COMPANY RESEARCH AND ANALYSIS REPORT

SymBio Pharmaceuticals Limited

4582

Tokyo Stock Exchange Growth Market

9-Nov.-2026

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SymBio Pharmaceuticals Limited
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https://www.symbiopharma.com/en/index2.html

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SymBio Pharmaceuticals Limited
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Summary

Aiming to conclude licensing agreements for BCV and the IVD business within 2026

SymBio Pharmaceuticals Limited <4582> (hereafter, also “the Company”) is a bio-venture advancing development from the clinical trial stage, targeting therapeutic areas with high unmet medical needs*, and is promoting efficient business operations through a “no lab or fab” strategy. Its currently marketed product is TREAKISYM® Intravenous Solution (hereafter, “TREAKISYM”), a treatment for hematologic cancers, and its development product is the antiviral drug brincidofovir (hereafter, “BCV”). BCV is being developed in three therapeutic areas: post-transplant viral infections, cancer, and neurodegenerative diseases.

* Areas in which no effective existing drugs or treatments are available despite strong demand from patients and physicians.

1. Development trends of brincidofovir (BCV)

Research has established that BCV exhibits strong antiviral activity against a wide range of DNA viruses as well as antitumor activity, and the Company is currently developing multiple pipelines in three therapeutic areas. The most advanced program, for adenovirus (AdV) infection following hematopoietic stem cell transplantation, is in a global Phase III clinical trial that began in the second half of 2025, with the aim of submitting an approval application in 2028 and launching in 2029. For progressive multifocal leukoencephalopathy (hereafter, “PML”), the Company concluded a Cooperative Research and Development Agreement (CRADA) with the U.S. National Institutes of Health (hereafter, “NIH”) in February 2026 and began an investigator-initiated Phase II clinical trial. Patient enrollment is expected to be completed in 2027, and the Company aims to submit an approval application in 2028 by utilizing the Accelerated Approval program*. In addition, preparations are underway to begin investigator-initiated Phase II clinical trials for pipelines targeting malignant brain tumors, head and neck cancer, and EBV-associated gastric cancer, all of which showed favorable preclinical results. The Company is negotiating toward the early conclusion of agreements with marketing partners for AdV infection and PML, and with development and marketing partners for the oncology pipelines. If approval is obtained for multiple indications, the business value of BCV could exceed ¥100.0bn, and future developments are attracting attention.

* A program for diseases with high unmet medical needs, under which accelerated approval is granted when clinical benefit is predicted based on an intermediate or surrogate endpoint. Drugs granted accelerated approval are required to conduct post-marketing clinical trials, and approval may be withdrawn depending on the results. The review period is approximately six months.

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2. Results trends for 1H FY12/26 and fundraising plan

For 1H FY12/26, net sales declined 27.3% year on year (YoY) to ¥469mn, while operating loss was ¥3,635mn (an increase of ¥1,481mn YoY). In addition to lower TREAKISYM sales due to the impact of drug price revisions and the penetration of generics, research and development expenses rose to ¥2,997mn (up ¥1,415mn) in line with progress in BCV development, widening the loss. For the full fiscal year, the Company has maintained its initial forecasts of a 197.5% YoY increase in net sales to ¥3,891mn and operating loss of ¥4,231mn (a decrease of ¥209mn YoY). The forecasts incorporate partnering revenue of ¥3,000mn. In addition to BCV, the Company expects to conclude partnering agreements for the "pM Engine"*, an ultra-high sensitivity immunochromatography system announced in October 2025. As research and development expenses are expected to expand to ¥6,077mn (up ¥2,779mn), the loss is expected to remain at a level similar to the previous fiscal year. The Company was in a state of negative net worth as of the end of June 2026, and its cash and deposits had declined to ¥977mn. Accordingly, on August 17, it announced the issuance of privately placed bonds and share acquisition rights through a third-party allotment. The Company aims to secure research and development funds for the time being through the exercise of the share acquisition rights and other means, while also pursuing cost reductions to achieve an early exit from negative net worth.

> * A portable in vitro diagnostic system jointly developed with Nippon Steel Chemical & Material Co., Ltd. that enables immediate, on-site quantitative measurement of antigens such as viruses with ultra-high sensitivity approximately 100 times greater than conventional technologies. In addition to enabling the early detection and diagnosis of viral infections and other diseases, the system is expected to be applied in industrial fields.

3. Growth strategy through 2030

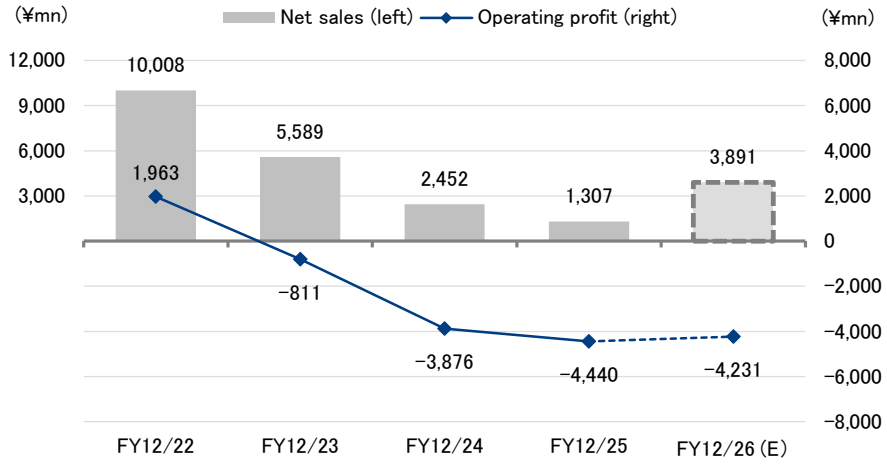
As its business strategy going forward, the Company has set the launch of BCV for at least 2 indications by 2030 as its top priority, while in parallel advancing its pipelines in the large-market oncology and neurodegenerative disease areas through a partnering strategy, with the aim of maximizing the business value of BCV. Although BCV will remain in the development stage for the time being, its immense potential makes future developments a focus of considerable attention.

Key Points

- Focusing on 3 therapeutic areas—post-transplant viral infections, cancer, and neurodegenerative diseases—with the aim of launching 2 products by 2030
- Developed an ultra-high sensitivity portable measurement system useful for the early diagnosis and treatment of viral infections
- Plans to raise research and development funds through a capital increase by third-party allotment
- FY12/26 forecasts incorporate partnering revenue of ¥3.0bn

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Results trends



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

Company profile

A bio-venture advancing development in therapeutic areas with high unmet medical needs

The Company is a bio-venture founded in March 2005 by Fuminori Yoshida, the current Representative Director, President, and Chief Executive Officer. Its business strategy is based on the basic policy of developing and providing new drugs in therapeutic areas with high unmet medical needs, and is characterized by a business model that aims to achieve highly probable and rapid drug discovery by in-licensing development candidates for which proof of concept (POC) in humans has been obtained and conducting development from the clinical trial stage.

