COMPANY RESEARCH AND ANALYSIS REPORT

Tsubota Laboratory, Inc.

4890

Tokyo Stock Exchange Growth Market

7-Jul.-2025

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Summary

Enhancement of pipeline and license agreements in the field of eye disease are progressing smoothly

Tsubota Laboratory, Inc. <4890> (hereafter, also "the Company") is a bio-venture company launched from Keio University that develops medical devices and drugs that harness violet light with potential effects in curtailment of myopia progression and activation of the brain. It listed on the Tokyo Stock Exchange's (TSE) Growth Market in June 2022. With a mission of brightening the future with VISIONary INNOVATION*, the Company aims to "deliver revolutionary innovations for myopia, dry eye, presbyopia, and brain diseases."

* Development of Vision (eye disease) and Visionary (having foresight) innovative medical and healthcare products

1. Development pipeline situation

The results of clinical trials conducted in Japan for the myopia progression curtailment device TLG-001, the main development pipeline, will be known in the spring of 2026. If favorable results are obtained, an application for approval will be submitted, and sales are expected to begin in 2027 from licensee JINS HOLDINGS<3046>. With this, the Company will receive royalty income. In addition, in March 2025, the Company concluded a license agreement with Beijing Yijie Pharmaceutical Technology Co., LTD. (BYPT) for the target region of China (including Hong Kong, Manila, and Taiwan) (total contract amount of ¥1.03bn, excluding sales royalties). For TLM-003, which is being developed as a myopia progression curtailment treatment drug, licensee Rohto Pharmaceutical <4527> began phase-2 clinical trials in Japan in April 2025, and in October 2024, a license agreement was concluded with overseas pharmaceutical companies regarding the purchase of non-clinical and clinical trial data. The licensee companies are expected to use the data to prepare for clinical trials. In addition, in October 2024, the Company concluded an exclusive evaluation agreement with Rohto Pharmaceutical (for ¥100mn) with a view to acquiring intellectual property rights for, and commercializing, innovative eyedrop drugs. Also, the Company has added TLN-017, a drug for treating corneal and conjunctival disorders, and TLM-023, a myopia progression curtailment treatment drug, to its new pipeline.

2. Overview of FY3/25 results

In the FY3/25 results, the Company reported ¥1,357mn in net sales (up 101.5% year on year (YoY)) and operating profit of ¥281mn (vs. a loss of ¥636mn in the previous fiscal year), setting a record high for the first time in four fiscal years, with net sales topping ¥1.0bn for the first time. The majority of net sales came from one-time contract payments, and the Company concluded agreements with Rohto Pharmaceutical and three overseas companies. In terms of expenses, there was an increase in labor costs due to bolstering the personnel structure (the number of employees increased by 10 from the end of the previous fiscal year to 17 employees) and an increase in R&D expenses (up ¥48mn from the previous fiscal year to ¥254mn), but the effect of increased sales and the non-recurrence of provision for loss on contracts of ¥328mn* recorded in the previous fiscal year led to a significant increase in ordinary profit.

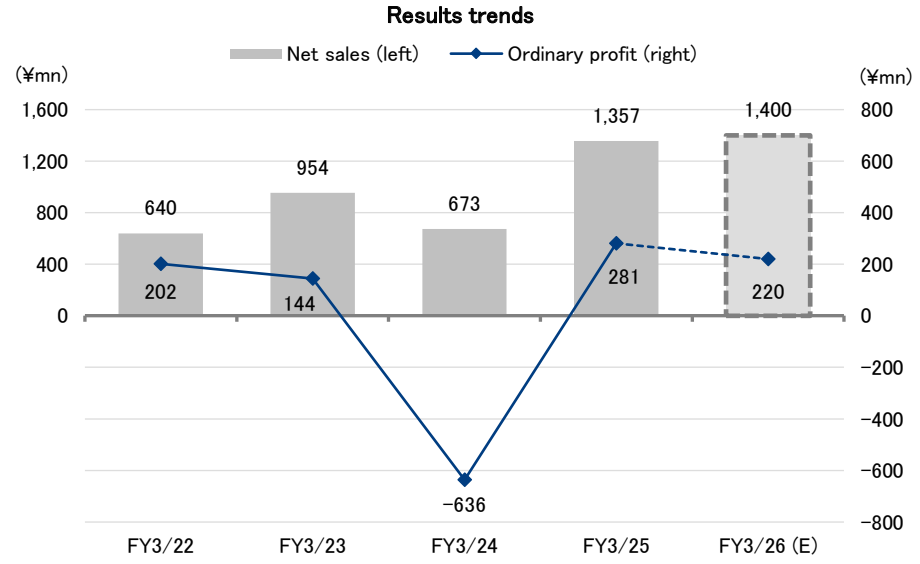
* A provision made in conjunction with the Company's outlook for expenses to rise more than expected based on the prolonging of the clinical trial for TLG-001.

3. FY3/26 forecasts and future initiatives

In the FY3/26 results forecast, the Company projects ¥1,400mn in net sales, an increase of 3.2% YoY and ¥220mn in ordinary profit, a decrease of 21.9%. While the Company is expected to achieve continuous revenue growth by continuing to advance out-licensing contracts for its pipeline, it is expected to see a decrease in profits due to an increase in R&D expenses, including patent-related expenses (up from ¥296mn in previous fiscal year to ¥550mn), in order to strengthen its R&D and intellectual property strategies, but it will still secure a profit for the second consecutive fiscal year. In addition, in order to accelerate business expansion overseas, after opening an office in China in the previous fiscal year, the Company opened an office in the United States in May 2025. The Company will continue to expand its pipeline and accumulate out-licensing contracts, aiming for growth by promoting global expansion. In particular, with respect to drugs and medical devices that suppress the progression of myopia, the number of patients continues to increase worldwide, and there is enormous potential demand, so future development trends will attract attention.

Key Points

- Concluded four license agreements with companies in Japan and overseas in FY3/25
- Set new record highs in FY3/25 in net sales, ordinary profit, and net income
- For FY3/26, the Company is expecting a profit for the second consecutive fiscal year due to an increase in one-time contract payments
- Attention is being paid to development trends for both drugs and medical devices that suppress the progression of myopia, for which potential demand is large



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

Company profile

Bio-venture company originating from a university founded to pursue R&D and commercialization of products in the field of eye disease

1. History

The Company's predecessor is Dry Eye KT, Inc. was established by Representative Director Kazuo Tsubota, who was a professor at in the Department of Ophthalmology at Keio University School of Medicine, in 2012 (it changed the company name to the current one in February 2015). Inspired by a desire to work on something that contributes to the world before his retirement, Professor Tsubota decided to launch this business with the aim of commercializing science from the ophthalmology field, where he personally conducted research for many years, in order to resolve the issue of excess imports in the field. Additionally, since only a few domestic universities were delivering innovations that actually contribute to society with the results of their research activities at the time, he implemented business activities with a goal of clarifying the path to a successful university-launched bio-venture ahead of others.

