working to increase corporate value while diversifying business risk.

* The ZERO Diopter Project is an initiative whose aim is to bring about a world where people are able to see clearly without the need for vision correction. Specifically, the project involves holding seminars and events with objectives that include spreading knowledge about mechanisms of myopia and means of dealing with it, raising awareness of daily routines that help prevent deterioration of vision, and encouraging people to undergo eye examinations that enable early detection of diseases. It furthermore entails holding seminars and examinations in companies and schools interested in health management, as well as carrying out myopia awareness campaigns and consultation sessions in municipalities and local communities.

The Company engages in operations in three business domains, namely those of pre-disease and prevention, progression control, and full recovery (drug discovery). In the pre-disease and prevention domain, the Company provides services for facilitating health management and develops ophthalmic medical devices under the ZERO Diopter Project. In the progression control domain, the Company develops Kubota Glass and emixustat hydrochloride (HCl) with indications for Stargardt disease. Under its basic strategy for drug development, the Company aims to achieve revenue growth by gaining both milestone payments linked to progress achieved in development and royalty payments on product sales after product launch. To such ends, the Company concludes co-development and sales license agreements with pharmaceutical companies after conducting in-house development carried out until having reached the stage of completing Proof of Concept (POC)* in humans. For medical devices as well, the Company proceeds by concluding co-development and sales license agreements when large-scale clinical trials are required.

* POC (Proof of Concept): POC refers to the process of proving the anticipated effects of a drug, as determined by basic research, through an actual administration trial of the drug in human subjects.

Business Plans



Source: Reprinted from the Company’s financial results briefing materials

In other areas, the Company implements an intellectual property (IP) strategy, which is crucial in terms of it maintaining corporate competitiveness. As such, the Company has 53 granted patents in medical device inventions, 31 granted patents in drug inventions, and more than 100 pending patents as of the end of February 2023. The Company has 12 employees on a consolidated basis as of the end of December 2023, which is an increase of five employees compared to the end of FY12/22. Whereas the Company previously employed mainly administrative staff, it has since hired marketing professionals and other such talent in seeking to build an organization of experts equipped to engage in Kubota Glass sales. When it comes to research and development in the ophthalmology field, the Company enlists a distinctive approach that entails building an asset-light management structure, which involves proceeding with development enlisting external partners on a project-by-project basis, while gaining advice from specialist advisors. The Company has two subsidiaries, one of which is Kubota Vision Inc. of the U.S. and the other of which is Kubota Vision Japan KK of Japan. The U.S. subsidiary mainly engages in activities that include maintaining contact with advisors and searching for candidate licensee companies. Meanwhile, the Japanese subsidiary will mainly engage in operations involving Kubota Glass effective from 2024.

Outline of major development pipeline projects and status of progress

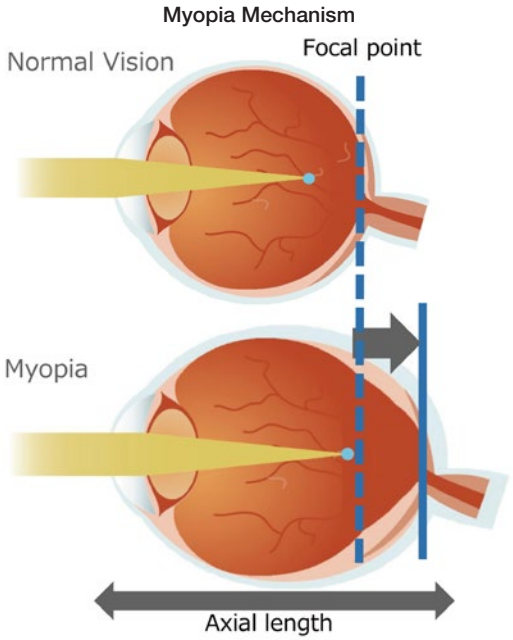
Key focus for 2024 on heightening customer satisfaction through Kubota Glass product improvement and service enhancement

1. Wearable myopia control device Kubota Glass

(1) Myopia market trends and mechanism

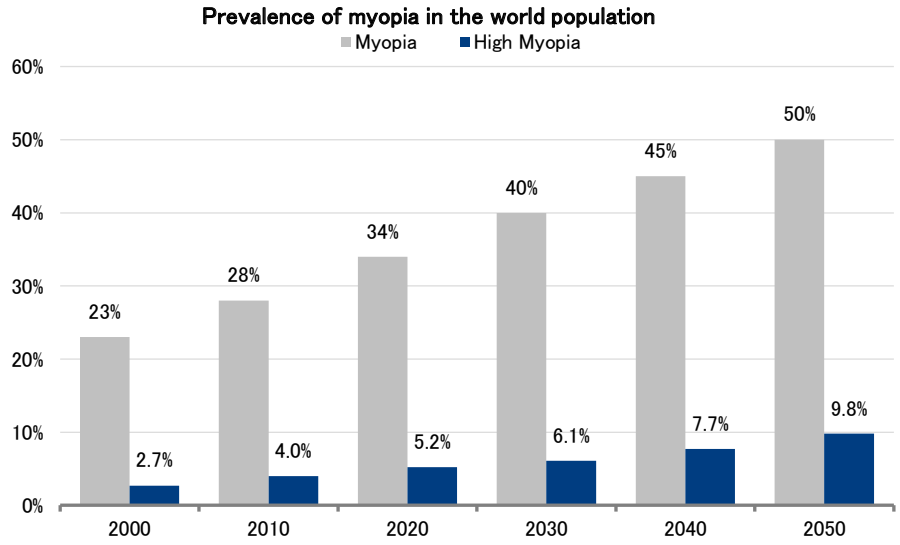
The Company is focused on the development of Kubota Glass, a technology aiming to treat and control the progression of myopia. Myopia is classified into refractive myopia, axial myopia, pseudo myopia, nuclear myopia and certain other types. Many myopia cases are classified as axial myopia. Looking at how axial myopia works, an increase in the eye's axial length causes the retina to move behind the focal point, which results in blurry vision at a distance. It follows that if the axial length could be reduced, axial myopia could be corrected. Currently, there is no way to treat the underlying cause of axial myopia. Refractive correction, including the use of eyeglasses, contact lenses, and refractive surgery, is used to bend light rays so they focus on the retina, thereby correcting vision.

