

Kubota Pharmaceutical Holdings Co., Ltd.

4596

Tokyo Stock Exchange Growth Market

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* This is an English translation of a report issued on April 6, 2022.

Summary

Expecting the soft launch of Kubota Glass™ and phase 3 clinical study results for a drug candidate for Stargardt disease to be revealed in the second half of 2022

Kubota Pharmaceutical Holdings Co., Ltd. <4596> (hereinafter “the Company”) develops innovative therapeutic drugs and medical devices to preserve and restore vision, in keeping with its Corporate Philosophy, “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; emixustat hydrochloride (HCl), which is a drug candidate indicated for Stargardt disease*; and Patient Based Ophthalmology Suite (PBOS), which is a remote retinal monitoring device for patients with retinal diseases such as age-related macular degeneration (AMD).

* Stargardt disease (STGD): STGD is a genetically inherited retinal disease. It is also known as juvenile macular degeneration. With the progression of symptoms, STGD causes a decrease in vision and color blindness. It is a rare disease for which an effective treatment has not yet been established. The number of patients in Europe, the U.S. and Japan is estimated to be nearly 150,000, combined.

1. Status of development of Kubota Glass

Kubota Glass uses an original technology designed to actively stimulate the retina with artificial light (active stimulation technology*1). This technology enables Kubota Glass to reduce the eye’s axial length*2 more effectively than other companies’ products already in use, which employ passive stimulation with natural light. Kubota Glass is attracting attention for its potential to be a highly effective device in controlling the progression of myopia. The Company had planned to carry out the soft launch*3 of Kubota Glass in Taiwan in 2021, but the soft launch is now expected to be pushed back to the second half of 2022. This postponement was due partly to the impact of the COVID-19 pandemic, and a change in the manufacturing contractor for Kubota Glass. According to the results of a pre-launch market survey, there seems to have been strong interest in Kubota Glass. Depending on how well sales perform, the Company might possibly sell Kubota Glass in other Asian areas and countries as well. In addition, the Company plans to closely monitor sales conditions in Taiwan before it decides when to initiate global clinical studies, which will be needed to sell Kubota Glass as a medical device. The global myopic population has been increasing year after year. In terms of the potential market size, the Company believes that the worldwide market has the potential to grow as large as ¥1,300bn by 2030. Myopia is said to elevate the risk of retinal diseases that can lead to future blindness. In the Asian region, the prevalence of myopia in children and young adults (20 years old or under) has been rapidly increasing and myopia has become a public health issue. Considering these and other factors, we at FISCO believe that there is tremendous potential demand for Kubota Glass, and that future trends should be watched closely.

*1 Active stimulation technology: The Company’s original technology that seeks to treat and control the progression of myopia by projecting myopically-defocused virtual images generated using nanotechnology (micro-LEDS) on the peripheral visual field to actively stimulate the retina. Patents are pending.

*2 The length from the cornea to the retina. The eye’s axial length for adults is around 24 mm on average. An elongation of even 1-2 mm can cause parallel rays of light to be brought to focus before the retina, resulting in blurred sight at a distance. (This condition is known as myopia.)

*3 Test sales undertaken for the purpose of troubleshooting and validating market fit in the process from manufacturing to sales, delivery, and aftercare.

Summary

2. Status of development of other major pipeline projects

The database lock for the phase 3 clinical study of emixustat HCl, a therapeutic drug candidate for Stargardt disease (STGD), is expected to be completed sometime around Q3 FY12/22. Depending on this data, the Company plans to submit the New Drug Application for emixustat HCl. Moreover, by the first half of 2023, the Company is expected to make progress on sales partnership agreements, which are currently under discussion with more than 10 companies, including major pharmaceutical companies. According to the Company's disclosure materials, the size of the market for STGD treatments is expected to grow to approximately US\$1.6bn in 2027,* highlighting the high expectations for this market. Meanwhile, regarding Patient Based Ophthalmology Suite (PBOS), in January 2022, the Company initiated a small-scale performance verification test at a medical institution in Japan. The Company's policy is to seek to conduct collaborative development and commercialization in the U.S. by advancing discussions with candidate partner companies based on objective evidence supplied by third-party institutions.

| * WISEGUY RESEARCH CONSULTANTS PVT LTD Global Juvenile Degeneration (Stargardt Disease) Market Research Report |

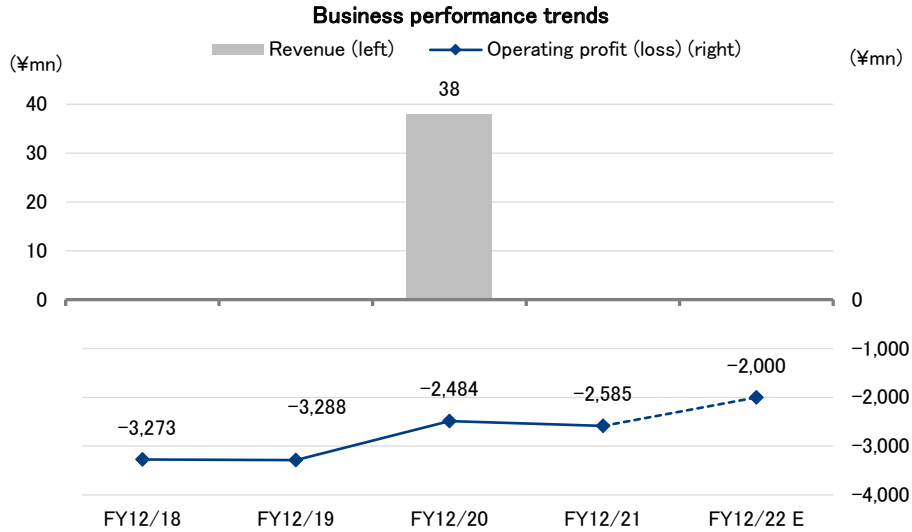
3. Business performance trends

Looking at consolidated results for FY12/21, the Company posted no revenue and operating loss of ¥2,584mn (compared with a loss of ¥2,484mn in FY12/20). Research and development (R&D) expenses rose ¥67mn YoY to ¥2,040mn due to an increase in development expenses for Kubota Glass. The Company does not expect to post revenue in FY12/22. However, if the sale of Kubota Glass begins, the Company will post revenue in FY12/22. Moreover, operating loss is expected to contract from FY12/21 to ¥2,000mn in FY12/22, due to a decrease in R&D expenses. Cash on hand stood at ¥4,415mn as of the end of FY12/21. Although the Company has secured around two years' worth of funds for operating activities, the Company is still in a development stage, so it will need to review its fund procurement situation as necessary. In 2H FY12/22, the soft launch of Kubota Glass and the results of the clinical study of the therapeutic drug candidate for Stargardt disease will be revealed, both of which hold an important key to determining the Company's future growth prospects. Accordingly, these trends should be watched closely.

