Quarterly trends and results

Earnings (cumulative)	FY12/20				FY12/21				FY12/21	
(JPYmn)	Q1	Q1–Q2	Q1–Q3	Q1–Q4	Q1	Q1–Q2	Q1–Q3	Q1–Q4	% of Est.	FY Est.
Sales	551	1,361	2,333	2,987	1,420	3,147	5,553		60.7%	9,151
YoY	-65.8%	-32.1%	16.2%	5.3%	157.6%	131.3%	138.1%			206.4%
Gross profit	128	330	611	867	1,010	2,275	4,046			
YoY	-79.0%	-37.7%	8.5%	0.2%	690.9%	589.5%	562.4%			
Gross profit margin	23.2%	24.2%	26.2%	29.0%	71.1%	72.3%	72.9%			
SG&A expenses	1,090	2,170	3,753	5,373	1,221	2,470	3,622			
YoY	-9.6%	-14.7%	-8.4%	4.0%	12.0%	13.8%	-3.5%			
SG&A ratio	197.6%	159.5%	160.9%	179.9%	85.9%	78.5%	65.2%			
Operating profit	-962	-1,840	-3,142	-4,506	-211	-195	424		31.2%	1,361
YoY	-	-	-	-	-	-	-			-
Operating profit margin	-	-	-	-	-	-	7.6%			14.9%
Recurring profit	-991	-1,883	-3,221	-4,616	-209	-204	414		30.7%	1,350
YoY	-	-	-	-	-	-	-			-
Recurring profit margin	-	-	-	-	-	-	7.5%			14.8%
Net income	-992	-1,885	-2,694	-4,090	-210	-206	325		28.3%	1,149
YoY	-	-	-	-	-	-	-			-
Net margin	-	-	-	-	-	-	5.9%			12.6%

Quarterly	FY12/20				FY12/21			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	551	809	972	654	1,420	1,726	2,406	
YoY	-65.8%	105.7%	-	-21.1%	157.6%	113.3%	147.6%	
Gross profit	128	202	281	256	1,010	1,265	1,771	
YoY	-79.0%	-	738.4%	-15.2%	690.9%	525.5%	530.6%	
Gross profit margin	23.2%	25.0%	28.9%	39.1%	71.1%	73.3%	73.6%	
SG&A expenses	1,090	1,080	1,583	1,620	1,221	1,249	1,152	
YoY	-9.6%	-19.4%	1.8%	51.8%	12.0%	15.6%	-27.2%	
SG&A ratio	197.6%	133.5%	162.9%	247.5%	85.9%	72.4%	47.9%	
Operating profit	-962	-878	-1,302	-1,364	-211	16	619	
YoY	-	-	-	-	-	-	-	
Operating profit margin	-	-	-	-	-	0.9%	25.7%	
Recurring profit	-991	-892	-1,338	-1,395	-209	5	618	
YoY	-	-	-	-	-	-	-	
Recurring profit margin	-	-	-	-	-	0.3%	25.7%	
Net income	-992	-893	-809	-1,396	-210	4	530	
YoY	-	-	-	-	-	-	-	
Net margin	-	-	-	-	-	0.2%	22.0%	

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 1000%.

Breakdown of SG&A expenses

Earnings (cumulative)	FY12/20				FY12/21			
(JPYmn)	Q1	Q1–Q2	Q1–Q3	Q1–Q4	Q1	Q1–Q2	Q1–Q3	Q1–Q4
SG&A expenses	1,090	2,170	3,753	5,373	1,221	2,470	3,622	
YoY	-9.6%	-14.7%	-8.4%	4.0%	12.0%	13.8%	-3.5%	
R&D expenses	438	834	1,745	2,267	473	912	1,286	
YoY	-7.1%	-13.4%	-11.5%	-7.2%	8.0%	9.4%	-26.3%	
SG&A expenses excl. R&D	651	1,336	2,008	3,107	747	1,557	2,335	
YoY	-11.1%	-15.5%	-5.6%	14.0%	14.7%	16.6%	16.3%	

Quarterly	FY12/20				FY12/21			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	1,090	1,080	1,583	1,620	1,221	1,249	1,152	
YoY	-9.6%	-19.4%	1.8%	51.8%	12.0%	15.6%	-27.2%	
R&D expenses	438	396	911	522	473	439	374	
YoY	-7.1%	-19.4%	-9.7%	11.0%	8.0%	11.0%	-59.0%	
SG&A expenses excl. R&D	651	685	672	1,098	747	810	778	
YoY	-11.1%	-19.3%	23.2%	83.9%	14.7%	18.3%	15.7%	

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

Cumulative Q3 FY12/21 results

- Sales: JPY5.6bn (+138.1% YoY)
- Operating profit: JPY424mn (loss of JPY3.1bn in cumulative Q3 FY12/20)
- Recurring profit: JPY414mn (loss of JPY3.2bn in cumulative Q3 FY12/20)
- Net income: JPY325mn (loss of JPY2.7bn in cumulative Q3 FY12/20)

Sales increased YoY in cumulative Q3 FY12/21, largely due to the transfer of sales from Eisai Co., Ltd. to the company's own sales force. However, there were headwinds such as the clearance of market inventory of the FD formulation sold by Eisai

prior to the switch to the company's own sales force in December 2020, delays in medical care due to the COVID-19 outbreak from late 2020, and constraints on sales activities due to tighter restrictions on facilities visits.