The first development candidate to be in-licensed was the anticancer agent bendamustine hydrochloride (product name in Japan: TREAKISYM), developed by Astellas Pharma GmbH (Germany; hereafter, "Astellas Pharma") for the treatment of malignant lymphoma, for which the Company concluded an exclusive development and marketing rights agreement for Japan in 2005. From 2006, the Company initiated clinical trials for relapsed/refractory low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL), and subsequently advanced development and sales while expanding indications to chronic lymphocytic leukemia (CLL), untreated (first-line) low-grade NHL/MCL, and relapsed/refractory diffuse large B-cell lymphoma (hereafter, "r/r DLBCL"). In 2017, the Company concluded an exclusive development and marketing rights agreement for Japan with Eagle Pharmaceuticals, Inc. for the liquid-type formulation of TREAKISYM, and commenced sales from 2020. Sales were initially conducted through its partner Eisai Co., Ltd., but since the termination of that agreement in December 2020, the Company has transitioned to an in-house sales structure. Net sales peaked at ¥10.0bn in FY12/22, but have since contracted to roughly one-tenth of the peak level, as the Company's market share declined after 3 of the 4 companies that obtained manufacturing and marketing approval for generic products in February 2022 launched their products, and as drug prices were reduced.

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Currently, the Company is advancing the development of BCV, in-licensed from Chimerix Inc. (U.S.) in 2019, in collaboration with academia, focusing on post-transplant viral infections, cancer, and neurodegenerative diseases. In the second half of 2025, the Company initiated a global Phase III clinical trial for AdV infection following hematopoietic stem cell transplantation, and in February 2026, it concluded a Cooperative Research and Development Agreement (CRADA) on the "use of BCV for the treatment of PML" with the National Institute of Neurological Disorders and Stroke (NINDS) of the NIH and began an investigator-initiated Phase II clinical trial.

The Company has also launched an IVD business as a new business. In October 2025, it announced that it had obtained a patent in Japan for an ultra-high sensitivity immunochromatography diagnostic system jointly developed with Nippon Steel Chemical & Material Co., Ltd. (hereafter, "NSC&M") (an international patent application has also been filed). The system is expected to enable the early diagnosis and treatment of viral infections and to be applied in industrial fields such as the environment, agriculture, and food. Going forward, the Company aims to conclude marketing partnership agreements with global IVD (in vitro diagnostics) companies and to earn upfront payments and royalty income.

The Company also has a consolidated subsidiary in the U.S., SymBio Pharma USA, Inc., which serves as a base for advancing overseas business development.

History

Date	Summary
March 2005	Established SymBio Pharmaceuticals Limited at Minato-ku, Tokyo
December 2005	Concluded a license agreement with Astellas Pharma GmbH (Germany) to acquire exclusive development and marketing rights in Japan for anti-cancer agent Bendamustine Hydrochloride
March 2006	Obtained manufacturer's license (packaging, labeling and storage) from Tokyo Metropolitan Government
March 2007	Concluded a license agreement with Astellas Deutschland GmbH (Germany) to acquire development and marketing rights in China, Taiwan, South Korea and Singapore for anti-cancer agent SyB L-0501
August 2008	Concluded a license agreement with Eisai Co., Ltd. <4523> to grant co-development and marketing rights in Japan for anti-cancer agent SyB L-0501
March 2009	Concluded sublicense agreement with Cephalon, Inc. (U.S.) to grant development and marketing rights in China for anti-cancer agent SyB L-0501
May 2009	Concluded a license agreement with Eisai to grant co-development and marketing rights in South Korea and Singapore for anticancer agent SyB L-0501
September 2010	Launched SYMBENDA® (generic name: bendamustine hydrochloride) in Singapore for the treatment of low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia
October 2010	Acquired manufacturing and marketing approval of anti-cancer agent for malignant lymphoma TREAKISYM® in Japan (launched in December 2010)
July 2011	Concluded a license agreement with Onconova Therapeutics, Inc. for anti-cancer agents SyB L-1101/SyB C-1101
October 2011	Launched SYMBENDA® (generic name: bendamustine hydrochloride) in South Korea for the treatment of chronic lymphocytic leukemia and multiple myeloma
October 2011	Listed on Osaka Securities Exchange JASDAQ Growth Market
February 2012	Launched INNOMUSTINE® in Taiwan for the treatment of low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia
October 2015	Concluded a licensing agreement with The Medicines Company (U.S.) to acquire exclusive development and marketing rights in Japan for post-operative, self-administered pain-management medication, SyB P-1501 (the agreement ended in November 2017)
May 2016	Established SymBio Pharma USA, Inc. at Menlo Park, California, USA
August 2016	Acquired manufacturing and marketing approval of anti-cancer agent for malignant lymphoma TREAKISYM® in Japan for the additional indication of chronic lymphocytic leukemia
December 2016	Acquired manufacturing and marketing approval of anti-cancer agent for malignant lymphoma TREAKISYM® in Japan for the additional indication of first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma
September 2017	Concluded a license agreement with Eagle Pharmaceuticals, Inc. to acquire development and marketing rights in Japan for bendamustine liquid formulations (RTD formulation and RI administration) *RTD: Ready-to-dilute, RI: Rapid Infusion
October 2017	Filed for arbitration for damages against The Medicines Company (U.S.) due to the non-fulfillment of the licensing agreement
July 2018	TREAKISYM® was newly listed as the standard treatment for malignant lymphoma in the 2018 edition of the Japan Society of Hematology's Guidelines for the Treatment of Hematopoietic Tumors
September 2019	Concluded an exclusive global license agreement with Chimerix Inc. (U.S.) concerning the rights to develop, manufacture, and commercialize the antiviral drug, brincidofovir (excluding smallpox)