Key Points

- Kubota Glass has the potential to grow into a key device for the treatment and control of the progression of myopia, helping to reduce the risk of future blindness
- The Company will advance negotiations on partner agreements for PBOS based on data from performance verification tests conducted by third-party institutions in Japan
- If the Company succeeds in developing a drug for Stargardt disease, the new pharmaceutical could have revenue potential of more than ¥100bn
- The Company aims to post revenue from Kubota Glass in FY12/22

Summary



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

Company profile

A U.S.-born venture 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, U.S.A., 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.)

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 (HCI), 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 HCI 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 HCI for geographic atrophy secondary to dry age-related macular degeneration. Currently, the Company is independently advancing a phase 3 clinical study of emixustat HCI for Stargardt disease, which is a genetically inherited retinal disease.

* 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 HCI has the effect of selectively inhibiting an enzyme called RPE65 that performs a key function in the visual cycle.

Looking at other main development pipeline projects besides Kubota Glass, a wearable myopia control device aiming to treat and control the progression of myopia, the Company is pursuing Patient Based Ophthalmology Suite (PBOS), which is a remote retinal monitoring device for retinal diseases such as age-related macular degeneration (AMD). PBOS allows patients to self-measure the condition of their retina at home. Moreover, in March 2019 the Company concluded a development agreement with TRISH,* which is a consortium affiliated with NASA, to develop a miniature OCT (Optical Coherence Tomography) device together with NASA. The miniature OCT device will allow monitoring of the health of astronauts’ retinas during spaceflight.

* 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.

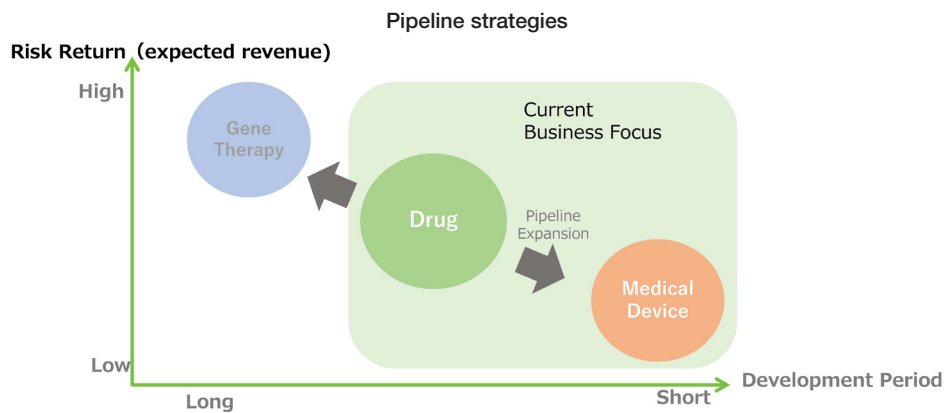
Aiming to become a big data company in the ophthalmology field by building an eco-system that collects and uses medical data from wearable devices, leading to new drug development

2. Growth strategy

The Company has adopted “World without Blindness” as its Corporate Philosophy. Guided by this philosophy, the Company aims to become a big data company in the ophthalmology field that builds a big data eco-system encompassing data collection to use – one that utilizes data for drug development and for diagnosis, prevention and treatment. This will be realized through efforts to translate innovation into a diverse portfolio of drugs and devices to preserve and restore vision for millions of people worldwide and efforts to collect vital data around the world through medical devices developed internally.

As for the Company’s development strategy, the Company’s business focus is on drug development and has expanded to medical device development, which requires relatively shorter development periods, in the last few years. This diversification strategy aims to increase corporate value while reducing overall risk in the pipeline by combining businesses with different risk-return profiles.

Company profile



Source: Published from the Company's results briefing materials

Moreover, drugs require a long development period. The Company aims to out-license drugs to partner companies, so that it can maximize corporate value. In the process, the Company considers a comprehensive range of key factors, such as a product's risks, development costs and period, and management resources. With clinical studies for Stargardt disease (STGD), the size of the clinical studies was not large given the small number of patients, so the Company carried out in-house development through to the phase 3 clinical study. Meanwhile, with products that involve larger clinical studies, the Company's strategy is to conduct in-house development until it reaches the stage of completing Proof of Concept (POC)* in humans. Thereafter, the Company will proceed with development by concluding co-development and sales license agreements with pharmaceutical companies. The Company will aim to capture milestone payments, which depend on progress with development, and royalty payments on product sales after products are launched.

* 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.

In other areas, the Company is implementing an intellectual property (IP) strategy. This IP strategy is crucial to maintaining corporate competitiveness. In therapeutic/drug inventions, the Company has 29 granted patents and 19 pending patents, whereas in medical device inventions, it has 6 granted patents, 17 pending patents, and 2 patents to be filed (as of February 2020).

As of the end of December 2021, the Company had a small workforce of approximately 10 employees on a consolidated basis (including contract employees). The Company's development strategy is being led primarily by two individuals. The first leader is Ryo Kubota, MD, PhD, who is Chairman, President and Chief Executive Officer of the Company. Dr. Kubota is an ophthalmologist and a researcher who invented Visual Cycle Modulation technology. The second leader is Masakazu Watanabe, PhD, who was appointed as Director and Chief Development Officer in 2020. Dr. Watanabe previously served as the head of the Asian region R&D division of Alcon Inc. <ALC>, a major global company in the ophthalmology field. He possesses a wealth of experience in development operations in the ophthalmology field. The Company has also brought onboard famous university professors, doctors and others in the ophthalmology field as advisors, and has received advice from these experts on development strategy and related matters. Another feature of the Company is that with regard to development projects, it has built up an asset-light management structure that efficiently advances development projects by collaborating with external partners.

■ Outline of major development pipeline projects and status of progress

Kubota Glass has the potential to grow into a key device for the treatment and control of the progression of myopia, helping to reduce the risk of future blindness

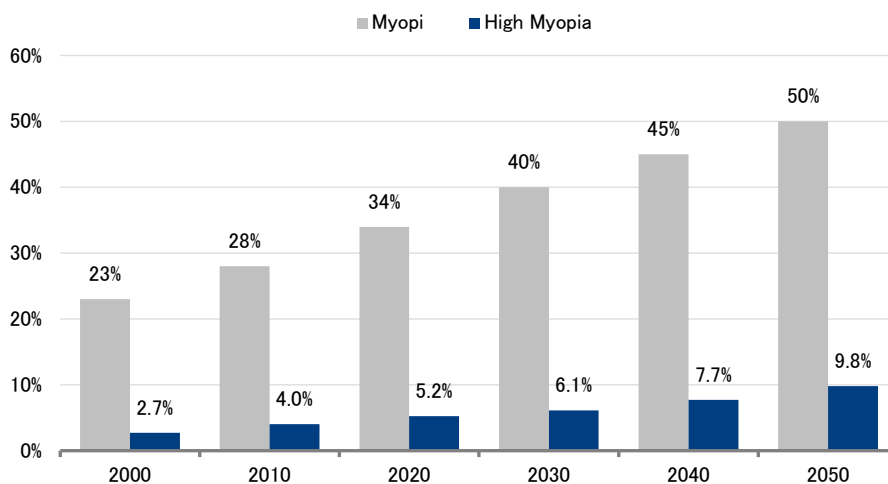
1. Wearable myopia control device Kubota Glass

(1) Market trends related to myopia

The Company is focused on the development of Kubota Glass, a wearable myopia control device 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 focuses images before the retina, causing 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.