Outline of major development pipeline projects and status of progress



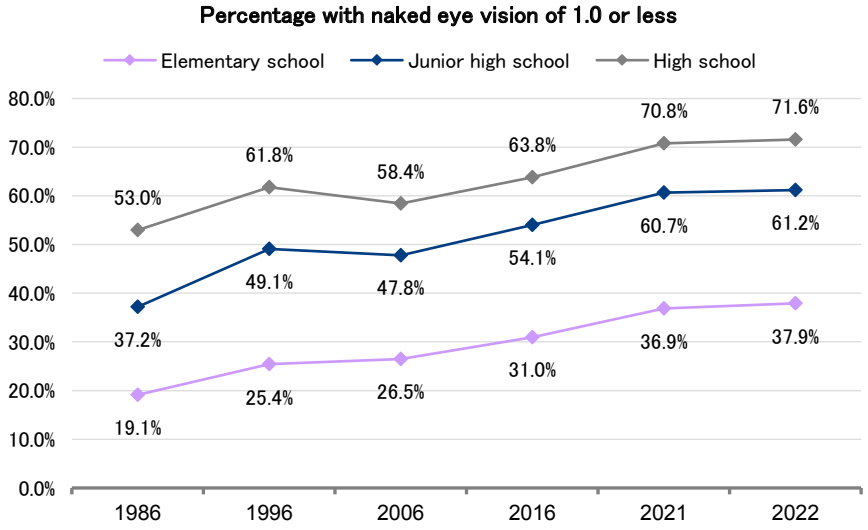
Source: Reprinted from the Company's results briefing materials

The myopic population has continued to increase as a trend globally, due partly to changes in lifestyle patterns. Myopia is now said to be one of the world's most familiar diseases. According to Company materials, the prevalence of myopia in the global population stood at around 28% in 2010 but is projected to rise to approximately 50% by 2050 (affecting around 4.7bn people). Since 2020, the World Health Organization (WHO) has sounded the alarm about the increasing prevalence of myopia worldwide, which has been due in part to more time spent at home because of the COVID-19 pandemic and the widespread use of smartphones. In particular, the number of people with high myopia is expected to increase to 9.8% of the global population by 2050, or about 930mn people, and myopia control has become an international issue.



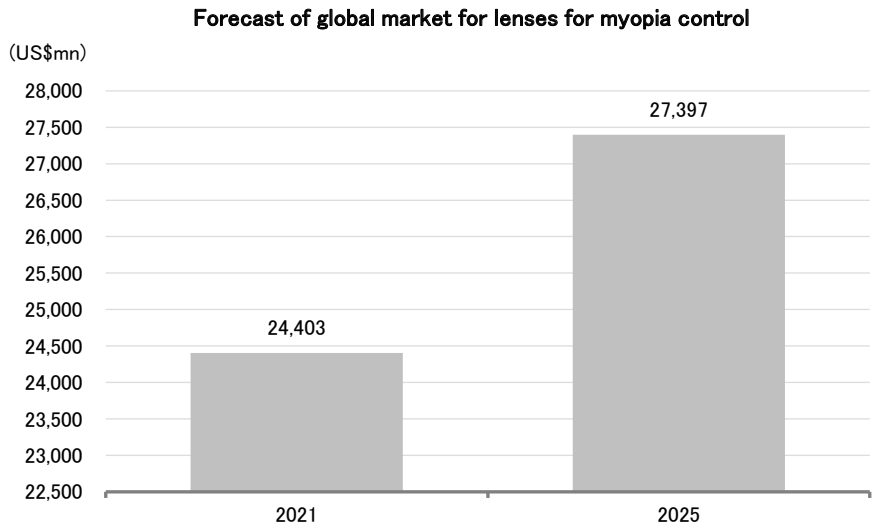
Note: The Impact of Myopia and High Myopia. Report of the Joint World Health Organization-Brien Holden Vision Institute Global Scientific Meeting on Myopia. March 2016.
Source: Prepared by FISCO from the Company's financial results briefing materials

Notably, the myopic population has been increasing sharply in Asian countries. There is an increasing number of countries where the prevalence of myopia in young people (20 years old or under) is over 80%, and by 2050, the cost of correcting myopia in Asian people is projected to reach ¥450tn. According to the "School Health Survey" by the Ministry of Education, Culture, Sports, Science and Technology, the percentage of students with naked eye vision of 1.0 or less is increasing every year and by 2022 71.6% of high school students and 61.2% of junior high school students have myopia, as do 37.9% of elementary school pupils, or more than 1 in every 3. If myopia progresses, the risk of severe, sight-threatening diseases such as glaucoma and cataracts is said to increase to a level 2-5 times higher than the risk faced by those with normal vision (emmetropia). Therefore, myopia is a disease for which a fundamental treatment is eagerly awaited.



Source: Prepared by FISCO from "School Health Survey," by the Ministry of Education, Culture, Sports, Science and Technology

The global market for myopia control lenses is projected to grow in size to US$27.3bn in 2025, from US$24.4bn in 2021. In this regard, developments going forward warrant close attention in terms of the likelihood of the Company encountering substantial demand if Kubota Glass, which is currently sold as a spectacle-type AR device, gains approval for use as a medical device with effectiveness in controlling myopia progression.



Note: Research by Azoth Analytics
Source: Prepared by FISCO from the Company's financial results briefing materials

(2) How Kubota Glass works

Kubota Glass technology is an active stimulation technology developed by the Company in-house that aims to control and treat the progression of myopia. It uses AR technology to actively stimulate the retina with artificial light. Images are projected using micro-LEDs, which emit a broad wavelength like natural light, and mirror lenses so that they are brought into focus in front of the peripheral retina, a process called myopic defocus. This serves to shorten the eye's axial length, or control its elongation, in order to control the progression of myopia. A POC clinical study has already been performed in humans and has confirmed that the technology is effective in controlling elongation of the axial length.* Data from clinical trials in children exists for competitor products, but the Company was the first to confirm the effectiveness in a trial conducted in adults.

