Quarterly trends and results

Earnings (cumulative)	FY12/23				FY12/24				FY12/24	
(JPYmn)	Q1	Q1-Q2	Q1-Q3	Q1-Q4	Q1	Q1-Q2	Q1-Q3	Q1-Q4	% of forecast	FY forecast
Sales	1,545	3,179	4,421	5,590	598	1,284			49.0%	2,623
YoY	-33.3%	-34.8%	-39.9%	-44.1%	-61.3%	-59.6%				-53.1%
Gross profit	1,243	2,473	3,476	4,411	471	996				
YoY	-34.5%	-38.3%	-36.4%	-42.0%	-62.1%	-59.7%				
Gross profit margin	80.5%	77.8%	78.6%	78.9%	78.8%	77.6%				
SG&A expenses	1,192	2,523	3,759	5,223	1,278	2,716				
YoY	-14.2%	-4.4%	-3.1%	-7.3%	7.2%	7.6%				
SG&A ratio	77.2%	79.4%	85.0%	93.4%	213.7%	211.4%				
Operating profit	51	-50	-283	-812	-807	-1,719			-	-3,702
YoY	-89.9%	-	-	-	-	-				-
Operating profit margin	3.3%	-	-	-	-	-				-
Recurring profit	48	67	-156	-736	-727	-1,481			-	-3,524
YoY	-89.9%	-95.4%	-	-	-	-				-
Recurring profit margin	3.1%	2.1%	-	-	-	-				-
Net income	4	-80	-789	-1,963	-777	-1,541			-	-3,628
YoY	-97.3%	-	-	-	-	-				-
Net margin	0.3%	-	-	-	-	-				-
Earnings (quarterly)	**FY12/23**				**FY12/24**					
(JPYmn)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**		
Sales	1,545	1,634	1,242	1,169	598	687				
YoY	-33.3%	-36.1%	-49.9%	-55.9%	-61.3%	-58.0%				
Gross profit	1,243	1,230	1,003	935	471	525				
YoY	-34.5%	-41.8%	-31.1%	-56.2%	-62.1%	-57.3%				
Gross profit margin	80.5%	75.3%	80.7%	80.0%	78.8%	76.5%				
SG&A expenses	1,192	1,331	1,237	1,463	1,278	1,438				
YoY	-14.2%	6.5%	-0.3%	-16.8%	7.2%	8.0%				
SG&A ratio	77.2%	81.5%	99.5%	125.2%	213.7%	209.4%				
Operating profit	51	-101	-233	-528	-807	-913				
YoY	-89.9%	-	-	-	-	-				
Operating profit margin	3.3%	-	-	-	-	-				
Recurring profit	48	19	-223	-580	-727	-754				
YoY	-89.9%	-	-	-	-	-				
Recurring profit margin	3.1%	1.1%	-	-	-	-				
Net income	4	-84	-709	-1,174	-777	-764				
YoY	-97.3%	-	-	-	-	-				
Net margin	0.3%	-	-	-	-	-				

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.
Note: "- "denotes YoY change of over 1,000%.
Note: Starting from FY12/22, the company switched to preparing consolidated financial statements in connection with the commencement of full- fledged operations at SymBio Pharma USA. As data for FY12/22 are on a consolidated basis, YoY comparisons are for reference only.

Breakdown of SG&A expenses

Earnings (cumulative)	FY12/23				FY12/24			
(JPYmn)	Q1	Q1-Q2	Q1-Q3	Q1-Q4	Q1	Q1-Q2	Q1-Q3	Q1-Q4
SG&A expenses	1,192	2,523	3,759	5,223	1,278	2,716		
YoY	-14.2%	-4.4%	-3.1%	-7.3%	7.2%	7.6%		
R&D expenses	550	1,204	1,824	2,638	691	1,532		
YoY	10.8%	19.3%	16.6%	3.3%	25.7%	27.2%		
SG&A expenses excl. R&D	642	1,319	1,936	2,584	586	1,184		
YoY	-28.1%	-19.0%	-16.4%	-16.1%	-8.7%	-10.2%		
Earnings (quarterly)	**FY12/23**				**FY12/24**			
(JPYmn)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
SG&A expenses	1,192	1,331	1,237	1,463	1,278	1,438		
YoY	-14.2%	6.5%	-0.3%	-16.8%	7.2%	8.0%		
R&D expenses	550	654	620	815	691	840		
YoY	10.8%	27.4%	11.8%	-17.8%	25.7%	28.5%		
SG&A expenses excl. R&D	642	677	617	649	586	598		
YoY	-28.1%	-8.0%	-10.0%	-15.5%	-8.7%	-11.7%		

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.