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. 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 nearly 5.0bn people). Notably, in East Asian countries such as Japan, China and South Korea, the prevalence of myopia in children and young adults (20 years old or under) has increased to more than 90% of their populations, making myopia a public health issue. People have been spending more time at home recently during the COVID-19 pandemic. It is believed that this is one factor that has led to an increase in the myopic population. If myopia progresses, the risk of 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.

Prevalence of myopia in the world population



Note: Research by Holden BA, et al. Ophthalmology, (2016)

Source: Prepared by FISCO from the Company’s financial results briefing materials

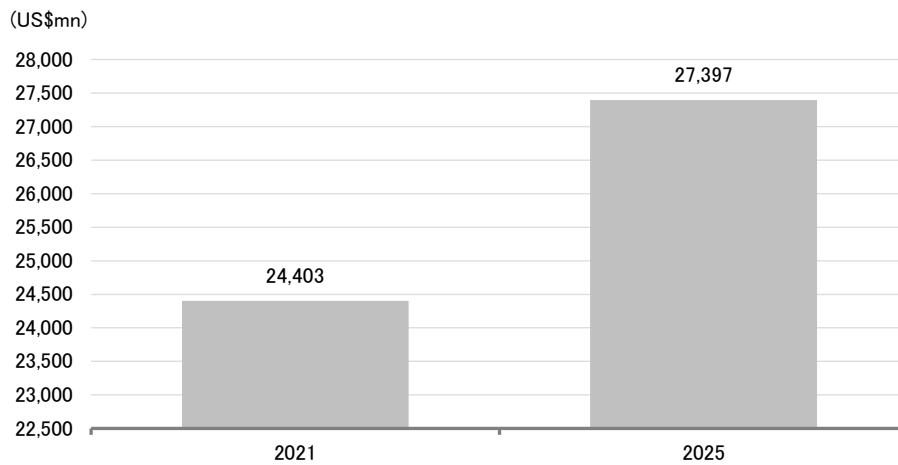
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Outline of major development pipeline projects and status of progress

The global market for lenses for myopia control is predicted to grow more than 10% in the next 5 years, from US\$24.4bn in 2021 to US\$27.3bn in 2025. If the Company successfully commercializes Kubota Glass, it estimates that potential demand for this product could reach up to ¥1,300bn* by 2030.

* An amount calculated by multiplying the Company-estimated adoption rate within the myopic population and the device price.

Forecast of global market for lenses for myopia control



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

(2) How Kubota Glass works

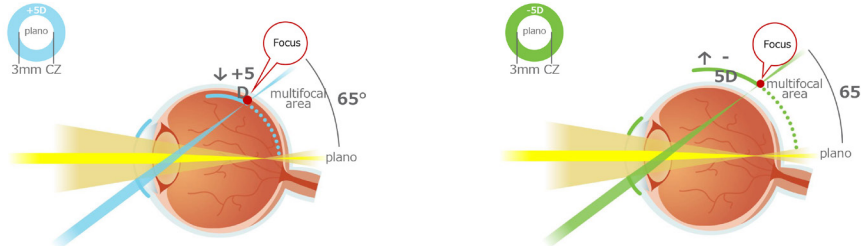
Kubota Glass enables the reduction of the eye's axial length through Kubota Glass technology (active stimulation technology), which was developed in-house. A POC clinical study has already been performed in humans and has confirmed a reduction in the axial length.* Kubota Glass technology works as follows. Myopically-defocused virtual images generated using nanotechnology (micro-LEDS) are projected onto the peripheral visual field to actively stimulate the retina, so that parallel rays of light are brought to a focus in front of the retina. Projecting such an image on the peripheral retina generates a growth signal that moves the retina inwards and reduces the axial length. Because myopically-defocused virtual images are projected onto the peripheral visual field, the projected images from the device gradually become difficult to perceive by the device user. Therefore, device users will find that the axial length of their eyes are reduced before they realize it.

* 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 the same effect with a wearable myopia control device prototype.

Outline of major development pipeline projects and status of progress

Theoretical basis of active stimulation technology: Myopic defocus

Projecting a myopically defocused image on the peripheral retina generates a growth signal that moves the retina inwards, inhibiting myopia progression, while a hyperopically defocused image causes the reverse effect (Benavente-Perez, A., IOVS 2014)



Projecting a myopically defocused image on the peripheral retina slows down myopia progression

“It is generally accepted that myopic defocus is a more potent signal to the emmetropization system than hyperopic defocus: one hour per day of myopic defocus cancels out 11 hours of hyperopic defocus.”

Source: Source: Nickla DL et al. Brief hyperopic defocus or form deprivation have varying effects on eye growth and ocular rhythms depending on the time-of-day of exposure. Exp Eye Res. 2017;161:132-142.

Source: Published from the Company's results briefing materials

Overseas, several companies have commercialized or developed devices that reduce the eye's axial length by stimulating the retina with natural light. One notable feature of Kubota Glass technology is that it can reduce axial length by stimulating the retina for shorter periods of time per day (1 or 2 hours). Even if the axial length is reduced temporarily, it returns to its original length over time. However, the Company's technology may be able to enhance the reduction effect further. To prepare guidelines for putting this technology into practice, the Company concluded collaborative research agreements with the State University of New York in July 2020 and Technological University Dublin (TU Dublin) in November 2020. Under these agreements, the Company is working closely with specialized researchers to accumulate research data on matters such as the device's effect on axial length over extended periods of use. This research data is expected to be eventually published in scientific papers. For now, it appears that the Company believes that the research is generating good data.

Features of Kubota Glass

Leverages the Company's original nanotechnology in electronic spectacle-style devices that actively stimulate the retina



- Medical application of conventional AR device
- The Company's original technology, called active stimulation technology, seeks to reduce the progression of myopia by actively stimulating the retina with artificial light.
- Application of the phenomenon of "myopic defocus," the process of defocusing light on the peripheral retina, to control myopia. Myopic defocus serves as the theoretical basis for products already approved by FDA.