> * A specialized ophthalmology research institute in the U.S. investigated the effect of an electronic tabletop optical projection device, which was a prototype based on Kubota Glass technology, on axial length in 12 subjects aged 21 to 32 years old with myopic tendencies. In May 2020, the Company announced that the results of the study confirmed that axial length decreases in the test eye compared to the control eye. In August 2020, the Company announced that it had confirmed similar effects with a wearable device on 25 subjects aged from 18 to 35.

The Company gained approval to manufacture medical devices in Taiwan and obtained ISO 13485:2016 certification for the design and development of ophthalmic medical devices in 2021, and furthermore completed medical device registration in the U.S. in 2022. However, the Company will move ahead with overseas expansion upon having initially perfected its products while selling spectacle-type AR devices in Japan. The Company has set its sights on developing products based on Kubota Glass technology, particularly with respect to future applications involving smart glasses, smart contact lenses, and other such products for a world without eyeglasses.

(3) Comparisons with competitor products

Devices controlling the progression of myopia are being developed by various companies, and one product has already been approved in places such as the U.S. and China as a medical device and is currently on the market.*1 There are a number of products that use myopic defocus, including MiSight, but they all employ passive stimulation with natural light and sharply differ from devices like the Company's that apply AR technology to actively and effectively stimulate the retina with artificial light. For this reason, Kubota Glass only needs to be worn 1-2 hours a day, whereas competitor products must be worn for 12-15 hours, nearly all day. One of the strong points of Kubota Glass is that it can effectively control the progression of myopia when used for a short period of time. Moreover, a comparison of data from clinical trials at various companies suggest that Kubota Glass is top-class in the data on rates of myopia progression control and axial elongation control, so its effectiveness has also been found to be superior to competitor products. There are other treatment methods, eye drops and orthokeratology*2, but they have not become widespread due to side effects and higher risk. Moreover, surgical procedures such as LASIK and ICL (intraocular contact lens) are also options, but they cannot be said to be a curative therapy as they are highly invasive and there is still a risk of sight loss due to elongation of the eye axis length.

*1 MiSight 1 day, a contact lens from CooperVision of the U.S. became the first product approved in the U.S. for sale in 2019.
*2 A method for correcting myopia in which a specially designed contact lens with high oxygen permeability (differs from a regular contact lens) is worn at night to correct the shape of the cornea and allows the person to go without corrective lenses during the day. It was approved in Japan in 2009.

The safety of Kubota Glass is assured. It meets the safety requirements for classification as a Group 1 instrument under ISO 15004, which regulates the safety of light emissions from ophthalmic instruments. Group 1 is the class of instruments in which "no potential light hazard exists." It has also been certified as a medical device for children under ISO 13485, which requires an even higher level of safety. The Company is currently selling Kubota Glass in Japan as an AR device that simulates outdoor settings given that extensive clinical trials are still needed to confirm the efficacy of Kubota Glass technology, which is necessary in order for the Company to sell such products as medical devices with demonstrable benefits and advantages. However, the Company has been proceeding with research amid a scenario where Kubota Glass technology has earned a certain level of praise among ophthalmologists and scholars involved in myopia research and who contend that the technology is well suited to its intended applications.

In 2023, the Company concluded a joint research agreement for prospective intervention trials with China Medical University Hsinchu Hospital in Taiwan. The trials involve 45 participants with pediatric myopia (one-year observation period), undertaken to evaluate effectiveness both with respect to a group of participants administered 0.01% low-dose atropine eye drops and with respect to another group of participants fitted with Kubota Glass eyewear. Meanwhile, the trials will also evaluate potential for synergistic effects arising from therapy combining both. The findings of this research warrant close attention. Kubota Glass eyewear is characterized by its low level of invasiveness, high level of safety assurance, good usability such that the eyewear can be put on and taken off by children as young as six years old, high level of effectiveness, and amenability to being used together with other myopia treatments. As such, we at FISCO believe that there is adequate room for development of a market in the future for use of Kubota Glass as a myopia control device.

Features and Effectiveness of Kubota Glass and Competitor Products

Devices for myopia treatments	Kubota Glass	MiYOSMART <HOYA>	Stellest <Essilor>	MiSight <CooperVision>	DOT Lens <SightGlass Vision>	Violet light-transmitting lens <Tsubota Laboratory>	Low-level red-light therapy	Low-concentration atropine eyedrops (0.05%)	Orthokeratology
Mechanism of action	Active stimulation: Peripheral myopic defocus	Passive stimulation: Peripheral myopic defocus	Passive stimulation: Peripheral myopic defocus	Passive stimulation: Peripheral myopic defocus	Passive stimulation: Peripheral contrast reduction	Passive stimulation: Transmittance of violet light	Active simulation: Exposure to bright red light	Unknown	Passive stimulation: Peripheral myopic defocus
Specification	Spectacles lens	Spectacles lens	Spectacles lens	Soft contact lens	Spectacles lens	Spectacles lens	Tabletop device	Eye drops	Hard contact lens
Wear time	1.5–2 hours/day, 6 days/week	15 hours/day, 7 days/week	12 hours/day, 7 days/week	12–13 hours/day, 6 days/week	12 hours/day, 7 days/week	Constant wear	3 minutes, 2 times/day (4 hours between times), 5 days/week	N/A	When sleeping
Average age of test subject	13.6 years old	10.4 years old	10.7 years old	10.1 years old	8.1 years old	9.4 years old	9.4 years old	8.5 years old	9.2 years old
Spherical equivalent refraction (SER) reduction	0.46D	0.38D	0.53D	0.40D	0.40D	0.22D	0.59D	0.54D	N/A
Rate of myopia progression control	148%	69%	65%	69%	74%	27%	75%	67%	N/A
Axial length (AL) reduction	0.20mm	0.21mm	0.23mm	0.15mm	0.15mm	0.07mm	0.26mm	0.21mm	0.17mm
Rate of axial elongation control	91%	66%	64%	63%	50%	14%	66%	51%	45%

Note: The data on the effectiveness of competitor products is taken from the results of clinical trials for one year. The data on the effectiveness of Kubota Glass is estimated based on the results of a six-month clinical trial in children.
Source: Prepared by FISCO from the Company's financial results briefing materials