1H FY12/24 results (out August 1, 2024)

- Sales: JPY1.3bn (-59.6% YoY)
- Operating loss: JPY1.7bn (versus loss of JPY50mn in 1H FY12/23)
- Recurring loss: JPY1.5bn (versus profit of JPY67mn in 1H FY12/23)
- Net loss attributable to owners of the parent: JPY1.5bn (versus loss of JPY80mn in 1H FY12/23)

In February 2022, SymBio obtained approval for a partial change to the marketing authorization for the ready-to-dilute (RTD) intravenous formulation of Treakisym® 100mg/4ml, which was launched in January 2021, to add rapid infusion (RI) administration. Compared to the freeze-dried (FD) formulation, the RTD formulation reduces the time required for the complicated dissolution process. RI administration further benefits both patients and healthcare providers by reducing the infusion time from the 60 minutes required by the RTD formulation. In addition, the RI administration uses less saline solution and accordingly less salt (sodium chloride).

The switch from the FD to RTD formulation is almost complete. With over 90% of medical institutions administering the RI formulation to patients as of end-June 2024, progress was made in the switch to the RI formulation.

Sales decreased by 59.6% YoY to JPY1.3bn. The ongoing decline in usage of Treakisym® (bendamustine) per patient due to the COVID-19 pandemic has gradually eased. Concerns over the increased risk of infection for patients with blood cancers, especially those with malignant lymphoma, and the potential for prolonged or severe infections during or after treatment with bendamustine have led to decreased prescriptions of bendamustine, including its generics. Meanwhile, the penetration of generics has gradually progressed, affecting the results.

Gross profit was JPY996mn (-59.7% YoY), and the gross profit margin reached 77.6% (-0.2pp YoY). SG&A expenses were JPY2.7bn (+7.6% YoY), of which R&D expenses amounted to JPY1.5bn (+27.2% YoY). As a result, the operating loss was JPY1.7bn (compared to a loss of JPY50mn in 1H FY12/23).

Progress rates against full-year company forecast for FY12/24

In May 2024, the company announced a downward revision of its full-year earnings forecast for FY12/24 (see "Full-year company forecast" below for details). The progress rate for 1H against the revised full-year forecast is 49.0% for sales, while there is no progress rate for profit items due to negative figures. The operating loss was JPY1.7bn (full-year forecast: JPY3.7bn loss), the recurring loss was JPY1.5bn (full-year forecast: JPY3.5bn loss), and the net loss attributable to owners of the parent was JPY1.5bn (full-year forecast: JPY3.6bn loss).

The company believes that it is on track against the revised forecast and has maintained its full-year forecast.

R&D activities

Antiviral drug SyB V-1901 (generic name: brincidofovir)

In development of the intravenous and oral formulations of the antiviral drug brincidofovir (SyB V-1901; BCV IV and BCV Oral), the company is conducting joint research with top research institutions specialized in each field in Japan and overseas in light of the broad spectrum of the drug's effectiveness against dsDNA virus infections. It will consider conducting additional global clinical trials based on the scientific findings of the research.

Earlier clinical trials in the US and Europe conducted by US-based Chimerix Inc. have demonstrated that BCV Oral has broad-spectrum antiviral effects against a variety of dsDNA viruses. BCV IV is expected to be effective and safe for the prevention and treatment of many dsDNA virus infections, including adenovirus (AdV) infections after hematopoietic stem cell transplantation. In June 2021, Chimerix announced that the US FDA had granted BCV Oral approval for the treatment of smallpox.