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Date	Summary
September 2020	In the final arbitration ruling for the claim for damages filed against The Medicines Company (U.S.) due to the non-fulfillment of a licensing agreement, the Company will receive from the Medicines Company 50% of its expenses relating to the arbitration proceedings, including attorneys' fees
December 2020	Start of own sales of TREAKISYM®
January 2021	Concluded a joint research agreement with The Institute of Medical Science, The University of Tokyo to search for new indications for bendamustine and rigosertib
March 2021	Submitted an IND application to the FDA in the U.S. for a global joint clinical trial indicated for adenovirus infections (in infants) after hematopoietic stem cell transplantation
March 2021	Acquired marketing approval for a TREAKISYM® and rituximab combination therapy (BR therapy) and TREAKISYM®, rituximab, and polatuzumab vedotin combination therapy (P-BR therapy) indicated for r/r DLBCL
April 2021	Obtained marketing approval of the RTD formulation of TREAKISYM® for its use in BR and P+BR therapy for the treatment of r/r DLBCL
August 2021	Reached First Patient In (FPI) in a phase II global joint clinical trial of BCV indicated for adenovirus infections after hematopoietic stem cell transplantation
February 2022	Obtained approval for a partial change to the manufacturing and marketing approval for the RI administration of TREAKISYM®
June 2022	Submitted a clinical trial plan notification to the PDMA for a phase II global joint clinical trial of BCV indicated for patients with BKV infection after kidney transplantation (also submitted to the TGA of Australia in August 2022)
September 2022	All rights and obligations under a licensing agreement with Chimerix, Inc. (U.S.) regarding BCV transferred to Emergent BioSolutions Inc. (U.S.)
March 2023	Concluded cooperative research and development agreement (CRADA) with the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH) in the U.S.
April 2023	Concluded CRADA with National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) in the U.S.
May 2023	Obtained POC for humans in phase II clinical trial for BCV indicated for adenovirus (AdV) infections that develop after hematopoietic stem-cell transplantation
January 2024	Obtained use patent in Japan for BCV intravenous formulation indicated for AdV infections and other infections
January 2024	SymBio Pharma Ireland Ltd. established in Ireland
March 2024	BCV intravenous formulation obtained orphan drug designation for the treatment of AdV infection and prevention of CMV infection in immunodeficient patients
October 2025	Initiated a global Phase III clinical trial of BCV for AdV infection following hematopoietic stem cell transplantation in Europe
October 2025	Obtained a joint patent in Japan, as an outcome of joint research with Nippon Steel Chemical & Material Co., Ltd., for a high-sensitivity immunoassay method (and immunoassay device) targeting viral infections
February 2026	Concluded a Cooperative Research and Development Agreement (CRADA) with NIH/NINDS to conduct a clinical trial of BCV for progressive multifocal leukoencephalopathy (PML)
March 2026	First patient enrolled in the U.S. in the global Phase III clinical trial of BCV for AdV infection following hematopoietic stem cell transplantation
June 2026	First patient enrolled in the investigator-initiated Phase II clinical trial of BCV for PML at the NIH Clinical Center

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

Development strategy for BCV

BCV exhibits antiviral activity against a broad range of DNA viruses and strong potential to fill gaps in underserved therapeutic areas

1. Features and licensing agreement of BCV

(1) Features of BCV

BCV exhibits strong antiviral activity against a broad range of DNA viruses, and academic research has also revealed that it possesses antitumor activity. As a result, BCV is attracting increasing attention as a potential treatment for underserved therapeutic areas where effective therapies have yet to be established, including not only post-transplant viral infections but also various virus-induced complications, such as hematologic tumors, glioblastoma, and multiple sclerosis.

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Development strategy for BCV

Based on the half maximal inhibitory concentration (IC50) values, an indicator of the strength of antiviral activity, BCV has demonstrated stronger antiviral activity than other drugs against a wide range of viruses, including AdV and CMV (cytomegalovirus), suggesting potential therapeutic efficacy against numerous viral diseases and complications. It is rare for a single compound to cover such a broad spectrum of diseases, underscoring the significant potential of BCV.

Comparison of antiviral activity (IC50)

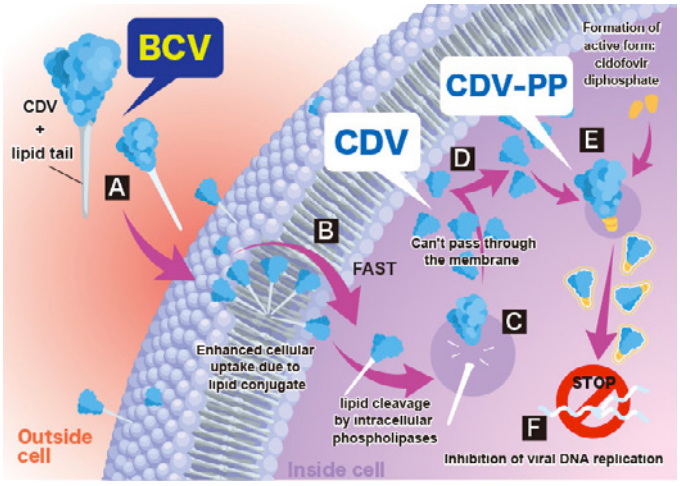
(Unit: μM)

Virus	BCV	Cidofovir	Maribavir	Letermovir	Ganciclovir	Foscarnet	Acyclovir
AdV	0.02	1.3	-	>10	4.5-33	Inactive	>100
BKV	0.13	115	-	-	>200	Inactive	>200
CMV	0.001	0.4	0.31	0.005	3.8	50-800	>200
EBV	0.03	65.6	0.63	>10	0.9	<500	6.2
JCV	0.045	>0.1	-	-	-	Inactive	-

Note: IC50 refers to the concentration that reduces virus production and replication by 50%; the smaller the value, the higher the efficacy. BCV has strong antiviral activity against a broad range of viruses.

One of the reasons for BCV's strong antiviral activity lies in its molecular structure. BCV has a structure in which a lipid chain is conjugated to CDV (cidofovir), a drug known for treating CMV retinitis. By conjugating a lipid chain, BCV more readily penetrates cells than CDV. After entering the cells, the lipid chain is cleaved, and the resulting CDV binds with diphosphate, thereby inhibiting the replication of DNA viruses (i.e., exhibiting strong antiviral activity). Furthermore, in terms of safety, Chimerix, the original developer, obtained approval from the U.S. Food and Drug Administration (FDA) in 2021 for oral BCV as a treatment for smallpox, confirming that the risk of serious side effects is extremely low.

How BCV works



Source: The Company's website

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Development strategy for BCV

As for the background to the Company's conclusion of a licensing agreement with Chimerix for BCV in 2019, at that time Chimerix had been developing an oral formulation of BCV for other indications; however, due to side effects such as diarrhea observed in the Phase III clinical trial and the failure to achieve statistically significant results, development was discontinued and Chimerix began seeking a licensing partner, whereupon the Company, having determined that there was potential for successful development, approached Chimerix to initiate licensing negotiations. The Company decided to in-license BCV because of its excellent safety profile and functionality (broad and strong antiviral activity), and because its target diseases—rare diseases—not only aligned with the Company's business policy of addressing underserved therapeutic areas but also included hematologic tumors, the same therapeutic area targeted by TREAKISYM, making it likely to generate sales synergies.