(4) Sales overview and plans for sales and development going forward

In August 2022, the Company launched sales of Kubota Glass in Japan for use as a spectacle-type AR device that simulates outdoor activities (priced at ¥770,000 tax inclusive).* It initially took around three months' time from order placement to delivery of the made-to-order eyewear, partially due to semiconductor shortages. However, the lead-time was recently shortened to a span of one to two months upon alleviation of the semiconductor shortages. FY12/23 sales amounted to ¥39mn (up ¥31mn YoY), with several dozen units having been sold. Adults between the ages of 40 and 60 years old account for approximately 50% of the purchaser demographic, a relatively large proportion of whom are business professionals. There are also some instances where purchasers buy additional products for their children after having confirmed effectiveness of the product upon having used it themselves. Whereas sales channels handling the product consist of a directly-managed store (one location), the Company's e-commerce website, and certain ophthalmology clinics and eyewear retailers (15 locations), among those sales channels the directly-managed store accounts for the highest proportion of sales. Another distinctive characteristic of the product is the notion that foreign nationals account for around 40% of product inquiries and store visits. By country, whereas the Company receives many product inquiries from China, Taiwan and elsewhere in the Asia region, it also encounters product inquiries from a wide range of other regions including Europe, North America, the Middle East, and Africa.

* Although the Company began selling Kubota Glass eyewear via a soft launch in the U.S. in June 2022 (priced at US$5,200) and furthermore concluded a distributor agreement with a major Taiwanese seller of ophthalmic instruments in July 2022, the Company currently limits sales of the product to Japan only in order for it to assign priority to achieving product improvement and building support services.

Kubota Glass

Source: Published in Kubota Glass official SNS

Feedback received by the Company in purchaser surveys was both negative and positive. Remarks on the negative side included, “the eyewear had no immediate effect,” “it took time to make optimal positional adjustments,” and “the eyewear stopped working after three months (due to initial defects).” Remarks on the positive side included, “the pace of my child’s myopia progression has slowed down,” “the eyewear resulted in reduced eye fatigue,” and “I now use eye drops less frequently.” Improvement in blood circulation around the retina due to consistent exposure of the retina to light by micro-LEDs conceivably relieves eye fatigue. Additionally, an open-ended questionnaire was administered to 283 adults who participated in a seminar on myopia held in October 2023 and were fitted with Kubota Glass eyewear. Feedback from 68.0% of the 277 respondents was positive given remarks such as those reporting sharper and improved vision. Conversely, feedback from 12.0% of the respondents was negative given remarks that included reporting not having sensed any particular change, feeling discomfort, and experiencing unclear vision. Based on such collective results of the survey, the Company has concluded that greater added value is needed with respect to Kubota Glass, which will involve making the product more user-friendly through further improvements and taking steps to enhance support services. As such, the Company will assign priority to engaging in such initiatives during FY12/24.

In terms of services, the Company adopted an appointment-only model in August 2023 based on the notion that the Company needs to thoroughly explain its products to customers visiting the directly-managed store. In September 2023, the Company also began providing an installment-based payment service and the Kubota Care product warranty support service (¥39,000 tax inclusive).* In February 2024, the Company made it possible for customers to use its installment-based payment service when making purchases through its e-commerce website. In December 2023, Kubota Glass became available at the “SUGI + Haneda Innovation City” Sugi Pharmacy location operated by Sugi Pharmacy Co., Ltd. Situated within a commercial facility adjacent to Haneda Airport, the store location enlists an interactive store approach whereby customers are able to experience cutting-edge healthcare solutions firsthand under the store’s future of healthcare concept. Customers are able to place orders for products of their liking on the spot via the e-commerce website after having tried out actual products at the store. Going forward, the Company intends to enhance its support structure in part by regularly notifying existing customers via SMS and other channels to encourage repeat purchases.

* Under the Kubota Care service, customers activate a one-year manufacturer warranty upon having registered within 30 days subsequent to receipt of a product. They may also opt for a three-year product warranty for services at a discounted price (¥12,000 tax inclusive for lens replacement, ¥9,900 tax inclusive for nose bridge replacement, and nose pad replacement free of charge).

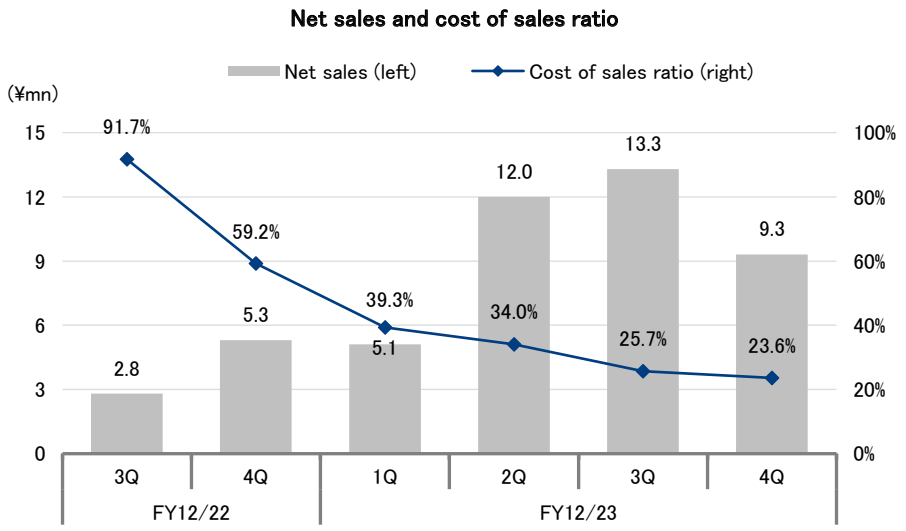
The Company will also persist with its initiatives to heighten awareness through seminars and events under its ZERO Diopter Project initiated in 2023. In particular, the Company will actively expand its health management support services while also holding forums that include seminars for schools and collaborative events* with business enterprises, amid a scenario where it has been encountering an increasing number of requests for seminars from large corporations given that eye strain has been added as one of the evaluation benchmarks enlisted in the 2024 Certified KENKO Investment for Health Outstanding Organizations Recognition Program of Japan's Ministry of Economy, Trade and Industry (METI).

* In March 2024, the Company held a collaborative event combining e-sports and English conversation language learning in conjunction with Gecipe Inc., which engages in metaverse business ventures centered around e-sports.