He came up with the idea of a myopia progression curtailment device using violet light, the Company's main development pipeline item at this point, in around 2014. It began with theorization that the difference in patients with diminished eyesight and those that maintained their eyesight level after intraocular lens (IOL) surgery stemmed from the intraocular lens itself (lenses that transmit violet light versus those that block it). He initially conducted research on chicks and then proceeded to research using myopia model mice. These activities obtained results that were consistent with the theory, and he discovered the mechanism of action for curtailing myopia progression. Specifically, he found that irradiation with 360–400nm violet light stimulates the OPN5 non-visual light reception protein in the inner layer of the retina, and resulting improvement in blood flow maintains choroid thickness. This mechanism curtails myopia progression (blood flow shortage causes choroidal thinning and this leads to myopia progression). Since sunlight contains violet light, shortage of exposure to violet light caused by decline in outdoor activities is a contributing factor to the steep rise in myopia prevalence in recent years.

Mr. Tsubota announced the research results in an academic journal submission and strengthened the intellectual property strategy by applying for patents in Japan and other countries. He also predicted that if OPN5 stimulation improved blood flow to the eye, it could also improve blood flow to the brain. The Company hence conducted research on depression, Parkinson's disease, and dementia too. Based on results from animal tests, it concluded a joint research contract related to depression and dementia using violet light with Sumitomo Dainippon Pharma Co., Ltd. (now, FrontoAct*1) in March 2019 (TLG-005). It also concluded a license agreement with JINS HOLDINGS for the myopia progression curtailment device (TLG-001) in May 2019 and is implementing joint research. It subsequently concluded a licensee agreement for myopia curtailment eyedrops (TLM-003) with Rohto Pharmaceutical in October 2020 and initiated joint research. The Company concluded a license agreement for a therapeutic agent that treats Meibomian gland dysfunction (TLM-001) with Maruho Co., Ltd. in April 2021 for Japan, the United States, France, the United Kingdom, Germany, and other countries. As an overseas corporate partner, it concluded an exclusive license agreement for TLM-003 in the United States and Europe with France-based Laboratoires Théa (Thea)*2 in December 2022. The Company has been actively arranging licensing deals.

*1 Sumitomo Pharma <4506> established FrontAct in April 2024 as a subsidiary responsible for healthcare areas other than pharmaceuticals, and the licensing rights for TLG-005 were also transferred to FrontAct. In June 2025, Sawai Group Holdings <4887> acquired all of FrontAct's shares.
*2 This is a major European independent drug group in the ophthalmology field. It has over 1,600 employees and sells products in 75 countries worldwide.

The Company listed its shares on the TSE Growth Market in June 2022, and had 17 employees (6 R&D employees, 7 business development employees, and 4 corporate unit employees) as of the end of March 2025.

History

Date	History
May 2012	Founded the Company's predecessor Dry Eye KT, Inc. for the purpose of developing and producing a new dry eye drug and dry eye care goods
June 2014	Submitted a patent application for myopia prevention goods and a myopia prevention set (TLG-001)
February 2015	Dry Eye KT, Inc. merged (absorption merger) Myopia Research Institute, Inc. and Presbyopia Research Institute, Inc. and changed its name to Tsubota Laboratory, Inc.
December 2015	Submitted a patent application for an irradiation device worn on the body that can prevent myopia or delay myopia progression (TLG-001)
March 2017	Submitted a patent application for a myopia prevention or curtailment drug, a method for creating a myopic mice guidance model, and a screening method for a myopia prevention or curtailment drug
May 2017	Submitted a patent application for a myopia prevention composite or functional food (TLM-005)
March 2019	Concluded a contract for joint research on depression and dementia using violet light (TLG-005) with Sumitomo Dainippon Pharma Co., Ltd. (now, Sumitomo Pharma Co., Ltd.)
April 2019	Started an exploratory clinical study using medical device TLG-001 aimed at curtailing myopia progression
May 2019	Concluded a license agreement for TLG-001 with JINS HOLDINGS Inc.
November 2019	Selected as a business for the New Energy and Industrial Technology Development Organization's (NEDO) FY2019 "Research and Development Startup Support Project/Seed-stage Technology-based Startups" (TLG-005)
October 2020	Concluded a license agreement for intellectual property and R&D results related to the Company's myopia curtailment eyedrops with Rohto Pharmaceutical Co., Ltd. (TLM-003) Concluded a joint R&D contract for the myopia curtailment mechanism, rebound, and other basic research with Rohto Pharmaceutical Co., Ltd. (TLM-003)
March 2021	Concluded a joint research contract for depression, mild dementia complications, and Parkinson's disease using brain-stimulation violet light glasses (TLG-005) with Sumitomo Pharma
April 2021	Concluded a license agreement with Maruho Co., Ltd. for a therapeutic agent that treats Meibomian gland dysfunction (TLM-001) covering Japan, the United States, France, the United Kingdom, Germany, and other countries
June 2021	Concluded a memorandum that added Taiwan, Vietnam, and Indonesia to countries covered by the license agreement with Rohto Pharmaceutical Co., Ltd. in October 2020
June 2022	Listed its shares on the TSE Growth Market
November 2022	Concluded an exclusive license agreement for North America and South America for TLG-001 with US-based Twenty Twenty Therapeutics (TTT) (likely to be terminated because of TTT's planned liquidation)
December 2022	Concluded an exclusive license contract for the United States and Europe for TLM-003 with France-based Laboratoires Théa
September 2023	Selection of "R&D for a cognitive function improvement device that addresses decline in the cognitive function of aging dogs" as a R&D Support Program for Growth-oriented Technology SMEs (Go-Tech Program)
March 2024	Selection of "development of an innovative medical device for retinitis pigmentosa" as a grant project for the TOKYO Strategic Innovation Promotion Program Selection of "development of device for treatment of irregular menstruation using light irradiation" as a grant project for the femtech development support and promotion program Concluded an intellectual property license agreement for intellectual property and R&D related to the Company's eyedrops (TLM-018) with Rohto Pharmaceutical Co., Ltd.
July 2024	Became the first Japanese company to open an office in China's Eye Valley in Wenzhou, Zhejiang Province, China
September 2024	Concluded an exclusive license agreement for a specific patent in China with Shenyang Xingqi Pharmaceutical Co., Ltd. in China
March 2025	Concluded a license agreement related to TLG-001 in China, Hong Kong, Macao, and Taiwan with Beijing Yijie Pharmaceutical Technology Co., LTD. in China

Source: Prepared by FISCO from the Company's annual securities report and press releases