The Company believes that Chimerix's failure to develop an oral formulation was due to the low absorption rate of the drug through the digestive tract, which made it necessary to administer a large amount of the drug. The Company considered that an intravenous formulation could be expected to achieve the same effect at one-tenth the dose of the oral formulation, thereby lowering the risk of side effects and increasing the probability of success. The agreement covers not only the intravenous formulation but also the oral formulation, leaving open the possibility of developing an oral formulation in the future. Smallpox is excluded from the scope of the agreement because the U.S. government needs to manufacture and stockpile smallpox treatments domestically as a countermeasure against bioterrorism.

(2) Licensing agreement

The licensing agreement for BCV is notable for being a global license that also includes manufacturing rights. The Company recognizes that controlling manufacturing in-house and establishing a framework to minimize business risks to the greatest extent possible will benefit all stakeholders, including patients, and is essential for achieving growth as a global specialty pharmaceutical company.

In September 2022, Chimerix announced the transfer of the BCV license to Emergent BioSolutions Inc. (hereafter, "EBS"), but this has no impact on the Company's exclusive global rights for the development, manufacture, and sale of BCV, with EBS effectively taking over as the Company's counterparty to the agreement. The royalty term for each indication and each country is 10 years from the start of sales, the patent term, or the market exclusivity period, whichever is longest, and the agreement expires when the last of these terms ends. Under the agreement, the Company will pay development and sales milestone payments (up to US$180mn) triggered by progress in its pipelines, as well as double-digit percentage royalties based on product sales.

Focusing on 3 therapeutic areas—post-transplant viral infections, cancer, and neurodegenerative diseases—with the aim of launching 2 therapeutic areas by 2030

2. Development pipeline

BCV is currently being developed across multiple pipelines in three therapeutic areas: post-transplant viral infections, cancer, and neurodegenerative diseases. Among these, development for AdV infection following hematopoietic stem cell transplantation and for PML has entered the clinical development stage, and if progress is smooth, the Company aims to submit marketing approval applications for each in 2028 and to launch them by 2030.

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Development strategy for BCV

In the oncology area, the Company plans to advance pipelines targeting glioblastoma, head and neck cancer, and EBV-associated gastric cancer, for which favorable results were obtained in preclinical studies, and is currently preparing for investigator-initiated Phase II clinical trials. If development advances to Phase III clinical trials, the Company will, for funding reasons, conclude licensing agreements with major pharmaceutical companies before proceeding with development. As all of these pipelines are being developed by adding BCV to existing standard therapies, existing anticancer drug manufacturers are expected to be potential partners. The Company began licensing negotiations with pharmaceutical companies in Japan, the U.S., and Europe in 2026.

In the neurodegenerative disease area, the Company will advance a pipeline targeting EBV-positive multiple sclerosis. Having completed preclinical studies in marmosets, entry into clinical trials is still some way off, but the Company sees significant value in pursuing development given that no effective treatment has yet been developed. The Company also has several other pipelines, but has decided to temporarily suspend their development until it has greater financial leeway.

Development status and future plans and goals for brincidofovir (intravenous formulation)

Development product	Indication	Progress	Future plans and goals
SyB V-1901 (intravenous formulation)	Adenovirus infection following hematopoietic stem cell transplantation	Global Phase III clinical trial underway. FPI achieved in March 2026; 25 patients enrolled as of August 2026, progressing broadly as planned.	Complete enrollment of all 180 patients in 2027 and aim for approval application in 2028
	Progressive multifocal leukoencephalopathy (PML)	Investigator-initiated Phase II clinical trial underway. FPI achieved in June 2026. Five patients enrolled as of the end of July, progressing smoothly.	Complete enrollment of all 18 patients within 2027 and, if results are favorable, aim for approval application utilizing the accelerated approval program
	Malignant brain tumor (glioblastoma)	Announced at the Society for Neuro-Oncology Annual Meeting in November 2025 that animal studies showed marked effects in inhibiting tumor growth and prolonging survival when used in combination with standard therapy.	Investigator-initiated Phase II clinical trial planned
	Head and neck squamous cell carcinoma (HNSCC)	Preclinical study results presented at the ESMO Congress in October 2025. Suggested that combination therapy with ICIs could be an effective treatment.	Investigator-initiated Phase II clinical trial planned
	EBV-associated gastric cancer	Preclinical study results presented at the ASCO Annual Meeting in May 2026. Suggested that combination therapy with ICIs could be an effective treatment.	Investigator-initiated Phase II clinical trial planned
	EBV infection-induced multiple sclerosis	Preclinical studies in marmosets completed. Suggested that BCV could be a promising treatment for EBV-positive patients.	Extended the Cooperative Research and Development Agreement with NIH/NINDS through March 2029 with the aim of entering clinical trials

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

(1) AdV infection following hematopoietic stem cell transplantation

For the pipeline targeting AdV infection following hematopoietic stem cell transplantation in pediatric (and adult) patients, the global Phase II clinical trial was completed in the first half of 2024, and a global Phase III clinical trial has been underway since October 2025. The first patient was enrolled in March 2026, and 25 patients had been enrolled as of August 18. The trial plans to enroll 180 patients at 81 sites, primarily in the U.S. and Europe, with a target of enrolling 69 patients by the end of 2026. Currently, only 42 sites are conducting the trial, and the pace of enrollment is expected to accelerate as the number of sites increases. If the trial results are favorable, the Company plans to submit a marketing approval application in the second half of 2028, with a potential launch in 2030. For sales, the Company intends to conclude a partnership agreement with a company that has a global sales network.

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Development strategy for BCV

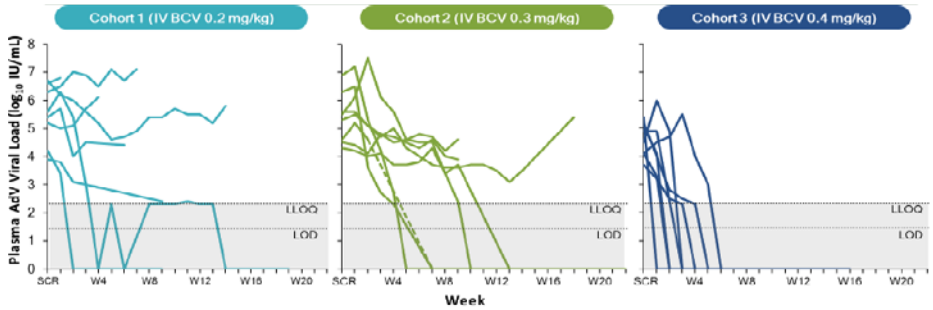
AdV is a virus found in nature that causes infectious diseases such as pharyngitis, tonsillitis, conjunctivitis, gastroenteritis, and hemorrhagic cystitis through infection of the respiratory tract, eyes, intestines, urinary tract, and other organs. While infection in healthy individuals rarely leads to serious illness, patients with compromised immunity after hematopoietic stem cell transplantation are at high risk of serious disease, and as no effective treatment is yet available, the development of therapeutic and preventive drugs is strongly desired. The number of hematopoietic stem cell transplants in Japan, the U.S., and Europe is 35,000 per year, of which fewer than 4,000 patients are estimated to develop AdV infection. Owing to the small number of patients, the program has received Orphan Drug Designation in Japan and Europe and Fast Track Designation* in the U.S. In addition, use patents have been obtained in Japan, the U.S., and Europe, and a framework for maximizing business value from an intellectual property standpoint is already in place.