Post-transplant infectious diseases

Based on a global advisory board review held in February 2020, the company has decided to prioritize the global development of BCV IV primarily in Japan, the US, and Europe, targeting disseminated AdV infections occurring after hematopoietic stem cell transplantation, a niche area with a high unmet medical need. In March 2021, the company filed an IND application with the US Food and Drug Administration (FDA) to conduct a Phase II clinical trial primarily in pediatric patients suffering from AdV infections (also including adults). This development program was granted fast-track designation by the FDA in April 2021, and the investigational drug was administered to the first patient in August 2021. In May 2023, BCV has demonstrated proof of concept in humans in the same study. Positive data demonstrating efficacy from the study were presented orally at the 65th Annual Meeting of the American Society of Hematology in December 2023. Similar presentations were made at other major academic conferences, including the 2024 Tandem Meetings in the US in February 2024 and the 50th Annual Meeting of the EBMT in April 2024. In addition, a use patent for BCV related to the treatment of AdV infections and infectious diseases was established and registered in Japan in January 2024.

In May 2024, a Phase IIa clinical trial post-hematopoietic stem cell cytomegalovirus infection was initiated in the US. In June 2024, the first patient was enrolled, and the trial is currently ongoing.

BK virus nephropathy after kidney transplantation is considered a disease with serious consequences for the recipient, the donor, the medical practitioner, and society, as it may result in serious conditions such as decreased renal function and graft loss. In order to find an early solution to this problem, SymBio submitted a clinical trial notification for a global Phase II study in patients infected with BK virus after receiving kidney transplant to the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan in May 2022 and to the Therapeutic Goods Administration (TGA) of Australia in August 2022. The investigational drug was administered to the first patient in Australia in August 2022. While the trial was initially planned for completion in 2025, delays in the accumulation of cases have led to a review of the protocol.

Polyomaviruses, particularly JC virus (JCV), are known to cause severe brain diseases among dsDNA viruses, and the development of effective treatments is highly anticipated. In November 2022, the company concluded a material transfer agreement (MTA) with US-based Penn State College of Medicine, and initiated a non-clinical study evaluating the efficacy of BCV in a mouse model of polyomavirus infection. In July 2024, the first report of these research findings, which included new insights, was published in the journal mBio.

Hematological malignancies

In addition to antiviral activity, the company expects brincidofovir to have antitumor effects. Through joint research with the National Cancer Centre Singapore and University of California San Francisco Brain Tumor Center, SymBio is investigating new indications for the drug in oncology, including rare brain tumors and EB virus-positive lymphoma. In March 2022, the company commenced joint research with Brown University of the US to investigate the antitumor effects of brincidofovir on glioblastoma (GBM) caused by cytomegalovirus (CMV) infection.

In December 2022, the results of collaborative research with the National Cancer Centre Singapore (NCCS) on the therapeutic efficacy of BCV in the treatment of rapidly progressing NK/T-cell lymphoma were presented at the 64th American Society of Hematology (ASH) Annual Meeting.

At the 17th International Conference on Malignant Lymphoma (ICML) in June 2023, research into biomarkers that predict the anti-tumor effect of BCV was presented. In April 2024, the anti-tumor effects of BCV for B-cell lymphoma was presented as a poster at the American Association for Cancer Research Annual Meeting. In June 2024, the anti-tumor effects of BCV on peripheral T-cell lymphoma (PTCL) was presented as a poster at the European Hematology Association (EHA2024 Hybrid Congress).

Other

SymBio has been preparing for clinical development of brincidofovir for multiple sclerosis, a rare disease related to EB virus. In August 2022, the company signed a collaboration agreement for the transfer of human materials with the National Institute of Neurological Disorders and Stroke (NINDS) of the US National Institute of Health (NIH). In March 2023, SymBio signed a cooperative research and development agreement (CRADA) with NINDS to obtain information necessary to conduct future clinical trials. In October 2023, the results of the research were presented at the 9th Joint ECTRIMS-ACTRIMS Meeting in Milan, Italy.