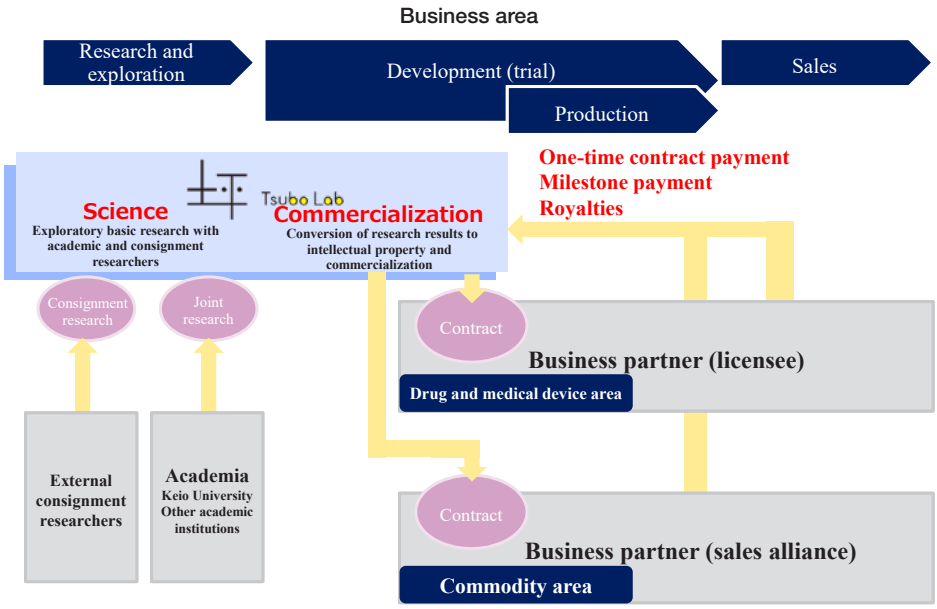
Strength in science and commercialization

2. Business model and strengths

With a mission of brightening the future with VISIONary INNOVATION, the Company aims to "deliver revolutionary innovations for myopia, dry eye, presbyopia, and brain diseases" and is steadily promoting business activities. It seeks to increase enterprise value by solving societal issues, such as the steep rise in myopia globally, decline in quality of life (QOL) due to dry eye, and strong needs for presbyopia preventive treatment.

(1) Business model

As its business model, the Company pursues the formation of intellectual property from, and finds joint development partners for development candidates created from exploratory basic research with Keio University, other academic institutions, and external consignment researchers, obtains one-time contract payments and milestone income by concluding development and sales contracts, and acquires royalty income based on sales volume after the start of development candidate sales. The Company's development candidates include drugs and medical devices that require production and sales approval from regulatory authorities based on clinical trial results and also commodity products that do not need these approvals. Since one-time contract payments and milestone income are currently the primary income source, sales fluctuate depending on progress with these efforts. Once sales ramp up for development candidate products and expand, income stability will be enhanced by increased royalty income. For example, in a case with a contract that projects roughly ¥200.0bn total sales of the product by the contract partner and income of ¥20.0bn for the Company as a 10% share, the Company will negotiate a one-time contract payment, milestone income, and the royalty rate (percentage of total income for each of these sources will differ depending on the contract).



Source: From "Business Plan and Items Related to Growth Possibilities"

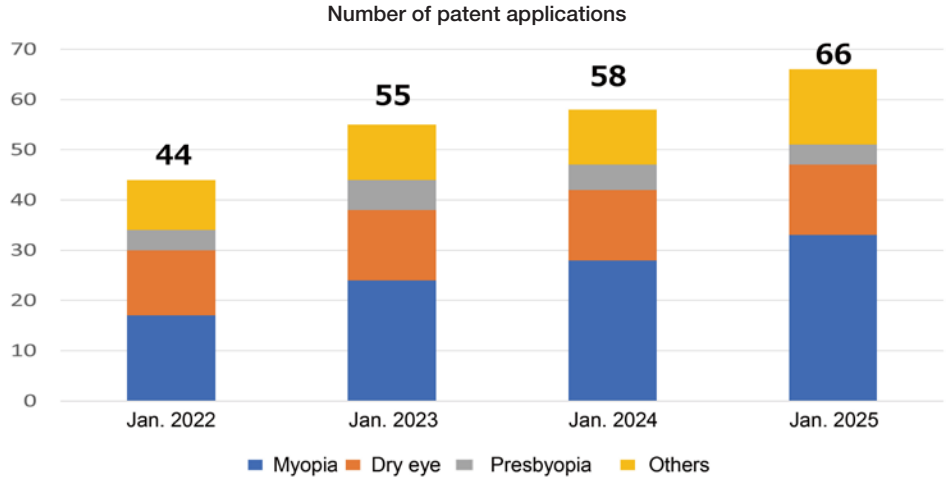
The Company currently does not have any development candidates approved as drugs or medical devices and only receives royalty income from commodity products. Commodity product commercialization examples are the Rohto Pharmaceutical supplement "Rohto Clear Vision Junior," JINS' violet-light transmission glasses "Violet+" and eyeglass frame that enhances moisturizing effect around the eye "JINS PROTECT MOIST," and NEC's <6701> notebook PC (violet-light irradiation) "LAVIE Limited-Edition Model" (released in 2023). The Company is currently promoting the development of various products based on violet-light technology.

(2) Company strengths

An important strength is the Company's established regulatory science operation. Regulatory science refers to the science of appropriately and promptly forecasting, assessing, and determining the quality, efficacy, and safety for commercialization of R&D results in the medical field based on scientific knowledge. It reflects the ability to develop scientific policies and testing methods for R&D activities and prepare and evaluate data. These are key factors in intellectual property strategy, such as formulating academic papers and acquiring patents, and licensing.

On the intellectual property front, the Company had 66 patent application submissions as of the end of January 2025 with a breakdown of around 50% in the myopia field, around 20% in the dry eye field, and 11 application submissions in presbyopia field and other areas (including brain disease). Furthermore, the total impact factor*, an indicator that assesses the level of impact of published academic papers (31 papers), improved from 168.3 in 2023 to 187.8 in 2024 and 5.2 to 6.1 per paper, and this trend confirms rising assessment of the Company's academic papers.

* This factor shows the average number of citations of an academic paper carried in a scientific journal in all academic papers published in the subject fiscal year.



Source: The Company's results briefing materials

In research operations, the Company is currently working with two research teams at Keio University (School of Medicine, School of Science and Engineering) and implementing joint research. It is also securing researchers with necessary skills as needed via outsourcing arrangements. These resources provide the operations to carry out research work. While the Company itself has 6 full-time R&D employees as of the end of March 2025, its overall scale including outsourced members is 43 people. The outsourcing system has the advantage of making it possible to keep R&D costs fluid. The Company has been holding Tsubo Lab Conferences since 2023, where outside researchers and related parties gather and, after signing a NDA (non-disclosure agreement), present and discuss the details of their individual research, using the meeting as an opportunity to create new pipelines.

Another strength is commercialization. In this case, commercialization refers to early arrangement of contracts (development contracts and joint research) for development candidates. The Company has concluded development contracts with 8 companies* since 2019 and conducts joint research and other contracts (including contract research, consignment research, and outsourcing) with more than 20 companies and organizations. It was also selected for three grant projects by public entities in FY3/24 (violet light treatment for retinitis pigmentosa, irregular menstruation, and aging dog cognitive functions). These results can be attributed to the Company's intellectual property strategy, which leads to early contracts, as well as the fact that the evidence is well covered, including the mechanisms of action, by the publication of papers based on non-clinical and clinical research data. By leveraging this strength, the Company will continue advancing developments with early licensing, acquiring royalty income via sales of medical devices and drugs, and enhancing corporate value.

