Quarterly trends and results

Earnings (cumulative)	FY12/21				FY12/22				FY12/23
(JPYmn)	Q1	Q1-Q2	Q1-Q3	Q1-Q4	Q1	Q1-Q2	Q1-Q3	Q1-Q4	FY forecast
Sales	1,420	3,147	5,553	8,257	2,316	4,874	7,356	10,008	7,000
YoY	157.6%	131.3%	138.1%	176.4%	63.1%	54.9%	32.5%	21.2%	-15.2%
Gross profit	1,010	2,275	4,046	5,800	1,898	4,010	5,467	7,600	
YoY	690.9%	589.5%	562.4%	569.1%	87.9%	76.3%	35.1%	31.0%	
Gross profit margin	71.1%	72.3%	72.9%	70.2%	82.0%	82.3%	74.3%	75.9%	
SG&A expenses	1,221	2,470	3,622	4,784	1,389	2,638	3,878	5,636	
YoY	12.0%	13.8%	-3.5%	-11.0%	13.8%	6.8%	7.1%	17.8%	
SG&A ratio	85.9%	78.5%	65.2%	57.9%	60.0%	54.1%	52.7%	56.3%	
Operating profit	-211	-195	424	1,016	509	1,372	1,589	1,964	-331
YoY	-	-	-	-	-	-	274.5%	93.3%	-
Operating profit margin	-	-	7.6%	12.3%	22.0%	28.2%	21.6%	19.6%	-
Recurring profit	-209	-204	414	1,001	479	1,447	1,843	2,000	-351
YoY	-	-	-	-	-	-	344.8%	99.8%	-
Recurring profit margin	-	-	7.5%	12.1%	20.7%	29.7%	25.1%	20.0%	-
Net income	-210	-206	325	2,032	163	1,108	1,556	1,179	-370
YoY	-	-	-	-	-	-	378.9%	-42.0%	-
Net margin	-	-	5.9%	24.6%	7.0%	22.7%	21.2%	11.8%	-

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	2,482	2,653
YoY	157.6%	113.3%	147.6%	313.1%	63.1%	48.2%	3.1%	-1.9%
Gross profit	1,010	1,265	1,771	1,754	1,898	2,112	1,456	2,133
YoY	690.9%	525.5%	530.6%	585.0%	87.9%	67.0%	-17.8%	21.6%
Gross profit margin	71.1%	73.3%	73.6%	64.9%	82.0%	82.6%	58.7%	80.4%
SG&A expenses	1,221	1,249	1,152	1,163	1,389	1,249	1,240	1,759
YoY	12.0%	15.6%	-27.2%	-28.2%	13.8%	0.0%	7.6%	51.3%
SG&A ratio	85.9%	72.4%	47.9%	43.0%	60.0%	48.8%	50.0%	66.3%
Operating profit	-211	16	619	592	509	863	216	375
YoY	-	-	-	-	-	-	-65.0%	-36.7%
Operating profit margin	-	0.9%	25.7%	21.9%	22.0%	33.8%	8.7%	14.1%
Recurring profit	-209	5	618	587	479	969	396	156
YoY	-	-	-	-	-	-	-35.9%	-73.3%
Recurring profit margin	-	0.3%	25.7%	21.7%	20.7%	37.9%	16.0%	5.9%
Net income	-210	4	530	1,707	163	945	448	-377
YoY	-	-	-	-	-	-	-15.6%	-
Net margin	-	0.2%	22.0%	63.1%	7.0%	36.9%	18.0%	-

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)	FY12/21				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	3,878	5,636
YoY	12.0%	13.8%	-3.5%	-11.0%	13.8%	6.8%	7.1%	17.8%
R&D expenses	473	912	1,286	1,736	496	1,009	1,564	2,555
YoY	8.0%	9.4%	-26.3%	-23.4%	4.8%	10.6%	21.6%	47.2%
SG&A expenses excl. R&D	747	1,557	2,335	3,048	893	1,629	2,314	3,081
YoY	14.7%	16.6%	16.3%	-1.9%	19.5%	4.6%	-0.9%	1.1%