When it comes to expansion in overseas markets, we at FISCO contend that the Company is likely to take concrete action no earlier than 2025 or thereafter given a high likelihood of such initiatives being taken subsequent to it perfecting its products and services in Japan. In terms of sales territory, in addition to the U.S. and Taiwanese markets where the Company obtained authorization for sales of Kubota Glass eyewear as a medical device in 2022, China has also emerged as a strong candidate market given that the Company has received many business inquiries from the region. In China, the Company concluded a letter of intent related to sales of Kubota Glass with Sanming City, Fujian Province in August 2023. Although specific details of the arrangement have yet to be determined, the Company has apparently been engaging in ongoing information exchange. The city of Sanming (population 2.8 million) has been designated as a model city for medical treatment and health in Fujian Province and is accordingly known as an urban location that engages in progressive initiatives in the healthcare sector. In 2018, the Chinese government drew up a national plan that stipulates myopia reduction targets for individual municipalities and accordingly sets forth the objective of reducing incidence of myopia among high school students to no more than 70% by 2030. This gives rise to possibilities in terms of Kubota Glass being enlisted for use under one of Sanming City's myopia control measures going forward. The Company has also been engaging in negotiations with business enterprises hoping to enter into distributor agreements for sales in China.

On the product development front, the Company plans to amass evidence in the course of conducting small-scale clinical trials as well as long-term trials carried out under various conditions, with aims that include pinpointing variations in efficacy associated with trial subject attributes in determining if additional efficacy can be obtained in part by modifying axial length and index of refraction in conjunction with improvements to existing products. The Company will also take steps to reduce manufacturing costs by revamping design and components. Looking at the Company's cost of sales ratio on a quarterly basis subsequent to launch of Kubota Glass, the cost of sales ratio decreased from 91.7% in FY12/22 3Q to 23.6% in FY12/23 4Q. The decrease is seemingly attributable to the Company's efforts geared to reducing component costs particularly with respect to semiconductors. The Company apparently expects that the cost of sales ratio will hold to the 20% range for the time being. Meanwhile, the Company has been moving forward with initiatives also encompassing those under its IP strategy with its sights set on seeking commercial opportunities with contact lenses in the future.

Outline of major development pipeline projects and status of progress



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

eyeMO likely to be used in specified clinical study of patients with diabetic macular edema (DME) in Japan as well upon conclusion of agreement for eyeMO co-development with major Indian corporation

2. eyeMO home-based remote retinal monitoring device

(1) eyeMO features and competition

eyeMO* is a home-based remote retinal monitoring device for patients with wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and other retinal diseases. Patients use the device at home to measure and take images of the thickness of their own retina, and their attending physician reviews the data over the Internet and determines whether treatment (administering a drug) is necessary.

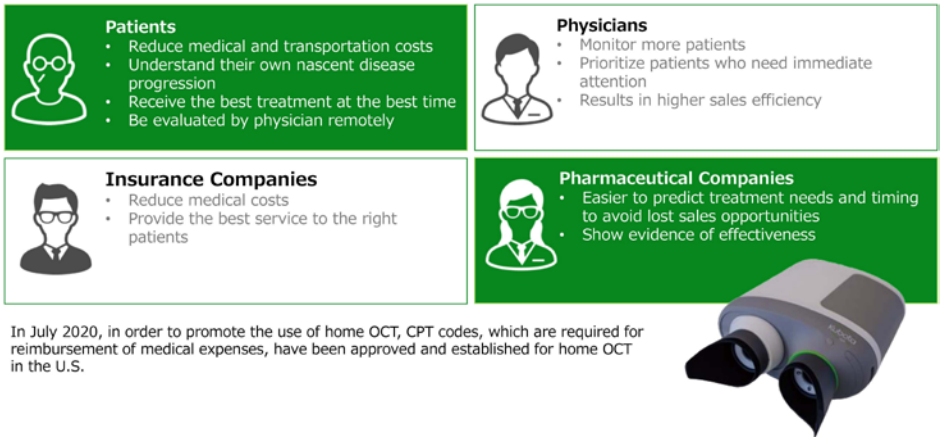
> * In December 2023, the Company decided on the product name "eyeMO," which was previously referred to as Patient Based Ophthalmology Suite (PBOS). The product name "eyeMO" is a combination of the two words "eye" and "monitoring."

Previously, these patients regularly visited hospitals to undergo OCT* tests and receive treatment (intraocular injections) as necessary. eyeMO enables such tests to be easily conducted at home. Doing so provides advantages such as eliminating the need to regularly visit hospitals for tests, allowing patients to be treated at the right time, and reducing the risk of a deterioration in symptoms. Many patients experience worsening symptoms when they are unable to regularly visit hospitals due to long distances or financial problems. For this reason, there is a large unmet need for a device that can be used to conduct tests easily at home. For hospitals, it is more beneficial from a management perspective to increase time spent on treatment rather than on testing. Pharmaceutical companies could also benefit from a higher sales volume than before as drugs are administered more appropriately. In these ways, one feature of this home-based ophthalmic care framework is that all related parties can benefit from it.

> * OCT (Optical Coherence Tomography): A testing device that uses infrared rays to take precise cross-sectional pictures of the retina. OCT is used as diagnostic tool for patients with retinal diseases such as glaucoma and age-related macular degeneration (AMD).

Outline of major development pipeline projects and status of progress

Potential advantages of remote retinal monitoring in the U.S.



Source: Reprinted from the Company's results briefing materials

No companies have commercialized home OCT yet. Only a few companies have developed home OCT products, including the Company, Notal Vision, Inc. and certain others. The Company's product offers a user-friendly design that reflects the needs of elderly patients. For example, the product has large buttons and a function that helps users operate the device with voice guidance. The testing time is shorter than competitor Notal Vision's product and it is easier to use. At the same time, it only has the minimum functions necessary. Approval for Notal Vision's product that will be sold in the U.S. is currently pending, so the Company is a little behind, but it appears to still have the opportunity to catch up going forward. There are still some institutional issues, including the risk of patients conducting simple tests at home, and some believe that the full-scale spread of the system will come only after an institutional design has been established.

