Quarterly trends and results

Earnings (cumulative)	FY12/21				FY12/22				FY12/22	
(JPYmn)	Q1	Q1–Q2	Q1–Q3	Q1–Q4	Q1	Q1–Q2	Q1–Q3	Q1–Q4	% of Est.	FY Est.
Sales	1,420	3,147	5,553	8,257	2,316	4,874			48.7%	10,003
YoY	157.6%	131.3%	138.1%	176.4%	63.1%	54.9%				21.1%
Gross profit	1,010	2,275	4,046	5,800	1,898	4,010				
YoY	690.9%	589.5%	562.4%	569.1%	87.9%	76.3%				
Gross profit margin	71.1%	72.3%	72.9%	70.2%	82.0%	82.3%				
SG&A expenses	1,221	2,470	3,622	4,784	1,389	2,638				
YoY	12.0%	13.8%	-3.5%	-11.0%	13.8%	6.8%				
SG&A ratio	85.9%	78.5%	65.2%	57.9%	60.0%	54.1%				
Operating profit	-211	-195	424	1,016	509	1,372			77.5%	1,770
YoY	-	-	-	-	-	-				74.2%
Operating profit margin	-	-	7.6%	12.3%	22.0%	28.2%				17.7%
Recurring profit	-209	-204	414	1,001	479	1,447			82.7%	1,750
YoY	-	-	-	-	-	-				74.8%
Recurring profit margin	-	-	7.5%	12.1%	20.7%	29.7%				17.5%
Net income	-210	-206	325	2,032	163	1,108			74.9%	1,480
YoY	-	-	-	-	-	-				-27.2%
Net margin	-	-	5.9%	24.6%	7.0%	22.7%				14.8%

Earnings (quarterly)	FY12/21				FY12/22			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	1,420	1,726	2,406	2,704	2,316	2,558		
YoY	157.6%	113.3%	147.6%	313.1%	63.1%	48.2%		
Gross profit	1,010	1,265	1,771	1,754	1,898	2,112		
YoY	690.9%	525.5%	530.6%	585.0%	87.9%	67.0%		
Gross profit margin	71.1%	73.3%	73.6%	64.9%	82.0%	82.6%		
SG&A expenses	1,221	1,249	1,152	1,163	1,389	1,249		
YoY	12.0%	15.6%	-27.2%	-28.2%	13.8%	0.0%		
SG&A ratio	85.9%	72.4%	47.9%	43.0%	60.0%	48.8%		
Operating profit	-211	16	619	592	509	863		
YoY	-	-	-	-	-	-		
Operating profit margin	-	0.9%	25.7%	21.9%	22.0%	33.8%		
Recurring profit	-209	5	618	587	479	969		
YoY	-	-	-	-	-	-		
Recurring profit margin	-	0.3%	25.7%	21.7%	20.7%	37.9%		
Net income	-210	4	530	1,707	163	945		
YoY	-	-	-	-	-	-		
Net margin	-	0.2%	22.0%	63.1%	7.0%	36.9%		

Source: Shared Research based on company data
Note: Figures may differ from company materials due to differences in rounding methods.
"- "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)	FY12/21				FY12/22			
(JPYmn)	Q1	Q1–Q2	Q1–Q3	Q1–Q4	Q1	Q1–Q2	Q1–Q3	Q1–Q4
SG&A expenses	1,221	2,470	3,622	4,784	1,389	2,638		
YoY	12.0%	13.8%	-3.5%	-11.0%	13.8%	6.8%		
R&D expenses	473	912	1,286	1,736	496	1,009		
YoY	8.0%	9.4%	-26.3%	-23.4%	4.8%	10.6%		
SG&A expenses excl. R&D	747	1,557	2,335	3,048	893	1,629		
YoY	14.7%	16.6%	16.3%	-1.9%	19.5%	4.6%		