* Conceptual image of product

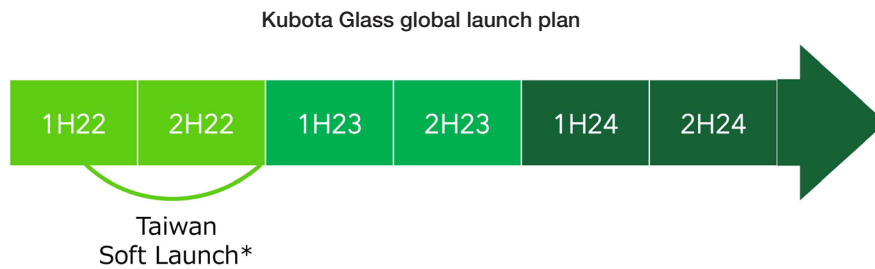
- While conventional products use passive stimulation, Kubota Glass technology leverages nanotechnology in its electronic glasses-based device and seeks to reduce the progression of myopia by actively stimulating the retina for shorter periods, thereby maintaining clear central vision during short daily wear.
- Perfect for 6 year olds and up
- Easy for children to use a spectacle-shape Kubota Glass

Source: Published from "Matters concerning Business Plan and Growth Potential"

Outline of major development pipeline projects and status of progress

(3) Schedule

The Company had initially planned to conduct a soft launch of Kubota Glass for children 6 years and older and adults in Taiwan in the second half of 2021. However, a factory in Germany that manufactures part of the device suspended operations due to the impact of the COVID-19 pandemic, hindering the procurement of parts. Also, the Taiwanese government imposed full-scale entry restrictions into Taiwan, including transit travelers, from May 2021, making it difficult to carry out local training by development engineers as initially planned. Based partly on these factors, the Company changed its manufacturing contractor. Accordingly, the launch period was pushed back to the second half of 2022.



* Launch for the purpose of troubleshooting and validating market fit in the process from manufacturing to sales, delivery, and aftercare

Source: Published from the Company's results briefing materials

While parts procurement is experiencing surging prices, it appears that the procurement issues themselves have been resolved. Incidentally, the Company's sales strategy at the soft launch stage calls for the Company to make independent direct sales its main sales channel, while using agencies to a certain extent. The Company plans to set the sales price at around ¥300,000 for device users aged 6 years old and above, and projects a sales volume of around several tens of units in the first lot. The Company is not permitted to state the indications and efficacy of the device in the product description because the product has not yet obtained certification as a medical device (Class II). Therefore, the device will be sold as ordinary eyeglasses for correcting myopia. In a pre-launch questionnaire survey, the Company obtained results indicating that more than 60% of the respondents wanted to purchase the product. Although the device is a high-end product, we at FISCO believe that the Company can expect to achieve a certain level of sales volume.

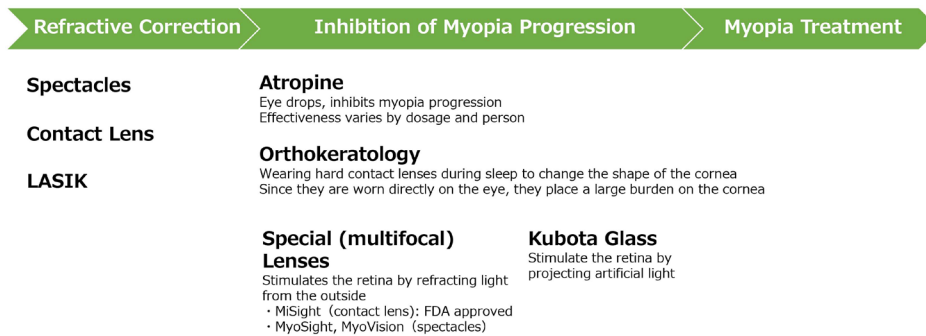
In addition, if sales in Taiwan are favorable, it looks like the Company is considering as one of its options the possibility of entering other areas and countries in the Asian region, assuming that it can advance negotiations with the regulatory authorities of each country and gain approval to sell its product. Also, the Company must conduct a global clinical study and acquire CE mark certification in order to sell the product as a medical device (Class II) that can be labeled with indications and efficacy. Initially, the Company had planned to conduct a clinical study in Europe in the second half of 2022, but it has now decided to determine when to start the clinical study while monitoring factors such as how sales perform in Taiwan. For this reason, sales of the device may start growing first in the Asian region, before it starts to do so in other parts of the world.

Outline of major development pipeline projects and status of progress

In particular, the Chinese market is one of the largest in the world, with the myopic population alone accounting for around 700 million people. The Chinese government has adopted the eradication of myopia as one of its national strategies. Based on these and other factors, China can be described as a market that should be watched closely. In China, eyeglasses and contact lenses that seek to reduce the eye's axial length using natural light are already being sold through ophthalmologists and eyeglasses retailers. We at FISCO believe that Kubota Glass has the potential to reduce axial length more effectively than products already in use by actively stimulating the retina with light, and that the Company has a major opportunity to capture market share based on this superior performance. In Japan too, myopia in children has become a public health issue, meaning that there is tremendous unmet demand. If good results can be obtained on the effect of the long-term use of Kubota Glass on axial length through collaborative research currently underway in the U.S. and Europe, these results could pave the way for a sales partnership agreement with a pharmaceutical or medical device manufacturer. This makes it even more crucial to closely watch the findings of this research.

Currently, several devices (spectacle-type and contact lens-type) to control the progression of myopia have been rolled out for sale, and atropine has obtained regulatory approval in Singapore as a therapeutic. That said, as noted earlier, it appears that Kubota Glass offers superior effectiveness in comparison to passive-type devices. Contact lenses (orthokeratology) present safety risks because they must be worn at night while the subject is asleep. Similarly, atropine has the risk of side effects. The current reality is that none of these treatment options have become established as the standard treatment for treating and controlling the progression of myopia. Although Kubota Glass has a relatively high price, it is fully possible to reduce the price through economies of scale driven by mass production. There are high hopes that Kubota Glass will grow dramatically in the future as a medical device that reduces the risk of blindness by treating and controlling myopia.

Comparison with existing myopia correction and treatment methods



Source: Published from "Matters concerning Business Plan and Growth Potential"

Additionally, the Company is working to develop a contact lens-type wearable myopia control device. Applications of this device could evolve in the future into wearable devices that realize augmented reality (AR) and virtual reality (VR), so a close eye should be kept on future development trends.

Outline of major development pipeline projects and status of progress

The Company will advance negotiations on partner agreements for PBOS based on data from performance verification tests conducted by third-party institutions in Japan

2. Remote retinal monitoring device PBOS: Patient Based Ophthalmology Suite

(1) PBOS features and competition





PBOS is a remote retinal monitoring device that can be used to diagnose the need for treatment (drug administration). It works by allowing patients with retinal diseases such as wet age-related macular degeneration and diabetic macular edema, to measure the thickness of their retinas themselves and send the images they take to their doctors via the Internet.

Previously, these patients regularly visited hospitals to undergo OCT* tests and receive treatment (intraocular injections) as necessary. PBOS 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, it appears that 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).

Notably, the need for home OCT has been increasing recently, due partly to measures to prevent the spread of the COVID-19 pandemic. Therefore, in order to promote the use of home OCT, the American Medical Association (AMA) published guidelines on procedures needed to apply insurance to home OCT on July 1, 2020. Accordingly, it can be said that the conditions needed for the widespread use of home OCT are already in place.