In Q3, sales of Treakisym® for the indication of relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) accelerated. This was partially because the backlog of delayed medical treatments cleared on COVID-19 measures, including vaccinations for the elderly. Other factors included the March 2021 approval of BR-therapy and P-BR therapy to treat r/r DLBCL, and Chugai Pharmaceutical's polatuzumab vedotin being added to the NHI drug list in May 2021.

Profits at the operating profit level down grew on reduced SG&A expenses and sales growth, and the company achieved profitability in cumulative Q3. SG&A expenses decreased 3.5% YoY to JPY3.6bn and R&D expenses decreased 26.3% YoY to JPY1.3bn. This included expenses for conducting clinical trials of intravenous formulations of Treakisym® and brincidofovir. Excluding R&D expenses, SG&A expenses rose 16.3% YoY to JPY2.3bn. The switch to in-house sales drove up the cost of sales.

Domestic

Preparations for in-house sales organization begin

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®.

The company has thus far deployed a nationwide network of marketing representatives as well as hematology experts to cover each region to establish a highly productive internal sales organization capable of making proposals that fit the needs of each region. With the termination of its alliance agreement with Eisai, in September 2020, the company concluded a basic agreement with Suzuken Co., Ltd and Toho Pharmaceutical Co., Ltd for the procurement and sale of pharmaceuticals to achieve nationwide distribution. 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.

During cumulative Q3, in January 2021, the company launched sales of the ready-to-dilute (RTD) formulation of Treakisym®, for which it obtained manufacturing and marketing approval in September 2020.

On March 23, 2021, the company obtained approval of a partial change to the manufacturing and marketing authorization for bendamustine-rituximab combination therapy (BR therapy) and bendamustine-rituximab-polatuzumab vedotin combination therapy (P-BR therapy) to treat r/r DLBCL patients. This enabled conventional lyophilized (freeze-dried [FD]) powder formulation of Treakisym® to be used in BR therapy right away. In April 2021, the company obtained approval of Treakisym® ready-to-dilute (RTD) liquid formulation for use in BR therapy and P-BR therapy for the treatment of r/r DLBCL. In May 2021, Chugai Pharmaceutical's polatuzumab vedotin was added to the NHI drug price list, enabling Treakisym® to be used in P-BR therapy.

Stable product supply

With the launch of sales of Treakisym® RTD formulation in January 2021, the company now markets both Treakisym® in both RTD formulation and FD formulation.

SymBio imports FD formulation Treakisym® for injection from Astellas Deutschland (consolidated subsidiary of Astellas Pharma) and Treakisym® RTD formulation from Eagle Pharmaceuticals Inc.

On the quality control front, the company conducts secondary packaging and quality screening on imported batches of both the FD and RTD formulations of TREAKISYM® to maintain stable quality.

On the supply front, the company is striving to replace the FD formulation of TREAKISYM® with RTD formulation in the market, but the current conversion rate is behind plan. Due to the possibility of the FD formulation being out of stock, SymBio began controlling shipments of FD from September 21, 2021. The company has secured sufficient quantities of the RTD formulation to ensure stable supply.

Treakisym® (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®)

The anticancer agent Treakisym® is used to treat malignant lymphomas, indicated for untreated low-grade non-Hodgkin's lymphoma and mantle cell lymphoma (marketing approval obtained in December 2016), refractory or relapsed low-grade NHL and MCL (October 2010), and chronic lymphocytic leukemia (August 2016).

The combination therapy of Treakisym® and rituximab (BR therapy) was newly included in the Practical Guidelines for Hematological Malignancies 2018 published by Japanese Society of Hematology as a standard treatment option, which applies to all of the approved indications. This has seen Treakisym® establish its position as a standard treatment for lymphatic cancer.

Also, SymBio obtained approval for the partial revision to the marketing authorization of Treakisym® in July 2018. Treakisym® can now be used in combination with new anti-CD20 antibodies and not just rituximab for the treatment of CD20-positive follicular lymphoma, the most common histological type of low-grade NHL. This allows the company to provide patients a new treatment option: combination therapy with obinutuzumab. In March 2019, SymBio obtained approval for the partial revision to its application to use Treakisym® as a pretreatment agent in tumor-specific T cell infusion therapy. This allows Treakisym® to be used as a pretreatment agent for Kymriah® intravenous infusion, which was the first chimeric antigen receptor T-cell (CAR-T) therapy approved in Japan. Growing use of Treakisym® as a pretreatment agent in regenerative medicine has solidified its positioning as standard therapy for malignant lymphomas.