* A program designed to deliver treatments for serious diseases and drugs addressing unmet medical needs to patients more quickly; designated drugs are eligible for priority meetings and reviews with the FDA. The approval review period averages 6 to 10 months.

The Phase II clinical trial evaluated safety, tolerability, and efficacy (changes in blood AdV levels), with patients divided into four groups: three receiving doses of 0.2 mg/kg, 0.3 mg/kg, or 0.4 mg/kg* twice weekly, and one receiving 0.4 mg/kg once weekly. No issues were found with safety or tolerability, and in terms of efficacy, results exceeded expectations—in the group receiving 0.4 mg/kg twice weekly (10 patients), AdV was cleared from the blood in all patients, with viral clearance confirmed within 4 weeks after treatment in 90% of them—thereby establishing POC in humans.

* Doses of 10 mg, 15 mg, and 20 mg for patients weighing 50 kg or more.

Clinical trial results for BCV intravenous formulation



Source: The Company's results briefing materials

In the Phase III clinical trial, of the 180 patients, 120 will receive BCV and 60 will receive CDV, which is currently used for treatment (for 4 to 12 weeks*), and the primary endpoint—the proportion of patients with undetectable adenovirus in the blood—will be compared. The 24 weeks following treatment will serve as a follow-up period to assess safety, during which safety endpoints (all-cause mortality and non-relapse mortality) will be evaluated. Based on the Phase II clinical trial results, which confirmed BCV's strong antiviral effect and favorable safety profile without the side effects, including renal impairment and myelosuppression, observed with CDV, we at FISCO consider the likelihood of achieving a statistically significant difference to be extremely high.

* The minimum treatment period is four weeks if blood adenovirus levels are undetectable for two consecutive measurements.

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(2) Progressive multifocal leukoencephalopathy (PML)

For the pipeline targeting PML, which is designated as an intractable disease, the Company concluded a Cooperative Research and Development Agreement (CRADA) with NIH/NINDS in February 2026. Under the agreement, an investigator-initiated Phase II clinical trial began at the NIH Clinical Center, and the first patient was enrolled in June 2026. The planned enrollment is 18 patients, and the trial is progressing smoothly, with five patients enrolled as of the end of July 2026. Completion of the trial is expected within 2027. If the results are favorable, the Company intends to submit a marketing approval application in 2028 using the Accelerated Approval program and to achieve an early launch.

PML is a disease in which JCV (JC virus), which latently or persistently infects many people, reactivates when immunity is compromised, causing multiple lesions in the brain; the annual number of patients in Japan, the U.S., and Europe is said to be fewer than 4,000. Initial symptoms include limb paralysis, cognitive impairment, and visual abnormalities; as the disease progresses, patients experience involuntary movements and cranial nerve palsy and become bedridden, and the disease is known for its high mortality rate and the short time from diagnosis to progression and death. In animal studies conducted at Pennsylvania State University (U.S.), a former joint research partner, BCV was confirmed to inhibit the proliferation of polyomaviruses (JC virus is a type of polyomavirus), and it is expected to be effective in preventing PML or suppressing the progression of symptoms.

(3) Malignant brain tumor (glioblastoma)

As an oncology pipeline, development is underway for glioblastoma as an indication. Glioblastoma is the most malignant type of brain tumor, with approximately 35,000 new cases per year in Japan, the U.S., and Europe combined. Standard treatments for glioblastoma are surgery, radiotherapy, and chemotherapy (temozolomide), but with a median survival after diagnosis of only 2 to 18 months and a five-year survival rate of below 5%, it is an area where the development of effective therapeutic drugs is strongly desired.

As an outcome of joint research with the Brain Tumor Center at the University of California, San Francisco, it was reported at the Society for Neuro-Oncology Annual Meeting held in November 2025 that animal studies using mouse models confirmed that BCV monotherapy inhibited tumor growth and prolonged survival, and that these effects were more pronounced when BCV was combined with standard therapy (radiotherapy and temozolomide).

Based on these research results, the Company intends to advance an investigator-initiated Phase II clinical trial of combination therapy with standard treatment (radiotherapy plus temozolomide). After confirming safety and efficacy, if the results are favorable, it will move to a Phase III clinical trial with the aim of launching the product. Preparations for initiating the clinical trial are currently underway. The Company has also begun searching for a co-development partner for the Phase III clinical trial.

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(4) Head and neck cancer

For the pipeline targeting head and neck cancer, the Company presented favorable preclinical data at the ESMO Congress held in Germany in October 2025 and decided to advance development toward launch. The term “head and neck” refers to the region of the face and neck between the skull base (the lower part of the head) and the clavicles, encompassing the nose, paranasal sinuses, oral cavity, pharynx, larynx, salivary glands, thyroid gland, and other structures. Cancers that develop in these areas are collectively referred to as “head and neck cancers.” In particular, EBV (Epstein-Barr virus) and HPV (human papillomavirus) are known to be involved in the development of nasopharyngeal and oropharyngeal cancers. More than 90% of head and neck cancers are squamous cell carcinomas (HNSCC), in which malignant tumors form in the skin or mucous membranes, and the Company will advance development with head and neck squamous cell carcinoma as the indication. The number of patients in Japan, the U.S., and Europe combined is estimated at 149,000, and the market for anticancer drugs is also large. The current standard therapy is generally combination therapy of a platinum-based drug such as cisplatin with an ICI (immune checkpoint inhibitor); however, platinum-based drugs are highly toxic and difficult to administer to patients with reduced renal function, including the elderly.

According to the abstract presented at the congress, preclinical studies showed that both high-dose BCV monotherapy and low-dose BCV plus ICI combination therapy achieved antitumor effects equivalent to standard therapy (ICI plus cisplatin), and that combining BCV with an ICI led, with statistical significance, to the infiltration of cancer-killing immune cells into tumor tissue and the destruction of cancer cells. These results suggest that BCV, which is less toxic than cisplatin, could become a new option for the treatment of head and neck cancer. Based on these research results, the Company is preparing to conduct an investigator-initiated Phase II clinical trial of high-dose BCV plus ICI combination therapy. If safety and efficacy are confirmed in this clinical trial, the Company will move to a Phase III clinical trial with the aim of launching the product.