(2) Co-development agreement concluded with AUROLAB

In December 2023, the Company announced that it had signed a letter of intent for co-development of eyeMO with AUROLAB (India), a medical device manufacturer specializing in the field of ophthalmology. According to the letter of intent, AUROLAB is to acquire an exclusive license relating to product development, manufacture, and sales with respect to eyeMO in seeking commercialization of the low-cost eyeMO device in the markets of India, Pakistan, Afghanistan, Bangladesh, Bhutan, Maldives, Nepal, and Sri Lanka, as well as select untapped markets in the Middle East, Asia, and Africa. Whereas the Company will hold discussions regarding specific contractual terms going forward, the arrangement will conceivably not affect the Company's short-term financial results given that it is poised to receive royalties based on sales.

AUROLAB is primarily engaged in the manufacture of intraocular lenses, surgical sutures, pharmaceutical products, surgical blades, and other such products. It is a group company of Aravind Eye Care Hospital (AECS), which is one of the most prestigious ophthalmic hospitals worldwide. AECS operates 14 ophthalmic hospitals, 6 outpatient eye examination centers, and 108 primary ophthalmic healthcare facilities in South India, and is renowned for ranking among the top in the world in terms of annual surgical procedure volume. Meanwhile, AUROLAB sells medical devices to ophthalmic hospitals in over 160 countries worldwide, beyond the AECS Group.

AUROLAB seeks to play a part in enabling early detection of retinal diseases while also furnishing support to patients with age-related macular degeneration (AMD) and diabetic macular edema (DME) by bringing the mass-produced and low-cost eyeMO device to ophthalmology clinics, public facilities and other such end-users. Developments regarding AUROLAB warrant close attention going forward.

(3) Conclusion of vendor agreement with IQVIA Services Japan

In December 2023, the Company announced that it had concluded a vendor agreement for eyeMO with IQVIA Services Japan, which is to act as a coordination management agency with respect to use of eyeMO in a specified clinical study to be funded by Chugai Pharmaceutical. Meanwhile, although the Company is poised to earn lease proceeds from use of the eyeMO device going forward, the monetary amount is likely to be negligible given that few units will be available for lease. The Company intends to conduct a feasibility study sometime in spring 2024 prior to the clinical study. The specified clinical study is to be carried out in part to verify whether patients with diabetic macular edema (DME) are able to use the eyeMO device at home on their own, and also to have medical professionals evaluate the validity of retinal thickness measurements and measurements of retinal status for identifying the presence of intraretinal and subretinal edema.

In looking at the status of the eyeMO clinical trials, two physician-led clinical trials have been completed. Initiated in January 2023 at the Joslin Diabetes Center, which is affiliated with Harvard University Medical School in the U.S., one of the trials evaluated the device's utility as a screening device for diabetic retinopathy patients, and the other trial compared the device with other OCT devices on the market. Findings of the trials are to be presented at an international conference. Meanwhile, further clinical trials are likely to be carried out going forward.

(4) Business model and market size

The Company's business model is likely to be based on a format where monthly usage fees are collected as a rental service, which will reduce the initial cost burden on patients. If insurance is applied, the burden on patients can be greatly reduced, so the adoption of eyeMO can be expected to accelerate. Because no fundamental treatment exists for macular degeneration and other retinal diseases, patients are highly likely to continue using eyeMO once they start using it, unless they become blind. As a recurring-revenue business, eyeMO is likely to grow into a steady source of revenue.

According to the International Diabetes Federation (IDF), approximately 460 million people were living with diabetes as of 2019, with that number expected to reach some 570 million by 2030 and 700 million by 2045. Among the various complications associated with diabetes, diabetic macular edema (DME) poses a risk of blindness. According to the Japan Preventive Association of Lifestyle Related Disease, approximately 10 million people are living with diabetes in Japan (including those strongly suspected of having diabetes), with estimates of around 500,000 people living with diabetic macular edema based on prevalence rates domestically and approximately 23 million people worldwide. Given that a definitive cure for diabetic macular edema has yet to be developed, the number of patients is expected to increase annually in proportion to the number of diabetes patients. As such, we at FISCO accordingly contend that there is significant potential for widespread adoption of eyeMO as an accessible diagnostic tool. An assumed annual rental fee of ¥10,000 for an eyeMO device and an adoption rate of 30% suggests potential for ¥1.5bn annually, and an assumed adoption rate of 10% worldwide suggests potential for ¥23.0bn annually.

Considering the option of launching emixustat hydrochloride (HCl) indicated for Stargardt disease enlisting the accelerated approval program in Japan and other countries

3. Emixustat hydrochloride (HCl)

Stargardt disease (STGD) is a genetically inherited retinal disease. The main symptoms are a decrease in vision and color blindness presenting from childhood to young adulthood. It is also known as juvenile macular degeneration and is estimated that there are just under 150,000 patients in Europe, the U.S., and Japan*1, with an incidence of 1 in 8,000 to 10,000, making it a rare disease. It is reported that most patients' vision drops to below 0.1. No effective treatments have been established at this time, making STGD a disease with high unmet medical needs. Emixustat hydrochloride (HCl) (hereinafter "emixustat") is designated in the U.S. as an orphan drug. According to a market research report*2, the STGD market will be approximately ¥230.0bn in 2027 (at a conversion rate of USD = ¥145), and the Company judges that its development has significant meaning.

*1 Market Scope, 2015 report on the Retinal Pharmaceuticals & Biologics Market; UN World Population Prospects 2015
*2 WISEGUY RESEARCH CONSULTANTS PVT LTD Global Juvenile Degeneration (Stargardt Disease) Market Research Report- Forecast to 2027

In 2022, the Company announced results of a phase 3 clinical trial (194 trial subjects) of emixustat HCl. In summary, whereas the Company ultimately did not file for approval due to a lack of significant statistical difference observed relative to the placebo group with respect to the primary endpoint and secondary endpoints, it ended up reconsidering its development strategy given that results of detailed data analysis suggested the presence of a significant difference limited to patients in the early stages of the disease.* Because the Company has been encountering difficulties with respect to carrying out clinical trials independently due to its current financial situation, it is currently preparing to hold discussions with the Pharmaceuticals and Medical Devices Agency (PDMA) to determine the possibility of it filing for approval for manufacture and sales of the drug enlisting means such as the accelerated approval program in Japan and other countries. Meanwhile, Japan's Sakigake Designation System was revised in December 2023, thereby allowing for citation of data from clinical trials conducted overseas with respect to clinical trial and other such data required when filing for approval. Given that emixustat HCl safety and tolerability have been confirmed, we at FISCO contend that it conceivably may gain approval if the Company files for the Sakigake designation.