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

 <p>Patients</p> <ul style="list-style-type: none"> • Reduce medical and transportation costs • Understand their own nascent disease progression • Receive the best treatment at the best time • Be evaluated by physician remotely 	 <p>Physicians</p> <ul style="list-style-type: none"> • Monitor more patients • Prioritize patients who need immediate attention • Results in higher sales efficiency
 <p>Insurance Companies</p> <ul style="list-style-type: none"> • Reduce medical costs • Provide the best service to the right patients 	 <p>Pharmaceutical Companies</p> <ul style="list-style-type: none"> • Easier to predict treatment needs and timing to avoid lost sales opportunities • Show evidence of effectiveness

In July 2020, in order to promote the use of home OCT, CPT codes, which are required for reimbursement of medical expenses, have been approved and established for home OCT in the U.S.



Source: Published from the Company's results briefing materials

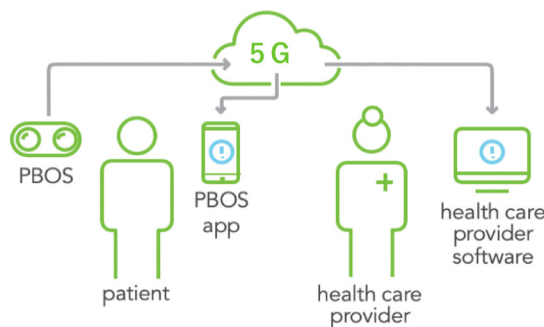
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Outline of major development pipeline projects and status of progress

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. In comparison with the product offered by Notal Vision, its competitor, the Company’s product stands out for its shorter test times and ease of use.

Remote Retinal Monitoring Device PBOS – Home-based miniature OCT (Optical Coherence Tomography)

Using the 5G network, PBOS is a low-cost home-based patient self-monitoring device, designed to monitor disease progression to support an effective treatment regimen



Source: Published from the Company’s results briefing materials

(2) Schedule

Looking at the current status of development, the Company has completed collaborative research with one of the largest ophthalmological university hospitals in Switzerland, a project it had been conducting since August 2020. The Company has finished making improvements to the measurement accuracy of retinal edema, and improvements to software including a 3D retinal cross-section imaging function using artificial intelligence (AI), which were the themes of this project. With this step, the Company has almost completed development of the product’s functions. Currently, the Company is conducting a small-scale clinical study to confirm the device’s user-friendliness at a medical institution in Japan (Kagoshima Sonoda Eye Clinic and Plastic Surgery). The completion date of this study has not been decided because it is an investigator-initiated clinical study. However, the study has been implemented since January 2022 targeting approximately 40 subjects for enrollment, so it could be completed relatively soon.

Dr. Shozo Sonoda is the principal investigator of the clinical study and the director of Kagoshima Sonoda Eye Clinic and Plastic Surgery. Dr. Sonoda actively conducts research and development aimed at applying AI to ophthalmic care. He is also a Councilor of the Japanese Society of Artificial Intelligence in Ophthalmology, which was recently established in 2020. Given that PBOS also generates images using AI, Dr. Sonoda was chosen to lead the clinical study as part of the use of AI in a clinical setting. The Company intends to advance discussions with prospective development and sales partner companies based on the evidence obtained from this clinical study. If the study can confirm an equivalent level of performance to OCT, the Company will make significant strides toward concluding a partnership agreement. Moreover, if a partnership agreement is concluded, the Company can be expected to conduct a clinical study in the U.S. In terms of prospective partner companies, it appears that several pharmaceutical companies that are developing drugs for age-related macular degeneration and other conditions, as well as Japanese companies, are showing interest.

Outline of major development pipeline projects and status of progress

The Company's disclosure materials contain a survey on the home OCT market* implemented in 2018. According to this survey, the percentages of ophthalmologists and patients who are interested in home OCT were both over 50%. Also, the percentage of ophthalmologists who estimate that their patients will embrace home OCT was 38% in the U.S. and 30% in Japan. With the COVID-19 pandemic still under way, interest in home OCT is expected to have increased further. If development succeeds in the U.S., the Company is expected to expand home OCT to Europe and Japan.

* A survey on the home OCT market prepared in 2018 by Novartis AG <NVS>, a major pharmaceutical company engaged in drugs for age-related macular degeneration.

(3) Business model and market size

The Company's business model in the U.S. 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 PBOS can be expected to accelerate. Because no fundamental treatment exists for age-related macular degeneration (AMD) and other retinal diseases, patients are highly likely to continue using PBOS once they start using it, unless they become blind. As a recurring-revenue business, PBOS is likely to grow into a steady source of revenue in the future.

The potential market size will cover patients with retinal diseases such as wet AMD and diabetic macular edema (DME) in the U.S. in the near term. According to the Company's disclosure materials,*1 the number of AMD patients in the U.S. is predicted to increase from 2.06mn in 2010 to 2.66mn in 2030, and then 5.44mn in 2050, marking a 2.7-fold increase. About 10% of those AMD patients is expected to have wet AMD. Among patients with dry AMD, a similar number of patients as those with wet AMD is expected to experience geographic atrophy of the macular region and worsening of symptoms, and these patients will also be eligible for PBOS. For this reason, the number of eligible patients is expected to reach around 1.10mn in 2050. Meanwhile, the number of diabetes patients in North America is expected to increase from 51mn in 2021 to 63mn in 2045.*2 The prevalence of diabetic retinopathy in diabetes patients in Japan is around 15-23%. Reports show that around 20% of those with diabetic retinopathy also concurrently experience DME.*3 Assuming similar percentages of patients in the U.S., the number of DME patients in the U.S. is expected to be around 1.8mn to 2.3mn in 2045. Combined with the number of AMD patients eligible for PBOS, the number of potential users in the U.S. is estimated to increase from around 2mn at present to 3mn sometime around 2050.

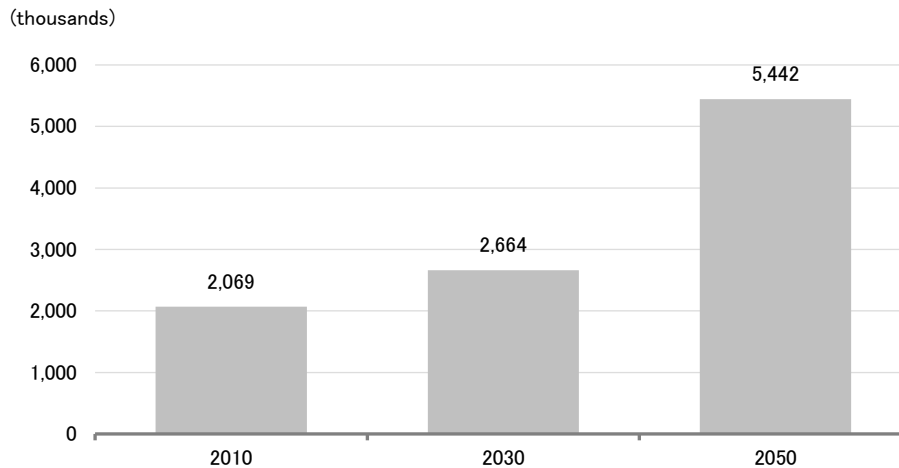
*1 Source: Market Scope, The Global Retinal Pharmaceuticals & Biologic Market, 2015

*2 Source: International Diabetes Federation "IDF Diabetes Atlas," Tenth Edition, 2021

*3 Sakiko Nakano, The 114th Annual Meeting of the Japanese Ophthalmological Society 2010:135 (based on a report that DME occurs in 20% of diabetic retinopathy patients)

Outline of major development pipeline projects and status of progress

Projected Number of AMD Patients in the U.S.