As Phase III clinical trials require substantial development funds, the Company began searching for a co-development partner in 2026. We at FISCO believe that major pharmaceutical companies handling ICIs are likely candidates as partners. This is because, if a combination therapy with BCV that may offer greater therapeutic efficacy than the existing standard therapy can be established, it could also be administered to patients who have been unable to receive combination therapy because cisplatin was a limiting factor. This, in turn, could be expected to lead to further expansion of market share in the head and neck cancer treatment market. ICIs used for head and neck cancer include pembrolizumab and nivolumab.

(5) EBV-associated gastric cancer

For the pipeline targeting EBV-associated gastric cancer, the Company presented favorable preclinical data at the ASCO Annual Meeting held in May 2026 and decided to advance development toward launch. EBV-associated gastric cancer is gastric cancer that develops in association with persistent EBV infection in tumor cells; tumor resection by endoscopic surgery is generally performed as treatment, while chemotherapy is administered to patients who cannot undergo surgery. However, as EBV-derived gene expression not only contributes to carcinogenesis but also strongly affects patients’ immune responses, no effective anticancer therapy has yet been established. Approximately 10% of gastric cancer patients are said to have EBV-associated gastric cancer, and the number of patients in Japan, the U.S., and Europe combined is estimated at approximately 13,000 per year.

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Development strategy for BCV

At the meeting, based on trial data, it was reported that BCV effectively destroyed EBV-positive gastric cancer cells in cell-based experiments, that BCV induced factors enhancing immune effects against EBV-positive gastric cancer cells, and that in animal studies the combination of BCV and an ICI strongly suppressed tumor growth, exceeding the effects of either monotherapy. Based on these research results, the Company has determined that combination therapy of BCV and an ICI could become a new treatment option for EBV-associated gastric cancer and is preparing to begin an investigator-initiated Phase II clinical trial. If safety and efficacy are confirmed in this clinical trial, the Company will move to a Phase III clinical trial with the aim of launching the product.

As Phase III clinical trials require substantial development funds, the Company began searching for a co-development partner in 2026. As this will be a combination therapy with an ICI, major pharmaceutical companies handling ICIs are seen as likely candidates. ICIs used for gastric cancer include pembrolizumab and nivolumab.

(6) EBV-positive multiple sclerosis

Recent research has revealed that EBV is involved in the onset of multiple sclerosis*, known as one of the intractable diseases, and the Company plans to advance development for this indication as well. Many therapeutic products, including injectable and oral drugs, have been approved, and the overall market is forecast to grow from US$29.3bn in 2025 to US$40.6bn in 2034. However, as the cause of the disease is unknown, these are only symptomatic treatments to prevent relapse or suppress progression, and no curative drug has yet been developed. For this reason, many companies are still pursuing development.

> * Multiple sclerosis is a neurological disease in which inflammation of the central nervous system or optic nerves, due to some cause, results in functional impairment of the brain, spinal cord, optic nerves, and other areas. The disease alternates between relapse and remission, and as symptoms progress, vision, limb function, cognitive function, and other functions decline. Patients are concentrated in North America and Europe, with approximately 3 million patients worldwide and approximately 18,000 in Japan.

Against this backdrop, the Company concluded a joint research material transfer agreement for BCV with NINDS of the NIH in 2022, followed by a Cooperative Research and Development Agreement (CRADA) in 2023, and has since been advancing the joint research. The research results were published as a paper in the Journal of Clinical Investigation, a prestigious academic journal, in November 2025.

In summary, the research revealed that the reactivation of EBV latent in lymphocytes in the body is one of the primary causes of multiple sclerosis, that very low doses of BCV markedly suppressed EBV activity, and that in experiments using cells derived from multiple sclerosis patients, BCV selectively inhibited only EBV-positive B-cell lymphocytes. These research results suggest that BCV could be a promising candidate as a treatment for patients with EBV-positive multiple sclerosis.

Following these positive research results for BCV, the Company announced in March 2026 that it would extend the joint development agreement with NIH/NINDS by 3 years. Going forward, the Company will develop a more suitable route of administration and formulation for clinical use, with the aim of entering clinical trials.

(7) Estimated number of patients and market size of therapeutic drugs in the oncology area

The estimated numbers of patients in Japan, the U.S., and Europe for the 3 oncology pipelines are approximately 35,000 for glioblastoma, approximately 149,000 for head and neck cancer, and approximately 13,000 for EBV-associated gastric cancer. The respective market sizes for therapeutic drugs are estimated at ¥273.0bn, ¥675.0bn, and ¥58.2bn. For all of these indications, existing standard therapies are either insufficiently effective or have issues with side effects, underscoring the significance of developing BCV.

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Development strategy for BCV

Estimated number of patients and market size of therapeutic drugs for oncology pipelines

Cancer type	U.S.	5 EU countries	Japan	Japan, U.S., and Europe total
Malignant brain tumor	¥150.0bn (14,500 patients)	¥90.0bn (13,500 patients)	¥33.0bn (2,350 patients)	¥273.0bn (35,000 patients)
Head and neck cancer	¥315.0bn (58,000 patients)	¥255.0bn (67,000 patients)	¥105.0bn (24,500 patients)	¥675.0bn (149,500 patients)
EBV-associated gastric cancer	¥17.7bn (2,430 patients)	¥18.5bn (4,350 patients)	¥22.0bn (6,700 patients)	¥58.2bn (13,480 patients)

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

The pipelines currently in clinical trials for post-transplant AdV infection and for PML are progressing smoothly, increasing the likelihood of launches by 2030, while the pipeline for multiple sclerosis, a large market, is also expected to advance toward clinical trials. In the oncology area, whether a co-development partner can be secured holds the key to success, and future developments are attracting attention. The potential market value of these pipelines alone is estimated to exceed ¥100.0bn, yet the Company's current corporate value (market capitalization) appears to barely reflect the potential of BCV.

Going forward, in addition to steadily advancing pipeline development, we at FISCO believe that concluding agreements with a marketing partner for post-transplant AdV infection and with development and marketing partners in the oncology area will be triggers for enhancing corporate value.

IVD business

Developed an ultra-high sensitivity portable measurement system useful for the early diagnosis and treatment of viral infections

In October 2025, the Company announced that, as an outcome of joint research with NSC&M, it had obtained a joint patent in Japan for a high-sensitivity immunoassay method (and its device), and it is working toward the early commercialization of the "pM Engine," an ultra-high sensitivity (pico-level) immunochromatographic test system* based on the patent.