* Eight companies: JINS HOLDINGS, Sumitomo Pharma, Rohto Pharmaceutical, Maruho, Laboratoires Théa (France), Twenty Twenty Therapeutics (US), Shenyang Xingqi Pharmaceutical (China), and Beijing Yijie Pharmaceutical Technology (China).

In April 2025, these efforts were recognized, in the 2025 Intellectual Property Achievement Awards sponsored by the Ministry of Economy, Trade and Industry and the Japan Patent Office, where the Company received the Award from Commissioner of the Japan Patent Office*. The reasons for winning the award included the development of a licensing business model centered on intellectual property, the establishment of a method for balancing patent strategy with the early conclusion of partnership agreements, and the creation of a smooth joint application process with universities and a mechanism for sharing global intellectual property.

* The Ministry of Economy, Trade and Industry presents this award to individuals who have contributed to the development, dissemination and awareness of Japan's intellectual property rights system, as well as to companies that have contributed to the operation and development of the system. Since 1987, the awards have been presented annually on April 18, which is "Invention Day."

Pipeline trends

Concluded four license agreements with companies in Japan and overseas in FY3/25

The Company's medical device and drug pipeline is currently moving forward with 13 developments (7 medical devices, 6 drugs), mainly in the myopia, dry eye, and brain disease fields.

Pipeline trends

Medical device and drug pipeline

Code	Expected indication	Related patents		Partner	Development stage
TLM-001	Meibomian gland dysfunction	Registered	Japan, US, UK, Germany, France	Maruho (global)	Domestic phase-1 clinical trial completed in February 2025
TLM-003	Myopia progression curtailment (curtailing sclera thinning)	Registered	Japan, South Korea, Europe	Rohto Pharmaceutical (Japan, three Asian regions*1)	Rohto Pharmaceutical started a phase-2 clinical trial in Japan in April 2025 Laboratoires Théa preparing clinical trial in Europe
		Applied	US, China, Thailand, Vietnam	Laboratoires Théa (US, Europe)	
TLM-007	Myopia progression curtailment (increase in eye blood flow)	Registered	Japan	Undecided	Lowered the development priority level
		Applied	US, Europe, China, Canada, Australia, Taiwan, South Korea, Asia		
TLM-017	Corneal and conjunctival disorders	Applied	Japan, US, Europe, China, Taiwan, South Korea, Vietnam, Indonesia	Undecided	Preparing clinical trial
TLM-018	Undisclosed (Eyedrop drug)	Applied	International (PCT) (including Japan)	Rohto Pharmaceutical	In process of applying for approval
TLM-023	Myopia progression curtailment	Applied	Japan, US, Europe, China, Australia, Brazil, Canada, Indonesia, India, South Korea, Mexico, Malaysia, Singapore, Thailand, Taiwan, Vietnam	Undecided	Preparing clinical trial
TLG-001*2	Myopia progression curtailment	Registered	Registered, Japan, Europe*3, Kazakhstan, Singapore, Taiwan, South Korea	JINS HOLDINGS (Japan)	Registered subjects for verification clinical trial in Japan
		Applied	China	BYPT (China, three Asian regions*4)	Completed. Planning to announce results in spring 2026. Concluded license agreement with BYPT for China and three regions in Asia in March 2025.
TLG-003*2	Keratoconus progression curtailment	Registered	Japan, India	Undecided	Completed designated clinical research
		Applied	US, Brazil		
TLG-005D	Depression	Registered	Japan	Undecided	Completed designated clinical research in May 2024
		Applied	US, Europe, China, Israel, Brazil, South Korea, India		
TLG-005P	Parkinson's disease	Registered	Japan, US, Europe, China, Canada, South Korea, Mexico	Undecided	Completed designated clinical research in March 2024
		Applied	Singapore, Thailand, Vietnam		
TLG-020	Retinitis pigmentosa	Applied	International (PCT) (including Japan)	Undecided	Applied with Clinical Research Ethics Committee
TLG-021	Irregular menstruation	Applied	In preparation	Undecided	Started designated clinical research in Japan in 2024

*1 Taiwan, Vietnam, Indonesia
*2 Violet light-related products (TLG-001, TLG-003) are covered by basic patents in addition to related patents. The Company has registered the basic patents in Japan, the US, China, Taiwan, and Korea and is applying in Europe, South Korea, and Singapore.
*3 UK, France, Germany, Italy
*4 Hong Kong, Macao, Taiwan
Source: Prepared by FISCO from the Company's results briefing materials

1. Drugs

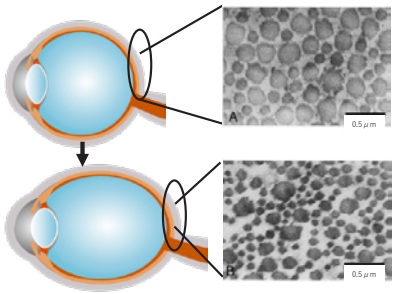
(1) TLM-003 (myopia progression curtailment)

The Company is developing three drugs that address myopia curtailment. TLM-003, which is the most advanced candidate among them, is an eyedrop drug that prevents myopia progression by administering eyedrops 1–2 times per day. Sclera*1 endoplasmic reticulum stress*2 is viewed as a source of myopia occurrence and the progression mechanism. Stimulation caused by endoplasmic reticulum stress results in thinning of the sclera and thereby makes the eye axis more prone to lengthening and causing myopia progression. It is thought that administering eyedrops containing 4-PBA (4-phenylbutyric acid), which has the effect of curtailing endoplasmic reticulum stress stimulation, can restrict myopia progression. 4-PBA is currently used as an oral drug to treat pediatric kidney disease. This is the first development of 4-PBA as an eyedrop, and the Company has already obtained a usage patent.

*1 White membrane portion on the outside of the eyeball.
*2 An endoplasmic reticulum is an organelle with a bag-shaped structure inside cells that handles the role of transporting substances within the cell. Endoplasmic reticulum stress refers to the state of excess accumulation of protein not correctly folded into the endoplasmic reticulum and protein that is not properly modified.

TLM-003 (myopia progression curtailment eyedrop drug): Started a domestic clinical trial

Curtails extension of the sclera through restriction of sclera thinning and thereby limits myopia



The sclera consists of Type-I collagen fiber and other extracellular matrix. In myopia, there is evidence of remodeling of the scleral tissue's collagen fiber, and it is not possible to curtail extension of eye axis length.