In the phase III clinical study of Treakisym® administered in BR therapy targeting r/r DLBCL, the company filed for approval for partial revision to manufacturing and marketing authorization in May 2020 and obtained that approval in March 2021. In April 2021, it obtained approval for partial revision to manufacturing and marketing authorization of Treakisym® RTD liquid formulation for use in BR and P-BR therapy as treatment for r/r DLBCL. The company has conducted a follow-up study with overall survival as the primary endpoint, because evaluating the survival data (e.g., overall survival and progression-free survival) for Treakisym® administered in BR therapy is crucial for establishing Treakisym® as a treatment for DLBCL. It is now making preparations to publicize the results of that study. Also, after Chugai Pharmaceutical Co., Ltd. applied for manufacture and marketing approval for polatuzumab vedotin in combination with BR therapy to treat r/r DLBCL in June 2020, the company applied for approval for partial revision to manufacturing and marketing authorization for Treakisym® in P-BR therapy and obtained approval in March 2021. Polatuzumab vedotin was added to the NHI drug price list in May 2021, and now Treakisym® may be used in P-BR therapy. Previously there were no effective treatments for the additional indication of r/r DLBCL, which was usually treated by a combination of anticancer agents as salvage chemotherapy, so development of a highly effective but safe new drug was sought after. Since BR therapy is already being used in the West to treat r/r DLBCL, patient organizations and related academic societies petitioned MHLW so that it could be used in Japan as soon as possible.

The company concluded an exclusive licensing agreement in Japan with Eagle Pharmaceuticals (based in New Jersey, US) in September 2017 for the RTD and rapid infusion (RI) formulations of Treakisym® (the RI formulation reduces administration time). Manufacturing and marketing approval of the RTD formulation was obtained in September 2020, and the company launched it in January 2021. The company has concluded clinical trials to confirm safety of the RI formulation and applied for approval in May 2021. Unlike the current FD formulation, the RTD formulation reduces the workload of medical professionals, because it eliminates the need for troublesome manual dissolution. The RI formulation can be administered in just 10 minutes, versus 60 minutes for the current FD and RTD formulation. This reduces the burden on patients and healthcare professionals, providing significant value added.

Rigosertib Sodium (SyB L-1101 [IV]/SyB C-1101 [oral]; anticancer agent; generic name: rigosertib Sodium)

Onconova Therapeutics, Inc., the licensor, conducted a global phase III trial (INSPIRE study) across more than 20 countries addressing higher-risk myelodysplastic syndromes (higher-risk MDS) with overall survival as the primary endpoint. The target is patients who do not respond to the current standard treatment with hypomethylating agents, relapse after treatment under the current standard of care, or are intolerant to hypomethylating agents. In August 2020, Onconova announced a comparator trial to physicians' choice of treatment failed to achieve the primary endpoint. The company leads clinical trials conducted in Japan and is looking to apply the knowledge gleaned from additional analysis of the INSPIRE study to rigosertib development going forward.

Regarding the oral formulation of rigosertib, Onconova completed a phase I/II clinical trial for the drug used in combination with azacytidine, whose results suggested the efficacy and safety of the combination therapy. To verify the tolerability and safety among Japanese patients, SymBio began a phase I clinical trial in Japan in June 2017 and completed patient enrollment in June 2019.

The company said it would conduct joint research into Treakisym® and rigosertib with the University of Tokyo's Institute of Medical Science and Gunma University regarding efficacy of using the two compounds in combination or with existing drugs and also explore new indications.

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

In September 2019, SymBio concluded an exclusive global license agreement with Chimerix Inc. (hereafter Chimerix) for brincidofovir (SyB V-1901, hereafter BCV IV and BCV Oral), an antiviral drug in intravenous and oral forms). The company

acquired exclusive global rights to develop, manufacture, and market BCV for all diseases except smallpox.

The company has concluded that it would prioritize global development of BCV IV (mainly in Japan, the US, and Europe) to treat adenovirus (AdV) infections in patients receiving hematopoietic stem cell transplantation to address an unmet medical need. In March 2021, the company submitted of an investigational new drug (IND) application to the Food and Drug Administration (FDA) of the US with the goal of obtaining permission for the launch of a phase II clinical trial for a phase II clinical trial of BCV IV as a treatment for adenovirus infections that primarily occur in children (although also in adults). In April 2021, the company received granted fast track designation from the FDA and on August 16, 2021, the investigational drug was administered to the first patient enrolled (first patient in [FPI]) in the clinical trial.

Based on safety and efficacy data acquired from its study, the company plans to review the drug's efficacy against dsDNA viral infections in patients receiving hematopoietic stem cell transplantation and extend its target indications to include multiviral infections. By exploring the potential for expanding target disease areas to viral infections related to organ transplants (including kidney transplants), the company aims to grow the market for and maximize the business value of BCV. Clinical trials by Chimerix have demonstrated superior, broad-spectrum antivirus activity of BCV Oral against dsDNA viruses, raising expectations for its potential as a safe and effective therapy to prevent and treat a range of viral infections in patients receiving hematopoietic stem cell transplantation.

Chimerix announced in December 2020 that the FDA had accepted its new drug application (NDA) for BCV as a medical defense against smallpox and that it had received FDA approval in June 2021. Further, 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.

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 on October 11, 2021, and launched full-scale operations aimed at accelerating global development of antiviral drug brincidofovir toward commercialization.

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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