In April 2023, SymBio also signed a CRADA with the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, to evaluate the efficacy of BCV in EB virus-related lymphoproliferative disorders.

In December 2022, the company concluded a sponsored research agreement with US-based Tufts University, and began a joint research study evaluating the efficacy of BCV in a herpes simplex virus infection model. This study aims to explore BCV's potential to treat neurological diseases, including Alzheimer's disease.

Rights

In September 2022, Chimerix announced that it had completed procedures to transfer the rights to brincidofovir to Emergent BioSolutions Inc. (headquarters: Maryland, US). The agreement, however, has no impact on the company's exclusive rights to develop, manufacture, and sell brincidofovir globally for all indications except orthopoxvirus diseases including smallpox and monkeypox.

In March 2024, the EU orphan drug designation for BCV, for the prevention of adenovirus and cytomegalovirus infections in immunocompromised patients, was transferred from Emergent BioSolutions to a subsidiary of SymBio.

Anticancer agent SyB L-0501 (FD formulation)/SyB L-1701 (RTD formulation)/SyB L-1702 (RI administration); generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate, product name: Treakisym®

SymBio will continue to explore new potential applications of TREAKISYM®, including via joint research with the University of Tokyo and Kyoto University.

Anticancer agent SyB L-1101 (IV)/SyB C-1101 (oral); generic name: rigosertib sodium

For rigosertib and TREAKISYM®, the company is searching for new indications as well as new applications for the drugs used in combination with each other or with other existing drugs, through joint research and the offering of academia-industry collaborative courses with the University of Tokyo. In April 2024, the drug's licensor Onconova changed its name to Traws Pharma Inc., headquartered in Pennsylvania, US.

Overseas business (SymBio Pharma USA)

In April 2024, the company appointed Mr. John Houghton as CEO and President of its wholly-owned subsidiary SymBio Pharma USA, Inc. SymBio Pharma USA is leading the global development of the antiviral drug brincidofovir.

In-licensing of drug candidates

The company is currently focusing on unrolling global development plans for the antiviral drug brincidofovir it in-licensed in September 2019, but also constantly looking into multiple licensing deals and looking for and evaluating promising new in-licensing drug candidates.

Full-year company forecast for FY12/24 (revised on May 2024)

	FY12/22			FY12/23			FY12/24			
(JPYmn)	1H results	2H results	FY results	1H results	2H results	FY results	1H results	2H forecast	FY forecast	YoY
Sales	4,874	5,135	10,008	3,179	2,411	5,590	1,284	1,339	2,623	-53.1%
Gross profit	4,010	3,589	7,600	2,473	1,938	4,411	996			
Gross profit margin	82.3%	69.9%	75.9%	77.8%	80.4%	78.9%	77.6%			
SG&A expenses	2,638	2,998	5,636	2,523	2,700	5,223	2,716			
SG&A ratio	54.1%	58.4%	56.3%	79.4%	112.0%	93.4%	211.4%			
R&D expenses	1,009	1,545	2,555	1,204	1,434	2,638	1,532	1,877	3,409	29.2%
YoY	10.6%	87.6%	47.2%	19.3%	-7.2%	3.3%	27.2%	30.9%	29.2%	
SG&A expenses excl. R&D	1,629	1,453	3,081	1,319	1,266	2,584	1,184	-1,877	-3,409	-231.9%
Operating profit	1,372	591	1,964	-50	-762	-812	-1,719	-1,983	-3,702	-
Operating profit margin	28.2%	11.5%	19.6%	-	-	-	-	-	-	
Recurring profit	1,447	553	2,000	67	-803	-736	-1,481	-2,043	-3,524	-
Recurring profit margin	29.7%	10.8%	20.0%	2.1%	-	-	-	-	-	
Net income	1,108	71	1,179	-80	-1,883	-1,963	-1,541	-2,087	-3,628	-
Net margin	22.7%	1.4%	11.8%	-	-	-	-	-	-	

Source: Shared Research based on company data.
Note: Figures may differ from company materials due to differences in rounding methods.

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