Source: The Company's results briefing materials

An experiment using myopic model mice proved the drug effective in inhibiting the progression of myopia, and in October 2020, the Company concluded a joint research agreement with Rohto Pharmaceutical. The two companies have carried out basic research since then. Since safety was confirmed by a phase-1 clinical trial conducted by Rohto Pharmaceutical starting in November 2023, a phase-2 clinical trial started in April 2025. According to public information, the planned number of subjects is 210 (ages 6 to 15), and the placebo-controlled comparative trial of the active drug will involve two groups, one a low dose, and the other a high dose. The trial period, including the follow-up period, is expected to be around three years, and if the results are good, it will proceed to phase-3 clinical trials. The drug is expected to be launched after 2030.

In overseas markets, in December 2022, the Company concluded an exclusive license agreement with Thea for intellectual property rights in areas mainly in Europe and the United States*1, and preparations for a clinical trial in Europe are progressing. In October 2024, the Company announced that it had concluded a license agreement with an overseas licensee regarding non-clinical trial data and some clinical trial results. The licensee is believed to be Thea, and the clinical trial data is thought to have been provided to the licensee by Rohto Pharmaceutical through the Company for a fee. In addition, in September 2024, the Company also concluded an exclusive license agreement with a major Chinese ophthalmic pharmaceutical manufacturer for the region of China*2, as global out-licensing activities have also progressed smoothly.

*1 EUR41.5mn in one-time contract payment and milestone payments + royalties
*2 USD18mn in one-time contract payment and milestone payments

(2) TLG-001 (dry eye)

TLM-001 (ointment) is a treatment for meibomian gland dysfunction. Meibomian gland dysfunction is a condition in which the amount of lipids secreted from the meibomian glands on the edge of the eyelids decreases for some reason, causing the tear film to become unstable, and resulting in symptoms such as eye discomfort and dryness. It is one of the causes of dry eye. The Company has proven through animal experiments and clinical trials that Vitamin D-related substances can revive this function, and in April 2021, the Company concluded an exclusive license agreement with Maruho for Japan, the United States, France, the United Kingdom, Germany, and other countries. Maruho's phase-1 clinical trial was completed in February 2025, and it was confirmed that there were no safety issues, so further development is expected going forward.

(3) New pipelines, etc.

Newly added pipeline items include TLM-017 (corneal and conjunctival disorder) and TLM-023 (myopia progression suppression), and these are currently in the preparation stage for clinical trials. TLM-023 is an eyedrop drug with a new mechanism of action using a newly-developed compound. In addition, TLM-018 (eyedrop drug) has undergone small-scale clinical trials at partner Rohto Pharmaceutical, and an application for marketing approval has been submitted. It may be launched as early as before the end of 2025.

2. Medical devices

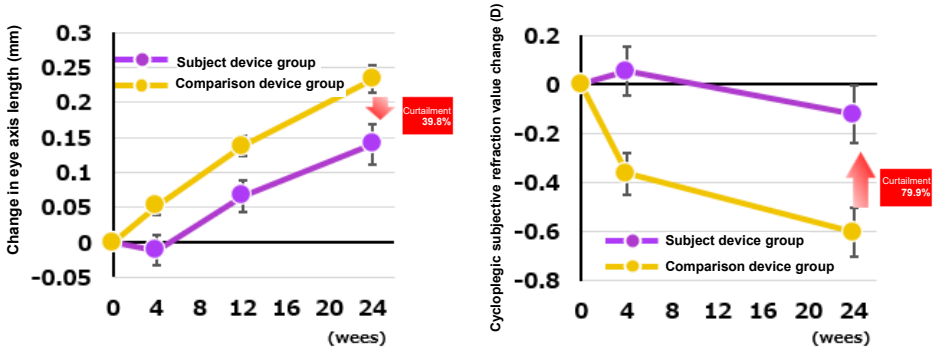
(1) TLG-001

The myopia progression curtailment device (TLG-001) attaches a violet light source to eyeglasses and actively irradiates the eye with violet light for roughly three hours a day. This stimulates OPN5 non-visual light reception protein in the inner layer of the retina and the resulting improvement in blood flow maintains choroid thickness, which is expected to curtail myopia progression.

After confirming safety in an exploratory clinical trial with myopic children in the past (six-month period) and obtaining favorable results for efficacy at the six-month inspection with 39.8% curtailment of advancement in eye axis lengthening versus the comparison group and 79.9% curtailment of cycloplegic objective and subjective refraction change, the Company started a verification clinical trial in June 2022. The trial method evenly allocates 160 children aged 6-12 with mild myopia (-1.5D to -3.0D) into a subject device group and comparison device group and has them wear the device daily for 12 months. For the next 12 months, it observes the situation without wearing the device. Nine tests are conducted over two years. The main endpoint is measurement of change in the cycloplegic objective refraction value for the period from the start of wearing the trial device until the 12-month timing and comparison with the other device group. Secondary endpoints are change in eye axis length and choroid thickness at the 1-month, 3-month, 6-month, 9-month, and 12-month points after starting use of the trial device. Since the Company confirmed in the exploratory clinical trial that there is a statistically meaningful difference in a short period (six months) and that myopia tends to progress over time, it anticipates obtaining results that are even more positive in this clinical trial.

Pipeline trends

Data from exploratory clinical research



Source: From "Business Plan and Items Related to Growth Possibilities"

The Company completed the recruitment of trial participants in October 2023, and the observation period ends in October 2025. After data collection and analysis, the Company should be able to announce clinical trial results in as early as spring 2026. JINS HOLDINGS, the development partner, plans to apply for production and sales approval if the results are positive, and this might facilitate the start of sales in Japan as soon as 2027. Since rise in the percentage of children with myopia has become a societal issue and statistical data indicate heightened risk of eye disease in the future in cases of severe progression of myopia, this device is likely to make inroads in Japan and other countries once it is available. Some forecasts project an increase in the percentage of the population with myopia, increasing to 50% globally in 2050 (vs. 28% in 2010). This business has substantial social significance.

In March 2025, the Company concluded a license agreement for TLG-001 with BYPT for China, Hong Kong, Macao, and Taiwan (total contract amount of ¥1.03bn, excluding sales royalties). The prevalence of myopia in China is as high as in Japan and South Korea, and the government has set a goal of keeping the myopic population in check, so research and development is being actively carried out. If the development is successful, it is expected to make a large contribution to revenue.

The Company has positioned the Chinese market as one of its key markets, and in July 2024 it opened an office in Eye Valley* in Wenzhou, Zhejiang Province, the center of ophthalmology, becoming the first Japanese company to do so (though for the time being, it will not assign any permanent employees). In addition to collecting information locally, it is also working to build relationships with local companies in research and clinical systems. In FY3/25, the Company concluded license agreements with two Chinese pharmaceutical companies, and the benefits of opening the office have quickly become apparent.

* This is a world-first multi-function facility for eye health science, technology, human resources, and industry that opened in June 2020. It promotes comprehensive progress in the eye health industry by attracting global advanced resources and is building a world-class hub for technology R&D, industry cultivation, academic exchange, high-end medical services, and innovative human resources. Just under 200 companies currently have a presence, including 32 research institutes.

