Quarterly trends and results

Earnings (cumulative)	FY12/22				FY12/23				FY12/23	
(JPYmn)	Q1	Q1-Q2	Q1-Q3	Q1-Q4	Q1	Q1-Q2	Q1-Q3	Q1-Q4	% of forecast	FY forecast
Sales	2,316	4,874	7,356	10,008	1,545				22.1%	7,000
YoY	63.1%	54.9%	32.5%	21.2%	-33.3%					-30.1%
Gross profit	1,898	4,010	5,467	7,600	1,243					5,526
YoY	87.9%	76.3%	35.1%	31.0%	-34.5%					-27.3%
Gross profit margin	82.0%	82.3%	74.3%	75.9%	80.5%					
SG&A expenses	1,389	2,638	3,878	5,636	1,192					5,857
YoY	13.8%	6.8%	7.1%	17.8%	-14.2%					3.9%
SG&A ratio	60.0%	54.1%	52.7%	56.3%	77.2%					
Operating profit	509	1,372	1,589	1,964	51				-	-331
YoY	-	-	274.5%	93.3%	-89.9%					-
Operating profit margin	22.0%	28.2%	21.6%	19.6%	3.3%					-
Recurring profit	479	1,447	1,843	2,000	48				-	-351
YoY	-	-	344.8%	99.8%	-89.9%					-
Recurring profit margin	20.7%	29.7%	25.1%	20.0%	3.1%					-
Net income	163	1,108	1,556	1,179	4				-	-370
YoY	-	-	378.9%	-42.0%	-97.3%					-
Net margin	7.0%	22.7%	21.2%	11.8%	0.3%					-
Earnings (quarterly)	**FY12/22**				**FY12/23**					
(JPYmn)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**		
Sales	2,316	2,558	2,482	2,653	1,545					
YoY	63.1%	48.2%	3.1%	-1.9%	-33.3%					
Gross profit	1,898	2,112	1,456	2,133	1,243					
YoY	87.9%	67.0%	-17.8%	21.6%	-34.5%					
Gross profit margin	82.0%	82.6%	58.7%	80.4%	80.5%					
SG&A expenses	1,389	1,249	1,240	1,759	1,192					
YoY	13.8%	0.0%	7.6%	51.3%	-14.2%					
SG&A ratio	60.0%	48.8%	50.0%	66.3%	77.2%					
Operating profit	509	863	216	375	51					
YoY	-	-	-65.0%	-36.7%	-89.9%					
Operating profit margin	22.0%	33.8%	8.7%	14.1%	3.3%					
Recurring profit	479	969	396	156	48					
YoY	-	-	-35.9%	-73.3%	-89.9%					
Recurring profit margin	20.7%	37.9%	16.0%	5.9%	3.1%					
Net income	163	945	448	-377	4					
YoY	-	-	-15.6%	-	-97.3%					
Net margin	7.0%	36.9%	18.0%	-	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)	FY12/22				FY12/23			
(JPYmn)	Q1	Q1-Q2	Q1-Q3	Q1-Q4	Q1	Q1-Q2	Q1-Q3	Q1-Q4
SG&A expenses	1,389	2,638	3,878	5,636	1,192			
YoY	13.8%	6.8%	7.1%	17.8%	-14.2%			
R&D expenses	496	1,009	1,564	2,555	550			
YoY	4.8%	10.6%	21.6%	47.2%	10.8%			
SG&A expenses excl. R&D	893	1,629	2,314	3,081	642			
YoY	19.5%	4.6%	-0.9%	1.1%	-28.1%			
Earnings (quarterly)	**FY12/22**				**FY12/23**			
(JPYmn)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
SG&A expenses	1,389	1,249	1,240	1,759	1,192			
YoY	13.8%	0.0%	7.6%	51.3%	-14.2%			
R&D expenses	496	513	554	991	550			
YoY	4.8%	16.9%	48.2%	120.3%	10.8%			
SG&A expenses excl. R&D	893	736	686	767	642			
YoY	19.5%	-9.2%	-11.9%	7.7%	-28.1%			

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

Q1 FY12/23 results

- Sales: JPY1.5bn (-33.3% YoY)
- Operating profit: JPY51mn (-89.9% YoY)
- Recurring profit: JPY48mn (-89.9% YoY)
- Net income attributable to owners of the parent for the quarter: JPY4mn (-97.3% YoY)

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 80% of medical institutions administering the RI formulation to patients as of end-March 2023, progress was made in the switch to the RI formulation. On the quality assurance front, SymBio also has taken steps to ensure the stable supply of the RTD formulation of TREAKISYM®.

Sales decreased 33.3% YoY to JPY 1.5bn. The decline was due to the following factors: 1) medical institutions were reluctant to purchase drugs due to price revisions; 2) the amount of drugs used per patient decreased during the COVID-19 pandemic; and 3) the launch of generic drugs in June 2022 affected SymBio's product sales. In addition, there was a temporary sales spike last year due to the switch from the FD formulation to the RTD formulation, which impacted this year's sales.

Gross profit totaled JPY1.2bn (-34.5% YoY) and the gross profit margin was 80.5% (-1.5pp YoY). SG&A expenses came to JPY1.2bn (-14.2% YoY), including R&D expenses of JPY550mn (+10.8% YoY). As a result, operating profit was JPY51mn (-89.9% from operating profit of JPY509mn in FY12/22).

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 February 2022, the company secured approval for a partial amendment to the marketing authorization for the ready-to-dilute (RTD) formulation of TREAKISYM® (in-licensed from US-based Eagle Pharmaceuticals, Inc.), 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 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.

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. As of end-March 2023, cumulative patient enrollment came to 22.

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.

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 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.

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 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.

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.

Overseas

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. SymBio Pharma USA plans to accelerate 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.

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