* A test system that uses the antigen-antibody reaction of immunochromatography to rapidly determine the presence or absence of antibodies; it is used in a wide range of fields, including medical settings, food, environmental hygiene, livestock, agriculture, and fisheries.

The features of the "pM Engine" include the ability to detect extremely small amounts of antigens such as viruses at concentrations below 1 picogram/mL (one trillionth of a gram per mL), a level of ultra-high sensitivity beyond that of existing technologies, as well as its compact, lightweight, and portable design, operability in hot tropical regions, built-in data transmission functionality, and the capability for point-of-care testing (POCT) in medical settings. For example, influenza tests generally involve collecting a sample from the nasal cavity and take around 10 to 20 minutes to determine infection, whereas the "pM Engine," with approximately 100 times greater sensitivity, is uniquely able to use saliva, which contains only small amounts of virus, as the sample, and can complete measurement rapidly in around 1 minute.

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Appearance and features of the “pM Engine”



Source: The Company’s results briefing materials

In May 2026, the Company established a stable supply chain with NSC&M for the supply of the nanocomposite particles that form the basis of the system, and with Nippon Gene Co., Ltd. for the manufacture of ultra-high sensitivity test kits. The commercialization of the “pM Engine” will make it possible to conduct tests at various locations, including at the bedside, and to share results immediately with medical institutions.

Leveraging the features of the system, the Company aims to commercialize it as a detection system for leishmaniasis antibodies, a tropical infectious disease. Leishmaniasis is a parasitic infection transmitted mainly by sand flies and is one of the diseases classified by the World Health Organization as a “neglected tropical disease (NTD)*.” The number of infections is estimated at 700,000 to 1 million per year. In particular, visceral leishmaniasis can cause symptoms such as fever, enlargement of the liver and spleen, and anemia several months to years after infection, and can be fatal if left untreated. Early diagnosis of infection and treatment of infected individuals are therefore of considerable importance. The Company is currently applying for a research and development grant from the GHIT Fund (Global Health Innovative Technology Fund), and if the application is accepted, it plans to use the grant to conduct demonstration trials.

> * Diseases transmitted mainly through insects and other vectors in impoverished tropical regions due to poor sanitary conditions, which cause severe physical disability or have high mortality rates. The World Health Organization has designated 21 such diseases as tropical diseases that humanity must bring under control.

The applications of the “pM Engine” are not limited to the medical field; broad deployment can be expected in non-medical fields as well, such as crop disease testing in agriculture, infectious disease testing in livestock, and safety testing in the food industry. With this in mind, the Company is negotiating marketing license agreements with several global IVD (in vitro diagnostics) companies with proven track records, and a major U.S. company is currently conducting a technical evaluation of the system. The Company aims to conclude a licensing agreement within 2026.

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Results trends

Operating loss widened in 1H FY12/26 due to higher research and development expenses

1. Overview of 1H FY12/26 results

In 1H FY12/26 consolidated results, net sales declined 27.3% YoY to ¥469mn, operating loss was ¥3,635mn (¥2,154mn loss in the same period of the previous fiscal year), ordinary loss was ¥3,608mn (¥2,340mn loss), and loss attributable to owners of parent was ¥3,619mn (¥2,369mn loss).

Consolidated results for 1H FY12/26

(¥mn)

	1H FY12/25	1H FY12/26	Change	% change
Net sales	646	469	-176	-27.3%
Gross profit	493	338	-155	-31.5%
SG&A expenses	2,647	3,973	1,325	+50.1%
R&D expenses	1,581	2,997	1,415	+89.5%
Other SG&A expense	1,065	976	-89	-8.4%
Operating profit	-2,154	-3,635	-1,481	-
Ordinary profit	-2,340	-3,608	-1,267	-
Profit attributable to owners of parent	-2,369	-3,619	-1,250	-

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

Net sales continued on a declining trend due to lower selling prices for TREAKISYM resulting from drug price revisions, as well as lower volumes as the shift to generics progressed. Generics are sold by 3 companies, and in the case of TREAKISYM Intravenous Solution 100mg/4mL, their drug prices are in the 30% range relative to the Company's price, with this price gap being a factor in the decline in market share.

The gross profit margin declined from 76.3% in the same period of the previous fiscal year to 72.0%, partly due to drug price revisions, and gross profit decreased 31.5% to ¥338mn. Among SG&A expenses, research and development expenses increased 89.5% to ¥2,997mn, partly reflecting the start of the global Phase III clinical trial of BCV for AdV infection following hematopoietic stem cell transplantation. Although other SG&A expenses, such as operating and administrative expenses, were held down at ¥976mn, down 8.4%, the increase in research and development expenses led to a wider operating loss. The balance of non-operating income and expenses improved ¥213mn YoY. This was mainly due to decreases of ¥82mn in bond issuance costs and ¥64mn in foreign exchange losses.

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Plans to raise research and development funds through a capital increase by third-party allotment

2. Financial position and measures to restore financial soundness

(1) Financial position

As of the end of 1H FY12/26, total assets decreased ¥1,959mn from the end of the previous fiscal year to ¥1,907mn. The main factors behind this change were a ¥200mn increase in prepaid expenses, offset by decreases of ¥1,906mn in cash and deposits, ¥138mn in inventories, and ¥109mn in accounts receivable–trade.

Total liabilities decreased ¥104mn from the end of the previous fiscal year to ¥2,490mn. The main factors behind this change were a ¥1,031mn increase in accounts payable–other, while convertible-bond-type bonds with share acquisition rights decreased ¥500mn and bonds payable decreased ¥650mn. Net assets decreased ¥1,854mn, resulting in negative net worth of ¥582mn. This was due to the recording of a loss of ¥3,619mn, together with the fact that the planned exercise of share acquisition rights did not progress owing to the sluggish share price, limiting capital enhancement, including the conversion of convertible bonds into shares, to ¥1,839mn.

Balance sheet

(¥mn)

	FY12/23	FY12/24	FY12/25	1H FY12/26	Change
Current assets	8,082	4,924	3,824	1,865	-1,958
(Cash and deposits)	6,517	3,963	2,883	977	-1,906
Non-current assets	87	44	43	41	-1
Total assets	8,170	4,968	3,867	1,907	-1,959
Total liabilities	960	770	2,595	2,490	-104
Net assets	7,209	4,197	1,272	-582	-1,854
Management indicators					
Equity ratio	84.9%	78.1%	23.9%	-44.6%	-68.5pp

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

(2) Measures to restore financial soundness

To achieve an early exit from negative net worth and restore financial soundness, the Company will implement the following five measures.

a) Steady execution of the business plan (accumulating cases in the global Phase III clinical trial for AdV infection and the Phase II clinical trial for PML, and securing upfront payments through partnering)

b) Stabilizing cash flow through refinancing

c) Steady execution of the licensing strategy (licensing commercialization rights in the U.S. and European markets for AdV infection, granting options on commercialization rights in the North American market for three oncology indications, and licensing marketing rights for the "pM Engine" to global IVD companies)

d) Capital enhancement (building a stable capital base through a capital increase by third-party allotment in conjunction with business alliances)

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e) Curbing the burn rate (monthly expenditures), including personnel expenses and rent, through a review of the organizational structure.