Earnings (quarterly)	FY12/21				FY12/22			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	1,221	1,249	1,152	1,163	1,389	1,249		
YoY	12.0%	15.6%	-27.2%	-28.2%	13.8%	0.0%		
R&D expenses	473	439	374	450	496	513		
YoY	8.0%	11.0%	-59.0%	-13.7%	4.8%	16.9%		
SG&A expenses excl. R&D	747	810	778	713	893	736		
YoY	14.7%	18.3%	15.7%	-35.1%	19.5%	-9.2%		

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

1H FY12/22 results

- Sales: JPY4.9bn (+54.9% YoY)
- Operating profit: JPY1.4bn (loss of JPY195mn in 1H FY12/21)
- Recurring profit: JPY1.5bn (loss of JPY204mn in 1H FY12/21)
- Net income attributable to owners of the parent: JPY1.1bn (loss of JPY206mn in 1H FY12/21)

SymBio has applied the Accounting Standard for Revenue Recognition (ASBJ Statement No. 29) from Q1 FY12/22. Under the previous accounting standard, the company recorded allowance for sales returns in the amount equivalent to gross profit. However, in accordance with the new accounting standard regarding variable consideration, the company no longer recognizes revenue at the time of sale and records refund liabilities as "other" under the current liabilities section of the balance sheet.

As a result of adopting the Accounting Standard for Revenue Recognition, 1H FY12/22 sales, operating profit, and recurring profit each increased by JPY57mn.

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), which makes TREAKISYM® RI more suitable for elderly patients.

With regard to switch from the FD to RTD formulation, virtually all medical institutions had started using the RTD formulation by end-June 2022. Further, with over 90% of medical institutions expressing an intention to convert to the RI administration as of end-June 2022, uptake of the RI administration is proceeding as planned. On the quality assurance front, SymBio also has taken steps to ensure the stable supply of the RTD formulation of TREAKISYM®.

Despite sales activities being constrained by factors including delays in treatment and restrictions on medical facility visits due to the COVID-19 pandemic, sales rose 54.9% YoY to JPY4.9bn. The increase was largely due to the approval in March 2021 of TREAKISYM® for the additional indication of combination use in bendamustine-rituximab (BR) therapy and in polatuzumab vedotin plus bendamustine-rituximab (Pola-BR) therapy to treat recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). The May 2021 NHI price listing of Chugai Pharmaceutical's antibody drug conjugate polatuzumab vedotin contributed to an increase in sales for the indication of r/r DLBCL.

Gross profit totaled JPY4.0bn (+76.3% YoY) and the gross profit margin was 82.3% (+10.0pp YoY). SG&A expenses came to JPY2.6bn (+6.8% YoY), including R&D expenses of JPY1.0bn (+10.6% YoY). As a result, operating profit was JPY1.4bn (versus an operating loss of JPY195mn in 1H FY12/21).

Establishment of an in-house sales organization

The business alliance agreement between SymBio and Eisai Co., Ltd. under which Eisai acts as a sales agent expired in December 2020, and the company switched to in-house sales for domestic sales of Treakisym®.

In conducting in-house sales, SymBio established a sales organization that can cultivate needs, provide information on the company products, and plan seminars. In addition to medical representatives, the company deployed hematology experts with extensive knowledge of the field throughout Japan. Further, the company concluded basic agreements with Suzuken Co., Ltd and Toho Pharmaceutical Co., Ltd for the procurement and sale of pharmaceuticals to build a nationwide distribution network. The company has established two distribution centers, one in Eastern Japan and the other in Western Japan, under management by S.D. Collabo Co., Ltd.