* Results of overall case data showed the progression rate of the primary endpoint of macular atrophy in the group administered emixustat was 1.280 mm^2/year and the placebo group was 1.309 mm^2/year and there were no significant differences (p=0.8091). However, based on the results of further analysis, when limiting the data to the group of test subjects with a smaller atrophy area at the baseline (in the early stages of the disease), it was confirmed that the macular atrophy progression rate in the 24th month in the emixustat group was controlled substantially, at 40.8%, compared to the placebo group, which suggested a significant difference (P=0.0206, emixustat group n=34, placebo group n=21). The small sample size for initial symptoms is due to the fact that the subject age was set to 16 years and older.

The Company must determine whether options in terms of either handling sales itself or otherwise concluding a sales partnership agreement when filing for manufacture and sales approval. Prior to filing for approval in the event that it has opted to handle sales in-house, the Company will need to establish a three-pillar pharmaceutical affairs structure (overall manufacturing and sales manager, quality assurance manager, and safety control manager) and will also need to establish a distribution structure and other such frameworks. On the other hand, the Company will be able to assign a majority of the responsibility for establishing such structures to a partner if it opts to conclude a sales partnership agreement. We at FISCO deem that the ideal situation would be that of the Company concluding a partnership agreement with a pharmaceutical company that exhibits potential as a sales partner in Japan and abroad, as this would alleviate such cost burdens. In either case, the Company is likely to determine its trajectory by the end of 2024. As such, developments in this regard warrant close attention.

NASA project currently suspended, but may be resumed with change in government administration

4. SS-OCT, a compact OCT device for astronauts

In 2019, the Company signed a development agreement with NASA to develop the Swept Source-OCT (hereinafter, "SS-OCT"), a compact OCT device, in order to conduct research into eye disorders that can occur in spaceflight. Phase 1 of the development mission was completed at the start of 2020. Phase 2 of development was suspended due to NASA's development budget being cut as a result of control of the U.S. government passing to the Democratic Party in 2021 and federal budget priority being put on pandemic-control measures to address the COVID-19 pandemic, and has remained suspended ever since.

A research report* has stated that approximately 69% of long-duration spaceflight crewmembers present with Spaceflight Associated Neuro-ocular Syndrome (SANS), which could lead to vision impairment and blindness. Based on this report, the purpose of this project is to research the effects of spaceflight on the ophthalmology field. The commercially available off-the-shelf (COTS) OCT devices currently deployed to the International Space Station (hereinafter, "ISS") are benchtop models and complicated to operate. In fact, astronauts staying in the ISS for several months were only able to conduct tests three times. The compact SS-OCT to be developed will allow the astronauts themselves to take daily measurements and save the records. The impact of spaceflight on retinal disorders will be analyzed in greater detail and this will help in the mitigation and prevention of disease risk.

> * Eye disorder symptoms such as blurry vision, optic disc edema, posterior globe flattening, and cotton wool spots have been reported.

The development mission is divided into three phases. Phase 1 of the mission was to perform Proof of Concept (POC) testing of a device using durable and inexpensive lasers. The Company set out to develop a device that measures the shape of the optic disc with high resolution using multiple lasers. In January 2020, the Company conducted a demonstration of the device at NASA and received strong evaluations from the NASA project personnel.* The Company completed phase 1 of development in February 2020 and submitted a development report to NASA and TRISH in April 2020. The Company posted development service revenue of ¥37mn from the NASA project as revenue for FY12/20.

> * The Company received the following comments from NASA personnel: "Your device is quite impressive with its small size, ease of use and its speed in data acquisition. A device such as this could be quite helpful on the International Space Station aiding NASA in its quest for understanding how spaceflight affects some of our astronauts' eyes," and, "All Phase 1 goals were not only attained, but surpassed. Physically, it has the appearance of a polished product, and it rests lightly and comfortably in your hands. I am truly excited to see the Phase 2 deliverable."

Phase 2 will comprise the process of determining the operationally required specifications regarding what kinds of imaging and analysis techniques will be employed using this device to investigate eye disorders caused by spaceflight. In Phase 3, the final stage, the Company will develop a device that will be usable in the actual spaceflight environment. In particular, together with its partner companies, the Company will jointly develop hardware that has the durability needed to withstand exposure to cosmic ray radiation and can be operated by the astronauts themselves in a zero-gravity environment.

The project is currently suspended but the Company meets regularly with NASA's project representative and has confirmed NASA's intention to continue with the project. For this reason, it is expected to resume as soon as a development budget is made available. At NASA, budgetary allocations are beginning to be made again, with a new moon-landing project getting started, for example, so we at FISCO believe that there is a sufficient likelihood the project will be resumed going forward.

Business performance and financial condition

FY12/24 results forecasts not disclosed, but Company intends to control costs in operations other than those of Kubota Glass

1. Business performance trends

(1) FY12/23 consolidated results

In the consolidated results for FY12/23, the Company recorded revenue of ¥39mn (up ¥31mn YoY), an operating loss of ¥1,504mn (a contraction of ¥534mn), loss before tax of ¥1,489mn (a contraction of ¥526mn) and loss attributable to owners of parent of ¥1,489mn (a contraction of ¥526mn).

The Company's revenue increased due to higher sales of Kubota Glass. In business expenses, research and development expenses declined by ¥724mn YoY to ¥788mn due to a decrease in development expenses for emixustat HCl and the wearable myopia control device. Additionally, SG&A expenses increased ¥31mn to ¥632mn mainly due to higher sales promotion expenses in relation to the Kubota Glass business. An impairment loss of ¥110mn was recorded under other operating expenses. This involved reexamination of the recoverable amount of assets associated with the Kubota Glass business, resulting in a decrease in the book value of such assets to the recoverable amount.*

* On March 18, 2024, the Company released a partial correction of its financial results as a result of it having recorded impairment loss in FY12/23.