Regarding refinancing, on August 17, the Company announced the conclusion of an unsecured bond facility agreement with EVO FUND and the issuance of the 2nd unsecured straight bonds (privately placed bonds), as well as the issuance of the 70th and 71st series of share acquisition rights (with exercise price adjustment clauses) through a third-party allotment. The first tranche of the unsecured straight bonds (zero-coupon bonds) was issued in an amount of ¥100mn on September 3, with payment completed the same day, and issuance may be made up to a maximum of ¥500mn under the facility (redemption date: September 3, 2029). On September 2, 480,000 share acquisition rights were issued for each of the 70th and 71st series (48 million potential shares per series), and payment of the issue price was completed the same day. The initial exercise price is ¥71, and the minimum exercise price for both series is set at ¥36. Proceeds from the issuance and exercise of the share acquisition rights would total ¥6,768mn if all rights are exercised at the initial exercise price, and are planned to be allocated to BCV development funds. However, following the announcement of the financing, the share price fell to ¥62 (closing price on August 28) due to dilution concerns*, and the amount raised may fall short of the amount initially anticipated. On the other hand, if a major licensing agreement is concluded going forward, a rise in the share price could result in proceeds exceeding initial expectations, and future developments will therefore be closely watched.

* If all of the 70th and 71st series of share acquisition rights are exercised, the dilution rate relative to the total number of issued shares as of the end of June 2026 would be 125.6%.

Use of the proceeds from the issuance and exercise of the 70th and 71st series of share acquisition rights

Use	Amount (¥mn)	Scheduled timing of expenditure
Redemption of the unsecured bonds	500	September 2026 to March 2028
BCV development funds (direct expenses)	4,554	September 2026 to March 2028
BCV development funds (indirect expenses)	1,714	September 2026 to March 2028
Total	6,768	

Source: Prepared by FISCO from the Company's news release

Outlook

FY12/26 forecasts incorporate partnering revenue of ¥3.0bn

1. FY12/26 forecasts

For FY12/26, the Company has maintained its initial forecasts of a 197.6% YoY increase in net sales to ¥3,891mn, operating loss of ¥4,231mn (¥4,440mn loss in FY12/25), ordinary loss of ¥4,291mn (¥4,647mn loss in FY12/25), and loss attributable to owners of parent of ¥4,331mn (¥4,776mn loss in FY12/25).

Outlook

Outlook for FY12/26 consolidated results

(¥mn)

	FY12/25 results	FY12/26 Company forecasts	YoY		1H progress rate
			Change	% change	
Net sales	1,307	3,891	+2,583	+197.6%	12.1%
Product sales	1,307	891	-416	-31.9%	52.7%
Partnering revenue	-	3,000	+3,000		-
Gross profit	947	3,639	+2,691	+284.1%	9.3%
SG&A expenses	5,388	7,870	+2,481	+46.1%	50.5%
R&D expenses	3,297	6,077	+2,779	+84.3%	49.3%
Other SG&A expense	2,090	1,793	-297	-14.2%	54.4%
Operating profit	-4,440	-4,231	+209	-	85.9%
Ordinary profit	-4,647	-4,291	+356	-	84.1%
Profit attributable to owners of parent	-4,776	-4,331	+445	-	83.6%

Note: Assumed exchange rate is ¥150/US$
Source: Prepared by FISCO from the Company's results briefing materials

Although TREAKISYM sales are expected to continue declining, down 31.9% YoY to ¥891mn, the Company expects partnering revenue of ¥3,000mn. This assumes upfront payments from a marketing licensing agreement for BCV targeting AdV infection and a marketing licensing agreement for the "pM Engine."

Gross profit is expected to increase 284.1% to ¥3,639mn owing to the contribution of partnering revenue, but with research and development expenses increasing 84.3% to ¥6,077mn, operating loss is expected to narrow only slightly. The assumed exchange rate is ¥150 per US$, and if the current exchange rate level persists, expenses for clinical trials conducted mainly overseas could exceed planned levels.

Aiming to achieve growth as a global specialty pharmaceutical company, with 2030 positioned as a turning point

2. Long-term strategy

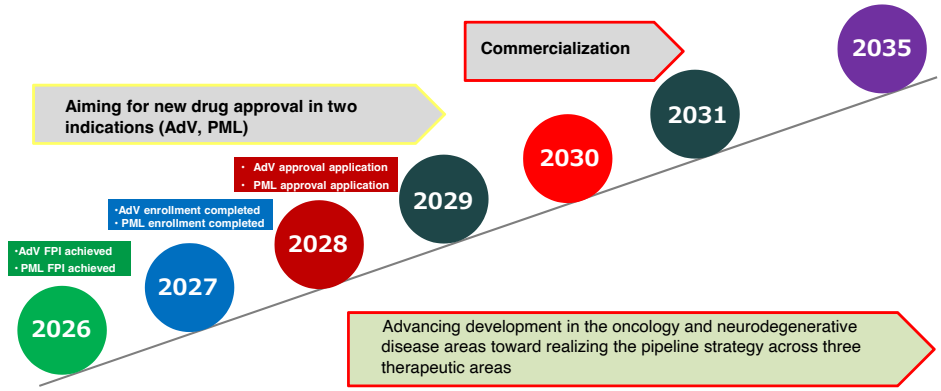
As a long-term goal, the Company aims to grow into a global specialty pharmaceutical company, targeting a 50/50 balance between domestic and overseas sales by 2030. While TREAKISYM continues to struggle in Japan, overseas sales are expected to ramp up with the launch of BCV for AdV infection and PML. Although the 50% level remains fluid, if the 2 products are successfully launched, achieving profitability from 2030 onward could come into view.

As part of the BCV platform expansion, the Company will for the time being focus its development and commercialization efforts on six pipelines in the areas of post-transplant viral infections, refractory cancers, and neurodegenerative diseases. However, given the active joint research being conducted with academia, it is quite possible that the Company could resume development of currently suspended pipelines or add new pipelines once it has greater financial leeway. If these development programs progress smoothly, the Company will be able to conduct partnership negotiations from a position of strength, further increasing the likelihood that BCV will become a blockbuster drug. Should this occur, the Company's corporate value (market capitalization), which currently remains in the ¥4.0bn range, is also expected to increase.

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Outlook

Future business roadmap



Source: The Company's results briefing materials

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