(2) TLG-005

The Company concluded a joint research contract with Sumitomo Pharma on the theme of "developing a therapeutic method using violet light" for brain diseases (depression, mild dementia, Parkinson's disease) in 2021 and implemented designated clinical research on each of these diseases. On July 9, 2024, the Company announced preliminary results related to clinical research efforts on both Parkinson's disease and depression. For Parkinson's disease (research on 20 patients), it found no problems with safety, the main endpoint, and regarding efficacy, the secondary endpoint, it obtained results suggesting an improvement in some symptoms in the evaluation test for Parkinson's disease symptoms* for prior to irradiation and 12 weeks afterwards. Sumitomo Pharma concluded that it was difficult to calculate commercial value, and announced the termination of its exclusive license in May 2024.

> * This test determines whether someone sees illusions, such as a person's face or an animal, in a landscape image and is used as substitute test for hallucinations. The frequency of hallucinations is known to increase in Parkinson's disease patients, and the test can help in ascertaining and managing symptoms.

In the clinical research on depression, meanwhile, the Company conducted a double blind comparative study for 70 patients diagnosed with major depressive disorder with the subject device (violet light irradiation) and a comparative device for all cases. The Company announced results that confirmed a meaningful improvement effect for the subject device versus the comparative device for the MADRS score*, which was the main endpoint, from prior to starting device use to after irradiation and also did not find any safety issues. However, based on a management strategy-based decision, Sumitomo Pharma made the decision to terminate its exclusive license for this drug to treat depression.

> * This is a general measure used to assess depression symptoms. It is widely used in clinical trials and clinical treatment to evaluate depression severity and treatment effect.

The results of a designated clinical study on mild cognitive impairment announced in February 2025 showed that 42 subjects were enrolled and there were no safety issues. In addition, the Company was unable to confirm statistical superiority in the primary efficacy metrics that were initially set and has decided to advance further detailed analysis based on the data.

(3) New pipeline

The Company added new pipeline items with TLG-020 for treatment of retinitis pigmentosa*, and TLG-021 for irregular menstruation.

> * This is a rare genetic progressive disease that causes abnormality in the retina that covers the inside of the eyeball, and it poses risk of blindness at an advanced stage. There is currently not an effective treatment method, and Japan has designated it as an intractable disease.

TLG-020 offers the possibility of a new treatment method for retinitis pigmentosa with violet light that is being jointly development with Keio University School of Medicine. It was selected in March 24 as a grant project as "development of an innovative medical device for retinitis pigmentosa" for the FY2023 TOKYO Strategic Innovation Promotion Program by the Tokyo Metropolitan Small and Medium Enterprise Support Center (¥80mn grant for a three-year project period). The Company plans to utilize the grant funds to verify efficacy and safeness in non-clinical research, and it is currently in the process of preparing for the start of designated clinical research. It is likely to secure licensing contracts in Japan and other countries if it can be proven that violet light is meaningfully better in curtailing progression of the disease than existing symptomatic treatments, given the strong unmet medical need.

Pipeline trends

TLG-021 was selected in March 2024 as a grant project as “development of device for treatment of irregular menstruation using light irradiation” in the FY2023 femtech development support and promotion program for women conducted by the Tokyo Metropolitan Small and Medium Enterprise Support Center (¥20mn grant for a project period through November 30, 2025). The Company plans to utilize the grant funds to conduct designated clinical research on a new treatment method aimed at confirming efficacy and safety in treating human irregular menstruation. It will also work on development of a medical device with an easy-to-use design for women in daily life. The violet light effect should improve circadian rhythm* via the brain center and eliminate irregular menstruation via the same effect. The results of the clinical research are expected to be revealed during FY3/26.

* The roughly body’s 24-hour cycle (body clock) is known as the circadian cycle.

Results trends

Set new record highs in FY3/25 in net sales, ordinary profit and net income

1. Overview of FY3/25 results

In the FY3/25 results, the Company achieved record highs in net sales, ordinary profit and net income for the first time in four fiscal years with net sales of ¥1,357mn (up 101.5% YoY), operating profit of ¥235mn (vs. a loss of ¥649mn in the previous fiscal year), ordinary profit of ¥281mn (vs. a loss of ¥636mn), and net income of ¥205mn (vs. a loss of ¥641mn). These were solid fiscal year results, as net sales and each profit line exceeded the Company’s initial forecast.

FY3/25 results

(¥mn)

	FY3/24 Results	FY3/25		YoY		vs. forecast
		Company forecast	Results	Change amount	Change (%)	
Net sales	673	1,200	1,357	683	101.5%	157
Gross profit	21	-	1,176	1,155	-	-
SG&A expenses	670	-	941	270	40.3%	-
(R&D expenses)	205	410	254	48	23.8%	-155
Operating profit	-649	131	235	885	-	104
Ordinary profit	-636	160*	281	917	-	121
Net income	-641	110*	205	847	-	95

* Revised using 3Q FY3/25 figures
Source: Prepared by FISCO from the Company’s financial results and results briefing materials

The increase in net sales was due to an increase in one-time contract payments associated with the concluding of four license agreements, both in Japan and overseas. The Company concluded an exclusive license agreement for certain patents with Shenyang Xingqi Pharmaceutical Co., Ltd., a major Chinese manufacturer of ophthalmic pharmaceuticals (total contract amount: USD18mn), and a license agreement for TLG-001 with BYPT (total contract amount: ¥1.03bn). The Company also concluded a license agreement for non-clinical and clinical data with another overseas pharmaceutical company. In Japan, the Company concluded an exclusive evaluation agreement with Rohto Pharmaceutical to evaluate intellectual property rights for an eyedrop drug that it is developing and to evaluate whether or not to accept a license agreement with a view to commercialization, and received ¥100mn for this. This eyedrop drug may show effectiveness in preventing and treating severe ocular surface diseases and dry eye, and is expected to become a new treatment option in Japan. Looking at each pipeline, the revenue was just under ¥1.1bn for TLM-003, just under ¥200mn for TLG-001, and the remainder was from one-time contract payments, consulting income, and royalty income, etc., from other pipelines.

Gross profit increased by ¥1,155mn YoY to ¥1,176mn. In the previous fiscal year, the Company recorded ¥328mn in provision for loss on contracts under cost of sales due to the prolonged clinical trial period for TLG-001, which was a factor in the decline in gross profit, but this negative factor did not occur again, leading to a significant increase in gross profit. Selling, general and administrative expenses increased by ¥270mn YoY to ¥941mn. This was mainly due to an increase in labor costs resulting from an increase in the number of employees (17 employees, an increase of 10 employees from the end of the previous fiscal year), and R&D expenses also increased by ¥48mn. R&D expenses were ¥254mn, ¥155mn lower than the initial forecast of ¥410mn, was because the forecast included patent-related expenses of ¥100mn. Excluding this factor, the actual decrease was ¥55mn. Because the Company outsources most of its R&D, expenses tend to fluctuate depending on the status of pipeline progress.

In August 2024, the Company relocated its headquarters to CRICK Shinanomachi (9th floor, Building 2, Shinanomachi Campus), an incubation center at Keio University, with the aim of bolstering collaboration with the Keio University School of Medicine and accelerating the commercialization of research results.