Note: Research by the US National Eye Institute, 2019
Source: Prepared by FISCO from the Company's financial results briefing materials

Assuming a monthly usage fee of ¥1,000 and an adoption rate of 50% for PBOS in 2050, the market size will be ¥18.0bn in 2050. At that time, PBOS is highly likely to have been widely adopted in Europe and Japan as well, so the global market for PBOS is expected to be several times larger in size. Retinal diseases such as AMD are one leading cause of blindness, and the elderly population will only continue to increase moving forward. Considering these factors, we at FISCO believe that PBOS harbors massive latent growth potential.

Leading causes of blindness

	Japan		U.S.		Europe	
1st	Glaucoma	21.0%	Age-related macular degeneration (AMD)	54.0%	Age-related macular degeneration (AMD)	26.0%
2nd	Diabetic retinopathy (DR)	16.0%	Cataracts	9.0%	Glaucoma	20.0%
3rd	Retinitis pigmentosa	12.0%	Glaucoma	6.0%	Retinitis pigmentosa	9.0%
4th	Age-related macular degeneration (AMD)	10.0%	Diabetic retinopathy (DR)	5.0%	Others	45.0%
5th	Retinochoroidal atrophy	8.0%	Others	25.0%		
6th	Others	34.0%				

Note: Data for Japan is from the "FY2013 Survey and Research Concerning Retinochoroidal and Optic Atrophy" report by the Intractable Diseases Treatment Research Project of the Ministry of Health, Labour and Welfare. Data for the U.S. is from research by Nathan C. et al., Causes and Prevalence of Visual Impairment Among Adults in the United States. Arch Ophthalmol. 122 (2004). Data for Europe is from research by Kocur I, Resnikoff S: Visual Impairment and blindness in Europe and their prevention. British Journal of Ophthalmology 86, 716-722 (2002)
Source: Published from the Company's results briefing materials

Outline of major development pipeline projects and status of progress

If the Company succeeds in developing a drug for Stargardt disease, the new pharmaceutical could have revenue potential of more than ¥100bn

3. Emixustat hydrochloride (HCl)

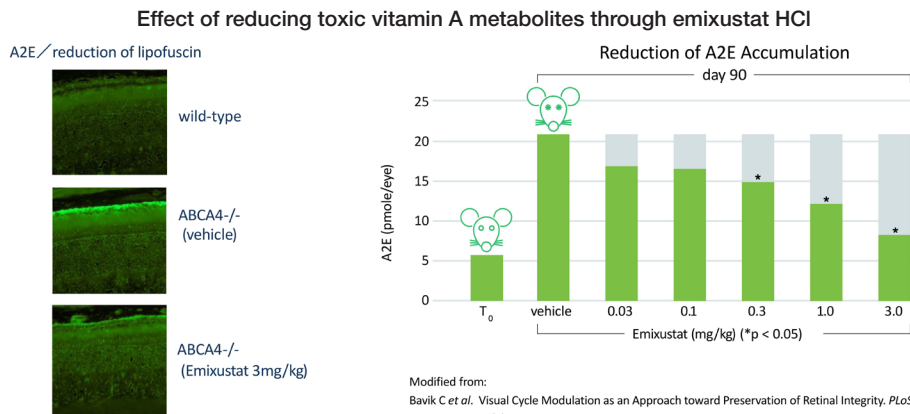
(1) Outline of Stargardt disease

Stargardt disease (STGD) is a genetically inherited retinal disease. It is also known as juvenile macular degeneration. It affects one in 8,000 to 10,000 people. There are estimated to be nearly 150,000 patients in the U.S., Japan and Europe combined. Estimates put the number of patients in the U.S. alone at 32,000 to 40,000.* The main symptoms are a decrease in vision and color blindness presenting from childhood to young adulthood. 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.

* Compiled by the Company based on Market Scope, "Retinal Pharma & Biologics Market" and "UN World Population Prospects 2015"

The main cause of STGD is believed to be a genetic mutation of the ABCA4 gene within the retina. The ABCA4 gene fulfills the role of processing toxic lipofuscin (hereinafter, "A2E"), which is generated by the visual cycle which governs the action of perceiving light. Mutations of the ABCA4 gene prevent it from fulfilling its original role, resulting in excessive accumulation of A2E in the retina and damage to photoreceptor cells. This mechanism causes a gradual progression of vision impairments.

In pre-clinical studies using animal models, emixustat HCl was confirmed to have the effect of inhibiting the build-up of A2E. It is believed that this is because emixustat HCl selectively inhibits an enzyme known as RPE65, which plays a crucial role in the visual cycle, and has the pharmacological effect of reducing the build-up of waste materials arising from the visual cycle. For this reason, the administration of emixustat HCl is expected to have the effect of inhibiting the progression of the symptoms of STGD.



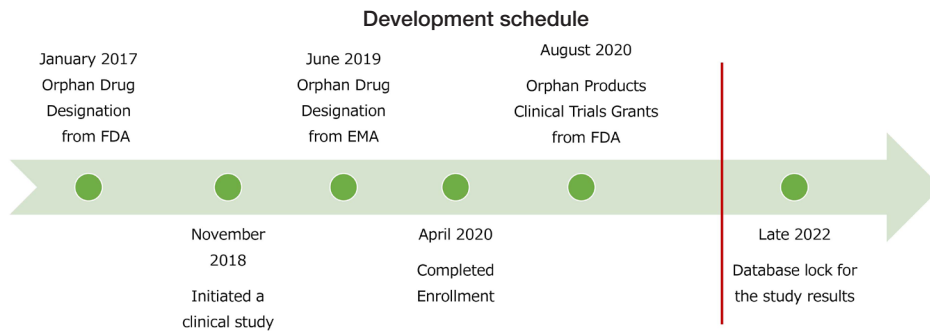
Source: Published from the Company's results briefing materials

Outline of major development pipeline projects and status of progress

(2) Schedule

On May 1, 2020, the Company announced the completion of enrollment of subjects in a phase 3 clinical study of emixustat HCl indicated for Stargardt disease (initiated in November 2018; number of subjects enrolled: 194; conducted at medical facilities in 11 countries worldwide).^{*} If the study proceeds steadily, the database lock for the study results is expected to be completed in Q3 FY12/22. If the results of the phase 3 clinical study are satisfactory, then the Company will proceed with the New Drug Application process with European and U.S. regulatory authorities. Moreover, the Company is advancing negotiations on sales partner agreements with more than 10 companies, including major pharmaceutical companies. If the results of the phase 3 clinical study are satisfactory, the Company will make significant strides toward concluding these agreements. Depending on the findings of the study results, additional studies may be required. In that event, the Company expects to conclude partner agreements and conduct the additional studies.