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®

In March 2021, SymBio obtained approval for the use of the FD formulation of TREAKISYM® in BR therapy to treat r/r DLBCL as an additional indication. In January 2021, the company commenced sales of the ready-to-dilute (or RTD) formulation of TREAKISYM® in-licensed from US-based Eagle Pharmaceuticals, Inc., having obtained marketing approval in September 2020. In April 2021, the company obtained approval for a partial change to the marketing approval of the RTD formulation for its use in BR and Pola-BR therapy for the treatment of r/r DLBCL. For the RI administration, the company completed clinical studies on safety and filed a partial change application in May 2021. This application was approved in February 2022, enabling the use of RI administration for all approved indications of the RTD formulation.

SymBio will continue to explore new potential applications of TREAKISYM®, including via specified clinical research with Saitama Medical University and joint research with Kyoto University.

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

Onconova Therapeutics, Inc., the drug's licensor, announced in August 2020 that INSPIRE, the pivotal Phase III study in higher-risk myelodysplastic syndromes (HR-MDS) patients comparing IV rigosertib to physicians' choice of treatment, did not meet its primary endpoint. SymBio is in charge of clinical development in Japan and is collaborating with Onconova regarding the future development of rigosertib.

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.

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 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 viruses, 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.

In May 2022, Chimerix announced that it had entered into an agreement with US-based Emergent BioSolutions Inc. to transfer its exclusive worldwide rights for BCV to the latter. SymBio's exclusive worldwide license to develop, manufacture, and commercialize BCV for all indications except for orthopoxvirus infections (including smallpox and monkey pox) will not be affected.

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 January 2022, the company successfully filed a clinical trial application to the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK.

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 impairs the function of the transplanted kidney. In order to find an early solution to this problem, in May 2022, SymBio submitted a clinical trial notification for a global Phase II study in patients infected with BK virus after kidney transplantation to the Pharmaceuticals and Medical Devices Agency (PMDA), and is preparing for clinical trials in Australia and other regions. The company also has been preparing for clinical development targeting EB virus-related diseases such as the difficult-to-treat multiple sclerosis, as well as post-COVID-19 condition assumed to be associated with EB virus. Through the accumulation of clinical trial data, SymBio will examine the efficacy of BCV in humans against various dsDNA virus infections and expand target indications to include multiviral infections. By doing so, it aims to expand the target market for and maximize the business value of BCV.

In addition to antiviral activity, the company expects BCV 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 BCV in oncology, including rare brain tumors and EB virus-positive lymphoma. In March 2022, the company commenced joint research with Brown University in the US to investigate the anti-tumor effects of BCV on cytomegalovirus-associated glioblastoma (GBM).

Overseas

With a view to accelerating global development of the antiviral drug brincidofovir, the company's US-based wholly-owned subsidiary SymBio Pharma USA, Inc. appointed Dr. Carolyn Yanavich as its Vice President and Head of Project Management and Clinical Operations in October 2021. In April 2022, SymBio Pharma USA appointed Dr. Yanavich as President, Chief Operating Officer, and Chief Development Officer.

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

	FY12/21			FY12/22			
(JPYmn)	1H Act.	2H Act.	FY Act.	1H Act.	2H Est.	FY Est.	YoY
Sales	3,147	5,110	8,257	4,874	5,129	10,003	21.1%
Gross profit	2,275	3,525	5,800	4,010			
Gross profit margin	72.3%	69.0%	70.2%	82.3%			
SG&A expenses	2,470	2,314	4,784	2,638			
SG&A ratio	78.5%	45.3%	57.9%	54.1%			
R&D expenses	912	824	1,736	1,009			
SG&A expenses excl. R&D	1,557	1,491	3,048	1,629			
Operating profit	-195	1,211	1,016	1,372	398	1,770	74.2%
Operating profit margin	-	23.7%	12.3%	28.2%	7.8%	17.7%	
Recurring profit	-204	1,205	1,001	1,447	303	1,750	74.8%
Recurring profit margin	-	23.6%	12.1%	29.7%	5.9%	17.5%	
Net income	-206	2,238	2,032	1,108	372	1,480	-27.2%
Net margin	-	43.8%	24.6%	22.7%	7.3%	14.8%	

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

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