Financial condition is sound and the Company is advancing business activities using cash on hand

2. Financial position

Looking at the financial condition as of the end of FY3/25, total assets increased by ¥207mn from the end of the previous fiscal year to ¥2,503mn. The main factors behind the change were a decline of ¥344mn in cash and deposits, an increase of ¥528mn in accounts receivable – trade, an increase of ¥62mn in consumption taxes refund receivable, and a decline of ¥13mn in fixed assets.

Total liabilities declined ¥12mn to ¥915mn. The change was mainly due to an increase of ¥115mn in accounts payable - trade and an increase of ¥81mn in income taxes payable, which were offset by an ¥87mn decline in contract liabilities and a ¥121mn decline in provision for loss on contracts. Interest-bearing debt dropped steadily by ¥26mn to ¥90mn. Total net assets increased by ¥220mn to ¥1,587mn. This was due to the fact that both share capital and legal capital surplus increased ¥7mn due to the exercising of stock acquisition rights, and the Company recording net income of ¥205mn.

The equity ratio increased by 3.8 percentage points from the end of FY3/24 to 63.4% in conjunction with the increase in net assets accompanying the increase in earnings. The Company's net cash declined ¥318mn to ¥1,448mn due to the increase in accounts receivable – trade, but it is believed to be at a level that is sufficient to support business activities for the time being. However, the Company generates the majority of its income from one-time contract payments and milestone income, and there might be a point at which it needs to raise funds if these income sources do not materialize as planned.

Balance sheet

(¥mn)

	End of FY3/22	End of FY3/23	End of FY3/24	End of FY3/25	Change
Current assets	1,515	2,568	2,223	2,445	221
(Cash and deposits)	1,174	2,161	1,883	1,538	-344
Non-current assets	102	104	71	57	-13
Total assets	1,617	2,672	2,295	2,503	207
Total liabilities	873	722	927	915	-12
(Interest-bearing debt)	223	139	116	90	-26
Total net assets	744	1,950	1,367	1,587	220
(Soundness)					
Equity ratio	46.0%	73.0%	59.6%	63.4%	3.8pp
Interest-bearing debt ratio	30.1%	7.1%	8.6%	5.7%	-2.9pp
Net cash	951	2,021	1,766	1,448	-318

Note: Net cash = Cash and deposits – interest-bearing debt
Source: Prepared by FISCO from the Company's financial results

Expecting higher profits for the second consecutive fiscal year in FY3/26 due to an increase in one-time contract payments

3. FY3/26 forecast

In the FY3/26 results forecast, the Company projects ¥1,400mn in net sales, an increase of 3.2% YoY, ¥200mn in operating profit, a decrease of 15.1%, ¥220mn in ordinary profit, a decrease of 21.9%, and ¥150mn in net income, a decrease of 27.1%. While net sales are expected to continue to increase as the Company advances pipeline out-licensing contracts, each profit line is expected to decline due to increased R&D expenses. However, while many biotech ventures continue to record losses due to development costs, it is commendable that the Company has been posting profits from FY3/20 onward, with the exception of FY3/24.

FY3/26 forecast

(¥mn)

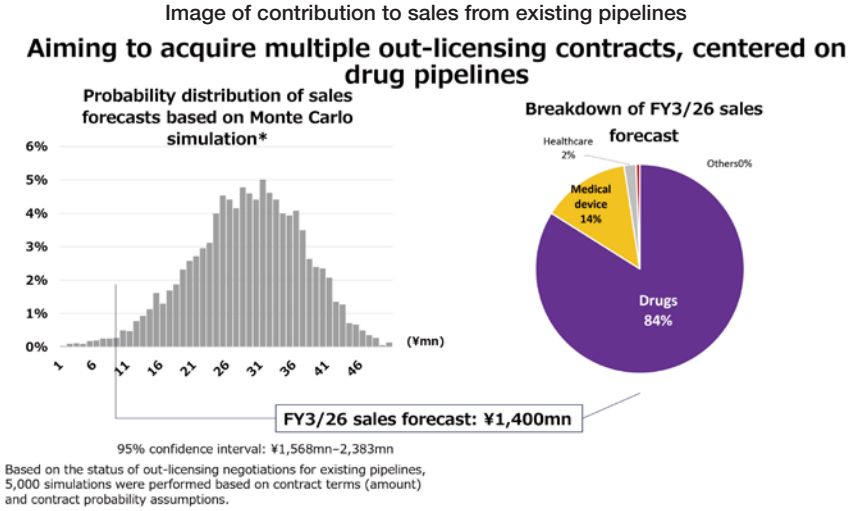
	FY3/25 Results	FY3/26 Company forecast	YoY	
			Change amount	Change (%)
Net sales	1,357	1,400	43	3.2%
(R&D expenses)	254	550	296	116.5%
Operating profit	235	200	-35	-15.1%
Ordinary profit	281	220	-61	-21.9%
Net income	205	150	-55	-27.1%
Net income per share (yen)	8.04	5.85		

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

Results trends

As in the previous fiscal year, the majority of sales are expected to come from one-time contract payments based on the signing of out-licensing contracts for development pipelines. The sales forecast was determined based on the status of negotiations for existing pipelines, assuming contract terms and contract finalization for each pipeline, and by conducting simulations. Net sales are expected to break down as follows: 84% from pharmaceuticals; 14% from medical devices; and 2% from healthcare products.

Image of contribution to sales from existing pipelines



Based on the status of out-licensing negotiations for existing pipelines, 5,000 simulations were performed based on contract terms (amount) and contract probability assumptions.

Source: The Company's results briefing materials

The Company is targeting multiple out-licensing contracts from FY3/26 onward as well. Its important management goals are to steadily advance pipeline R&D and enhance pipeline value by publishing academic papers and acquiring patents, and to add one to two new additions annually to further expand the pipeline.

Licensing situation for major pipeline items (○indicates out-licensing regions)

Pipeline (Expected indication)	Japan	China	Asia	Europe	United States
TLM-001 (Meibomian gland dysfunction)	Maruho	Maruho	Maruho	Maruho	Maruho
TLM-003 (Myopia progression curtailment)	Rohto Pharmaceutical	Undisclosed	Rohto Pharmaceutical	Laboratoires Théa	Laboratoires Théa
TLM-017 (Corneal and conjunctival disorders)	○	○	○	○	○
TLM-018 (Undisclosed, Eyedrop drug)	Rohto Pharmaceutical	○	○	○	○
TLM-023 (Myopia progression curtailment)	○	○	○	○	○
TLG-001 (Myopia progression curtailment VL eyeglasses)	JINS HOLDINGS	BYPT	○	○	○
TLG-003 (Keratoconus progression curtailment)	○	○	○	○	○
TLG-005D (Depression)	○	○	○	○	○
TLG-005P (Parkinson's disease)	○	○	○	○	○

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

The Company has no plans to strengthen its personnel structure other than hiring a few executive candidates, and therefore expects the increase in labor costs to be slight. R&D expenses are expected to increase by ¥296mn YoY to ¥550mn, of which approximately ¥60mn is included in patent-related expenses. Excluding those expenses, the increase would be ¥236mn. The decrease in operating profit appears small compared to the increase in R&D expenses, but this is because there will no longer be any purchase costs (included in cost of sales) for clinical trial data that were purchased from Rohto Pharmaceutical in the previous fiscal year under license agreements with overseas pharmaceutical companies.