^{*} In August 2020, the phase 3 clinical study was selected for the Orphan Products Clinical Trials Grant Program by the FDA. Part of the cost of the clinical study is being funded by this grant.



- Discussions for potential partnership have been initiated with 10+ pharmaceutical companies; waiting on the phase 3 study results for the next step
- Some companies are interested in licensing agreement for some countries and area prior to the phase 3 study results

Source: Published from the Company's results briefing materials

(3) Market size and competition

According to the Company's disclosure materials, the size of the global market for therapeutic drugs for STGD is projected to increase from US\$780mn in 2016 to US\$1,593mn in 2027, marking a 2-fold increase.^{*1} While STGD is a genetically inherited disease and has only a few patients, there is still no effective drug to treat the disease (the only treatment option is retinal photocoagulation to inhibit progression). The projected growth in the size of the market reflects the high drug price that is anticipated because of the development of a highly effective new drug. Emixustat HCl indicated for STGD has received orphan drug designation^{*2} in the U.S. and Europe. If development is successful, the drug is expected to contribute immensely to revenue.

^{*1} WISEGUY RESEARCH CONSULTANTS PVT LTD Global Juvenile Degeneration (Stargardt Disease) Market Research Report

^{*2} In June 2019, orphan drug designation was received in Europe. In Europe, medicines qualify for orphan designation if they are intended for diagnosis or treatment of a disease that is life-threatening or chronically debilitating and the prevalence of the condition in Europe is not more than 5 in 10,000. Orphan drugs receive incentives such as market exclusivity for 10 years after approval, a reduction in fees for applying for marketing approval of drugs, and priority approval process, along with preferential tax treatment and other benefits. In the U.S., orphan drug designation (market exclusivity for 7 years after approval) was received in January 2017.

Outline of major development pipeline projects and status of progress

Incidentally, approximately 30 drug candidates for STGD are under development, including those in the discovery phase, of which 10 are in the clinical phase. Of the new drug candidates for STGD, only two candidates, including the Company's emixustat HCl (the other drug candidate has initiated a phase 3 clinical study), have advanced to phase 3 clinical studies. Six candidates are in phase 2 clinical studies. The Company is highly likely to complete its phase 3 clinical study of emixustat HCl before the new drug candidates of other companies do so. Therefore, by leveraging this advantage, the Company will seek to conclude partnership agreements and generate revenue after launch.

New drug candidates for Stargardt disease in phase 2 and phase 3 clinical stages

(as of January 2022)

Product	Stage	Company
Emixustat hydrochloride	PIII	Kubota Vision Inc.
tinlarebant	PIII	Belite Bio Inc
ALK-001	PII	Alkeus Pharma
Avacincaptad pegol sodium	PII	IVERIC bio Inc.
Jcell	PII	jCyte Inc
Soraprazan	PII	Katairo GmbH
STG-001	PII	Stargazer Pharma
Vutrisiran	PII	Alnylam Pharmaceuticals Inc

Source: Published from the Company's results briefing materials

Pre-clinical studies of VAP-1 inhibitor candidates are currently under way to confirm the effect of controlling and easing pain

4. VAP-1 inhibitors

In the process of advancing basic research into emixustat HCl, the Company created many libraries of small molecule compounds. As part of these efforts, the Company found several tens of compounds that inhibit the action of VAP-1,* which is believed to play a role in inflammatory diseases such as atopic dermatitis, psoriasis, and osteoarthritis. In April 2020, the Company concluded a collaborative research agreement with LEO Pharma to further narrow down promising compounds from among those it has found. Under this agreement, screening evaluations were conducted over a period of one year.

* VAP-1 (Vascular adhesion protein-1): VAP-1 is a leukocyte adhesion molecule that exists on the surface of the endothelium. The abnormal activation of VAP-1 is recognized in inflammatory diseases such as atopic dermatitis, psoriasis, osteoarthritis, diabetic kidney disease, non-alcoholic steatohepatitis (NASH), and acute respiratory distress syndrome (ARDS). For this reason, it is believed that inhibition of the activity of VAP-1 has the effect of easing the symptoms of such inflammatory diseases.

Outline of major development pipeline projects and status of progress

As a result of the screening evaluation, candidate compounds that have a high effect on the target in small quantities and have high selectivity (i.e., few side effects) were identified. Because VAP-1 inhibitors have an expansive scope of application and a large potential market value, even major pharmaceutical companies are actively conducting development. However, no company has a successful track record of launching a product in the market. It is said that this is because no company has been able to control the risk of side effects as every candidate compound has low selectivity and inhibits substances other than VAP-1. In contrast, the Company's candidate compound has high selectivity (i.e., high safety), so it appears that it is worth continuing development activities.

In addition, some companies are interested in this compound's prospects for becoming new drug candidates for NASH, nephritis, and related diseases. The compound also affords a wide range of development possibilities. Notably, it is being watched closely as a compound that may be effective in inhibiting cancer cell metastasis. Accordingly, future trends around this compound will be monitored with interest.

Policy on continuation of development project for NASA

5. SS-OCT, a miniature OCT device for astronauts

The Company signed a development agreement with the Translational Research Institute for Space Health (TRISH) for NASA's Deep Space missions and initiated a project in 2019 to develop a Swept Source-OCT (hereinafter, "SS-OCT"), a miniature OCT device, to conduct research into eye disorders that can occur in spaceflight. 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 miniature SS-OCT that will be developed in this project is portable and can be used to take measurements easily, even by one person at a time. This enables measurements to be taken and stored daily. The device is expected to be used to analyze the impact of spaceflight on eye disorders in detail.

* 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."

Outline of major development pipeline projects and status of progress

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. Together with its partner companies, the Company will jointly advance the development of 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 Company currently continues to hold discussions on Phase 2. These discussions include exploring a new project in view of factors such as a change in the U.S. administration in 2021, and a reallocation of the federal budget to cover the cost of COVID-19 measures. It has not yet been determined when the project will be restarted. However, given that NASA personnel are considering the continuation of the project, it is believed that the project will be restarted as soon as a budget is allocated to it.

Business performance trends

In FY12/21, the Company recorded an operating loss on par with FY12/20, due to an increase in development expenses for Kubota Glass

1. Outline of FY12/21 results

In the consolidated results for FY12/21, the Company posted no revenue and losses were mostly on par with FY12/20. The Company recorded operating loss of ¥2,584mn (compared with a loss of ¥2,484mn in FY12/20), loss before tax of ¥2,616mn (compared with a loss of ¥2,437mn in FY12/20), and loss attributable to owners of parent of ¥2,616mn (compared with a loss of ¥2,437mn in FY12/20). Meanwhile, the amounts of the losses were smaller relative to the Company's forecasts, because the Company revised research and development expenses and general and administrative expenses.