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	1,240	1,759
YoY	12.0%	15.6%	-27.2%	-28.2%	13.8%	0.0%	7.6%	51.3%
R&D expenses	473	439	374	450	496	513	554	991
YoY	8.0%	11.0%	-59.0%	-13.7%	4.8%	16.9%	48.2%	120.3%
SG&A expenses excl. R&D	747	810	778	713	893	736	686	767
YoY	14.7%	18.3%	15.7%	-35.1%	19.5%	-9.2%	-11.9%	7.7%

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

Full-year FY12/22 results

- Sales: JPY10.0bn (+21.2% YoY)
- Operating profit: JPY2.0bn (+93.3%YoY)
- Recurring profit: JPY2.0bn (+99.8% YoY)
- Net income attributable to owners of the parent: JPY1.2bn (-42.0% YoY)

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, full-year sales, operating profit, and recurring profit each increased by JPY63mn.

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-December 2022, 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®.

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 21.2% YoY to JPY10.0bn. 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 JPY7.6bn (+31.0% YoY) and the gross profit margin was 75.9% (+5.7pp YoY). SG&A expenses came to JPY5.6bn (+17.8% YoY), including R&D expenses of JPY2.6bn (+47.2% YoY). As a result, operating profit was JPY2.0bn (+93.6% from operating profit of JPY1.0bn in 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 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-December 2022, cumulative patient enrollment came to 20.

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. The company is also preparing to conduct clinical trials in South Korea.

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 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 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.

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.

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

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			FY12/23	
(JPYmn)	1H results	2H results	FY results	1H results	2H results	FY results	FY forecast	YoY
Sales	3,147	5,110	8,257	4,874	5,135	10,008	7,000	-30.1%
Gross profit	2,275	3,525	5,800	4,010	3,589	7,600		
Gross profit margin	72.3%	69.0%	70.2%	82.3%	69.9%	75.9%		
SG&A expenses	2,470	2,314	4,784	2,638	2,998	5,636		
SG&A ratio	78.5%	45.3%	57.9%	54.1%	58.4%	56.3%		
R&D expenses	912	824	1,736	1,009	1,545	2,555	3,380	32.3%
SG&A expenses excl. R&D	1,557	1,491	3,048	1,629	1,453	3,081		
Operating profit	-195	1,211	1,016	1,372	591	1,964	-331	-
Operating profit margin	-	23.7%	12.3%	28.2%	11.5%	19.6%	-	
Recurring profit	-204	1,205	1,001	1,447	553	2,000	-351	-
Recurring profit margin	-	23.6%	12.1%	29.7%	10.8%	20.0%	-	
Net income	-206	2,238	2,032	1,108	71	1,179	-370	-
Net margin	-	43.8%	24.6%	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.

Full-year FY12/23 company forecast (out February 9, 2023)

The full-year FY12/23 earnings forecast calls for sales of JPY7.0bn (-30.1% YoY), operating loss of JPY331mn (operating profit of JPY2.0bn in FY12/22), recurring loss of JPY351mn (profit of JPY2.0bn), and net loss attributable to owners of the parent of JPY370mn (net income of JPY1.2bn).

The company expects lower NHI drug prices and marketing of generic versions of the company's Treakisym® to drag on sales. The company has filed patent infringement litigation regarding the generic versions of Treakisym® asking for an injunction against their manufacture and sale, but has not included any impact on sales due to the time required to reach a decision.

The company forecasts R&D spending of JPY3.4bn, including the following items.

- Global Phase II study launched in 2021 of antiviral drug BCV IV in patients infected with adenovirus
- Global Phase II study launched in 2022 of antiviral drug BCV IV in patients infected with BK virus after receiving kidney transplant
- Development of new indications and evaluation of new drug development candidates through joint research with academia

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