In addition, in May 2025, the Company opened an office within the SNBL Global Gateway (SGG)*, a business incubation center in Seattle, United States. Seattle is a core region on the West Coast where industry and academic institutions in the life sciences field are concentrated, and the Company plans to use the office as a hub for R&D and business partnerships to accelerate R&D and licensing activities in the North American market. As with the China office, activities will be conducted on a business trip basis for the time being.

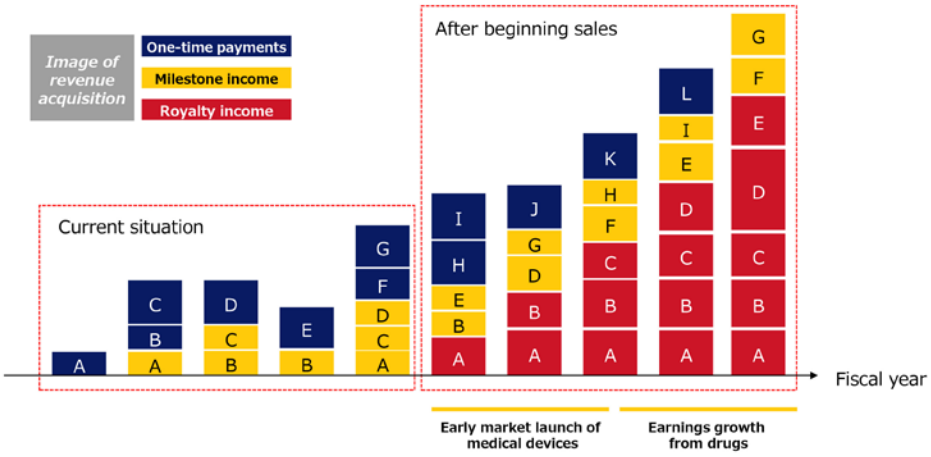
* SGG is a business incubation center jointly established by SNBL Co., Ltd. <2395> and SBI Holdings, Inc. <8473> in Everett, Washington in 2024. Under this agreement, the Company will receive local business support services provided by SGG, such as introductions to investors and experts.

Attention is being paid to drugs and medical devices for curtailing myopia progression, for which potential demand is large

4. Medium- to long-term growth outlook

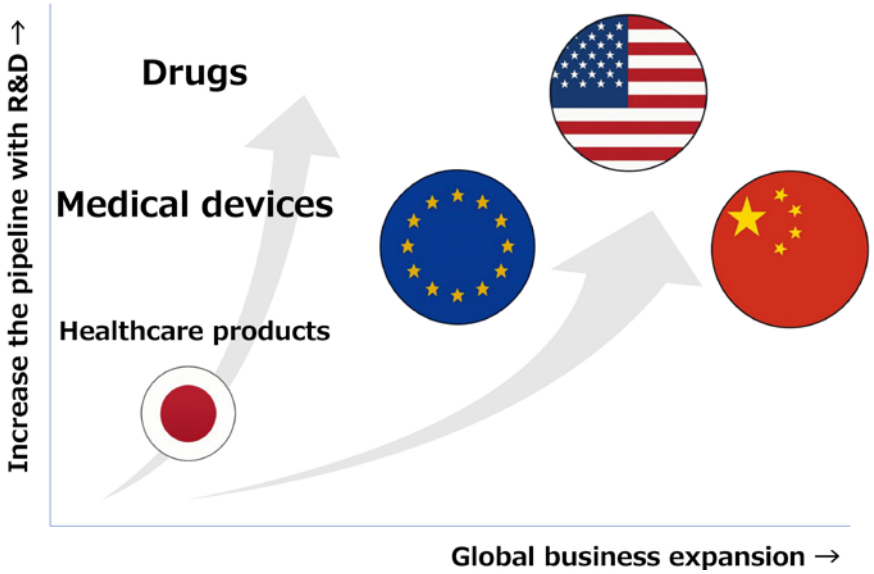
As a medium- to long-term growth strategy, the Company aims to achieve dramatic growth by expanding its development pipeline and receiving one-time contract payments and milestone payments associated with the licensing out of each pipeline product, as well as accumulating royalty income after market launch on a global scale.

Longer-term growth image



Source: The Company's results briefing materials

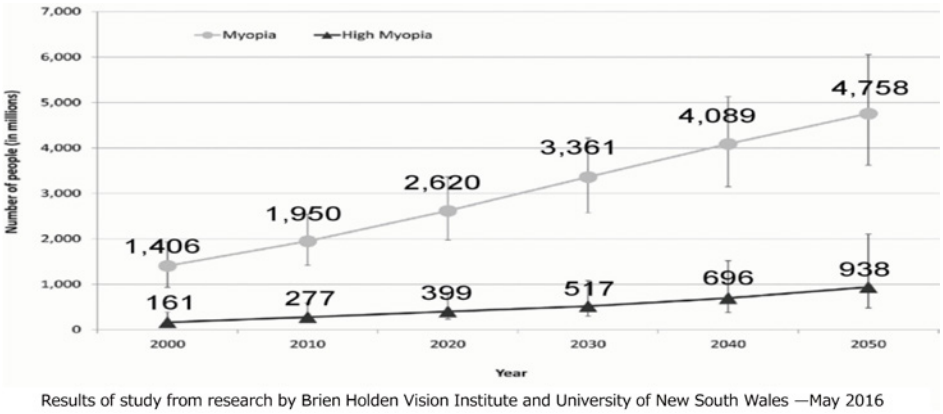
Growth strategy



Source: The Company's results briefing materials

In particular, as the number of myopic people continues to increase worldwide and it becomes more of a societal issue, attention is expected to increase in the future for drugs and medical devices that are expected to be effective in suppressing the progression of myopia. The global myopic population is expected to increase from 1.46 billion in 2000 to 4.75 billion in 2050, of which the severe myopic population is expected to increase from 160 million to 930 million. Since there is still no cure, the potential demand is considered to be enormous. In Japan, Santen Pharmaceutical Co., Ltd.'s <4536> eyedrop drug RYJUSEA® Mini ophthalmic solution 0.025% was released in April 2025 as a drug aimed at suppressing the progression of myopia, and it seems to have made a promising start. In addition to TLM-003, which is being jointly developed with Rohto Pharmaceutical, the Company is developing several pipelines, including TLM-023. In addition, in medical devices, TLG-001 may be released as early as 2027, so FISCO will be paying close attention to these developments.

Global myopic population



Source: The Company's results briefing materials

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