FY12/21 consolidated results

	FY12/20 Results	FY12/21		YoY		Difference from forecast
		Forecast	Results	% change	Change	
Revenue	37	10	-	-	-37	-10
Business expenses	2,579	-	2,644	2.5%	65	-
Research and development expenses	1,972	-	2,040	3.4%	67	-
General and administrative expenses	606	-	603	-0.4%	-2	-
Other operating income	57	-	59	-	2	-
Operating profit (loss)	-2,484	-2,900	-2,584	-	-100	315
Profit (loss) before tax	-2,437	-2,800	-2,616	-	-179	183
Profit (loss) attributable to owners of parent	-2,437	-2,800	-2,616	-	-179	183

(Unit: ¥mn)

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

Regarding revenue, the Company had forecasted revenue of ¥10mn from Kubota Glass in FY12/21, in comparison with the recording of development service revenue of ¥37mn from the NASA project in FY12/20. However, as noted earlier, the Company posted no revenue because the sales period was pushed back to 2022.

Business performance trends

Looking at the breakdown of expenses, research and development expenses amounted to ¥2,040mn, an increase of ¥67mn YoY. This increase was due to an increase in development expenses for Kubota Glass, which was partly offset by a decrease in research and development expenses for emixustat hydrochloride (HCl), for which enrollment of subjects has been completed, and a decrease in development expenses for Patient Based Ophthalmology Suite (PBOS). Additionally, general and administrative expenses decreased ¥2mn to ¥603mn. The Company controlled expenses by implementing cost-saving measures, while patent and business development related expenses increased in step with progress on various development projects. Subsidy income of ¥59mn associated with the phase 3 clinical study of emixustat HCl was recorded as other operating income.

The Company aims to post revenue from Kubota Glass in FY12/22

2. Outlook for FY12/22 results

In terms of consolidated results for FY12/22, particularly revenue, the soft launch of Kubota Glass is expected to make a top-line contribution. However, the Company's policy is to disclose its outlook at a stage when it becomes possible to make reasonable estimates after product launch. In addition, the Company is forecasting operating loss, loss before tax, and loss attributable to owners of parent of ¥2,000mn each.

Consolidated results outlook for FY12/22

	FY12/21 Results	FY12/22 (Unit: ¥mn)	
		Forecasts	Change
Revenue	-	-	-
Operating profit (loss)	-2,584	-2,000	584
Profit (loss) before tax	-2,616	-2,000	616
Profit (loss) attributable to owners of parent	-2,616	-2,000	616

Note: Forecasts are based on an assumed exchange rate of US\$1 = ¥115.
 Source: Prepared by FISCO from the Company's financial results

Looking at expenses, particularly research and development expenses, the Company expects to continue to incur development expenses, clinical study expenses, and other expense items for the commercialization of Kubota Glass, but it expects expenses such as clinical study expenses for emixustat HCl and development expenses for PBOS to peak out. Based on this outlook, research and development expenses are expected to significantly decrease YoY. This will serve as one factor behind a smaller operating loss. Moreover, regarding general and administrative expenses, marketing expenses and other expense items for the commercialization of Kubota Glass are projected to increase, despite continued cost-saving measures. The assumed exchange rate for the Company's forecasts is US\$1 = ¥115.

With cash on hand of ¥4.4bn, the Company has secured two years' worth of funds for operating activities

3. Financial condition

As of the end of FY12/21, total assets were ¥4,832mn, a decrease of ¥1,859mn from the end of FY12/20. In terms of the main factors behind this change, the decrease in total assets was primarily due to the expenditure of cash on hand in connection with operating activities. Cash on hand (cash and cash equivalents and other financial assets (current and non-current)) decreased ¥1,922mn from the end of FY12/20 to ¥4,415mn.

Business performance trends

Total liabilities were ¥679mn, a decrease of ¥19mn from the end of FY12/20. Current and non-current lease liabilities decreased by a combined ¥119mn, while there were increases of ¥6mn in trade payables and ¥97mn in accrued liabilities. Moreover, total equity amounted to ¥4,152mn, a decrease of ¥1,840mn from the end of FY12/20. Share capital and capital surplus increased by a combined ¥392mn due to the issuance of shares upon exercise of share acquisition rights. Also, other components of equity increased by ¥384mn in line with the yen's depreciation toward the end of FY12/21. Meanwhile, loss brought forward (accumulated deficit) increased due to the recording of loss attributable to owners of parent of ¥2,616mn.

Although cash on hand has remained on a downtrend, amounting to ¥4,415mn at the end of FY12/21, the Company has secured approximately two years' worth of funds for operating activities. That said, the Company will remain in a development stage for the foreseeable future. Accordingly, in July 2020 the Company issued its 25th Stock Acquisition Rights through a third-party placement, for the purpose of raising development funds. The exercise ratio as of the end of February 2022 relative to the number of diluted shares of 9mn (dilution ratio: 21.3%) was 39.5%, and the amount of funds procured was approximately ¥900mn. From August 2021 onward, the stock price has fallen below the minimum exercise price of ¥197, so there has been no progress on exercising these stock acquisition rights. For this reason, if the stock price remains below the minimum exercise price for some time, the Company can be expected to consider a new round of fund procurement at some time in the future. Incidentally, the proceeds raised through the most recent issuance of stock acquisition rights were scheduled to be allocated to expenses of approximately ¥1.74bn related to the phase 3 clinical study of the new drug for Stargardt disease (approx. ¥0.8bn in 2020, approx. ¥0.5bn in 2021, and approx. ¥0.4bn in 2022) and development expenses of approximately ¥1.8bn for Kubota Glass, the Company's wearable myopia control device (approx. ¥0.6bn in 2020 and approx. ¥1.2bn in 2021).

Consolidated statements of financial position and business indicators

	End of FY12/18	End of FY12/19	End of FY12/20	End of FY12/21	Change
	(Unit: ¥mn)				
Current assets	11,177	8,177	6,417	4,625	-1,791
(Cash and cash equivalents and other financial assets)	10,938	7,970	6,317	4,415	-1,900
Non-current assets	112	563	274	207	-67
(Other financial assets)	-	487	22	-	-22
Total assets	11,290	8,740	6,691	4,832	-1,859
Current liabilities	661	538	506	542	35
Non-current liabilities	85	158	192	137	-54
Total liabilities	747	696	698	679	-19
Total equity	10,542	8,043	5,993	4,152	-1,840
[Business indicators]					
Ratio of equity attributable to owners of parent	93.4%	92.4%	89.6%	85.9%	-
Cash on hand*	10,938	8,458	6,338	4,415	-1,922

* Total of cash and cash equivalents and other financial assets (current and non-current)

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



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