FY12/23 consolidated results

(¥mn)

	FY12/22 Results	FY12/23 Results	YoY	
			Change	% change
Revenue	8	39	31	383.2%
Business expenses	2,119	1,433	-686	-32.4%
Cost of sales	5	11	5	102.3%
Research and development expenses	1,512	788	-724	-47.9%
SG&A expenses	601	632	31	5.2%
Other operating income	73	-110	-184	-
Operating profit (loss)	-2,038	-1,504	534	-
Profit (loss) before tax	-2,015	-1,489	526	-
Profit (loss) attributable to owners of parent	-2,015	-1,489	526	-

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

(2) Outlook for FY12/24 results

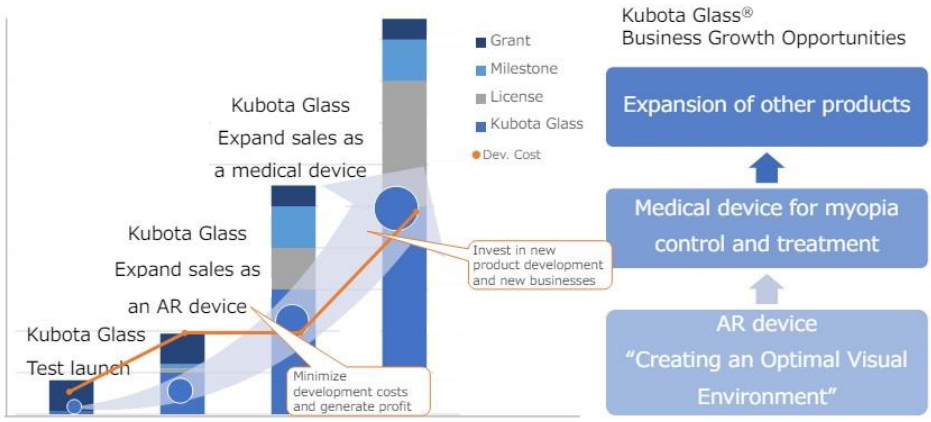
The Company did not disclose consolidated results forecasts for FY12/24. Revenue appears to be nearly entirely accounted for by revenue from sales of Kubota Glass. But results forecasts are difficult at the current time because the product is newish and it is difficult to determine objective demand at this stage. And, on the expenses side, while reflecting customer opinions on current products, the Company has decided to prioritize additional development while efforts will continue to be made to reduce manufacturing costs. Thus, due to the possibility of fluctuations in development costs, the Company has determined that it is difficult to rationally estimate earnings at this stage. The Company plans to promptly disclose its outlook when it becomes possible to make rational calculations based on the progress of the business going forward.

The Company is holding to its policy of paring down overall business expenses other than development expenses and sales-related expenses associated with Kubota Glass. The Company plans to reduce expenses of its U.S. subsidiary under its cost review efforts. The increase in yen-denominated costs incurred by the Company's U.S. subsidiary is largely attributable progressive depreciation of the yen over the last several years.

(3) Business strategy going forward

The Company's business strategy over the medium term entails initially generating profits by extending sales of Kubota Glass for use as an AR device and keeping development expenses to a minimum, after which it will seek expansion worldwide while working with partner companies in developing and selling Kubota Glass for use as a myopia control and treatment medical device. The Company will then furthermore proceed with development of other products drawing on the profits it has generated previously, thereby increasing its revenues as it gains licensing income as well as milestone payments.

Business Model : Business Growth Opportunities



Source: Reprinted from the Company's financial results briefing materials

Company to procure funds for operating activities from the stock market to sustain operations during the development stage for the time being

2. Financial condition

Total assets at the end of FY12/23 declined by ¥1,402mn compared to the end of FY12/22 to ¥3,016mn. In terms of the main factors behind this change, in current assets, cash and cash equivalents declined ¥1,281mn from the end of FY12/22 to ¥2,767mn in connection with expenditures on operating activities and inventories increased ¥29mn to ¥36mn. In non-current assets, property, plant and equipment decreased ¥74mn and other non-current assets decreased ¥16mn.

Total liabilities were ¥370mn, a decrease of ¥100mn from the end of FY12/22. Current and non-current lease liabilities declined by ¥5mn to ¥142mn, along with decreases of ¥84mn in accrued liabilities and ¥8mn in trade payables. Moreover, total equity amounted to ¥2,646mn, a decrease of ¥1,302mn from the end of FY12/22. Share capital and capital surplus increased by a combined ¥185mn due to the issuance of shares upon exercise of share acquisition rights. Meanwhile, loss brought forward (accumulated deficit) increased due to the recording of loss attributable to owners of parent of ¥1,489mn.

Cash on hand at the end of FY12/23 was ¥2,767mn, continuing a downtrend, but the Company has secured around two years' worth of funds for operating activities. The Company is currently in the process of raising funds through exercise of its 28th round of share acquisition rights, having thus far raised an additional ¥16mn in February 2024. With 50,367 such share acquisition rights yet to be exercised (equivalent to 5,036,700 shares), the Company would be able to raise around ¥400mn if it were to exercise all such share acquisition rights at the ¥81 minimum exercise price. Until Kubota Glass achieves profitability, however, the Company will have to incur expenses that include sales and marketing expenses, expenses for clinical trials to amass evidence, and additional development expenses, while also presumably having to incur other pipeline-related development costs. As such, the Company is bound to keep raising funds from the stock market while assessing circumstances with respect to cash on hand for the time being. In order for the Company to increase its corporate value amid these circumstances, FISCO contends it is crucial that its management focus on extending sales by enhancing strengths of the Kubota Glass brand while also moving toward achieving profitability with business involving eyeMO and emixustat hydrochloride (HCl). As such, we at FISCO deem that such developments warrant close attention going forward.

Consolidated balance sheet and business indicators

(¥mn)

	End of FY12/20	End of FY12/21	End of FY12/22	End of FY12/23	Change
Current assets	6,417	4,625	4,181	2,869	-1,312
Cash and cash equivalents	6,317	4,415	4,048	2,767	-1,281
Non-current assets	274	207	237	147	-90
Other financial assets	22	-	-	-	-
Total assets	6,691	4,832	4,419	3,016	-1,402
Current liabilities	506	542	360	282	-77
Non-current liabilities	192	137	109	87	-22
Total liabilities	698	679	470	370	-100
Total equity	5,993	4,152	3,949	2,646	-1,302
<business indicators>					
Ratio of equity attributable to owners of parent	89.6%	85.9%	89.4%	87.7%	-1.7pt

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

FISCO

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