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On May 13, 2021, SymBio Pharmaceuticals Ltd. announced earnings results for Q1 FY12/21.

Cumulative	FY12/20				FY12/21				FY12/21	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of Est.	FY Est.
Sales	551	1,361	2,333	2,987	1,420				15.5%	9,151
YoY	-65.8%	-32.1%	16.2%	5.3%	157.6%					206.4%
Gross profit	128	330	611	867	1,010					
YoY	-79.0%	-37.7%	8.5%	0.2%	690.9%					
GPM	23.2%	24.2%	26.2%	29.0%	71.1%					
SG&A expenses	1,090	2,170	3,753	5,373	1,221					
YoY	-9.6%	-14.7%	-8.4%	4.0%	12.0%					
SG&A ratio	197.6%	159.5%	160.9%	179.9%	85.9%					
Operating profit	-962	-1,840	-3,142	-4,506	-211				-	1,361
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					14.9%
Recurring profit	-991	-1,883	-3,221	-4,616	-209				-	1,350
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					14.8%
Net income	-992	-1,885	-2,694	-4,090	-210				-	1,149
YoY	-	-	-	-	-					-
Net margin	-	-	-	-	-					12.6%
Quarterly	**FY12/20**				**FY12/21**					
(JPYmn)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**		
Sales	551	809	972	654	1,420					
YoY	-65.8%	105.7%	-	-21.1%	157.6%					
Gross profit	128	202	281	256	1,010					
YoY	-79.0%	-	738.4%	-15.2%	690.9%					
GPM	23.2%	25.0%	28.9%	39.1%	71.1%					
SG&A expenses	1,090	1,080	1,583	1,620	1,221					
YoY	-9.6%	-19.4%	1.8%	51.8%	12.0%					
SG&A ratio	197.6%	133.5%	162.9%	247.5%	85.9%					
Operating profit	-962	-878	-1,302	-1,364	-211					
YoY	-	-	-	-	-					
OPM	-	-	-	-	-					
Recurring profit	-991	-892	-1,338	-1,395	-209					
YoY	-	-	-	-	-					
RPM	-	-	-	-	-					
Net income	-992	-893	-809	-1,396	-210					
YoY	-	-	-	-	-					
Net margin	-	-	-	-	-					

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

Cumulative	FY12/20				FY12/21			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	1,090	2,170	3,753	5,373	1,221			
YoY	-9.6%	-14.7%	-8.4%	4.0%	12.0%			
R&D expenses	438	834	1,745	2,267	473			
YoY	-7.1%	-13.4%	-11.5%	-7.2%	8.0%			
SG&A expenses excl. R&D	651	1,336	2,008	3,107	747			
YoY	-11.1%	-15.5%	-5.6%	14.0%	14.7%			
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			
YoY	-9.6%	-19.4%	1.8%	51.8%	12.0%			
R&D expenses	438	396	911	522	473			
YoY	-7.1%	-19.4%	-9.7%	11.0%	8.0%			
SG&A expenses excl. R&D	651	685	672	1,098	747			
YoY	-11.1%	-19.3%	23.2%	83.9%	14.7%			

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

Q1 FY12/21 results

- Sales: JPY1.4bn (+157.6% YoY)
- Operating loss: JPY211mn (loss of JPY962mn in Q1 FY12/19)
- Recurring loss: JPY4.6bn (loss of JPY991mn in Q1 FY12/19)
- Net loss: JPY4.1bn (loss of JPY992mn in Q1 FY12/19)

Sales increased YoY, largely due to the transfer of sales from Eisai Co., Ltd. to the company's own sales force.

Earnings were partially hindered by medical care delays due to COVID-19 since late 2020 and constraints on sales activities due to tighter restrictions on facilities visitations, but considering the clearance of market inventory of the lyophilized (freeze-dried [FD]) powder formulation of Treakisym® sold by Eisai prior to the switch to the company's own sales force in December 2020, demand for Treakisym® was strong in Q1.

For Q2, although there are lingering impacts of the clearance of market inventory distributed prior to the switch to the company' own sales force, there will be minimal impact on sales overall, and the company says that it anticipates sales growth on the additional indications for relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) that were approved on March 23.

Although SG&A expenses increased, losses at the operating profit level on down shrank thanks to the effect of sales growth. SG&A expenses increased 12.0% YoY to JPY1.2bn and R&D expenses increased 8.0% YoY to JPY473mn. This included expenses for conducting clinical trials of intravenous formulations of Treakisym® and brincidofovir. Excluding R&D expenses, SG&A rose 14.7% YoY to JPY747mn. 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 Q1, 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 the lyophilized (freeze-dried [FD]) powder formulation of Treakisym® used in bendamustine-rituximab combination therapy (BR therapy) and in bendamustine-rituximab-polatuzumab vedotin combination therapy (Pola-BR therapy) to treat r/r DLBCL patients. Treakisym® can be used in BR therapy right away, and once polatuzumab vedotin is added to the NHI drug price list and goes on sale, Treakisym® will be able to be used in Pola-BR therapy.

On April 28, 2021, the company obtained approval of a partial change to the marketing authorization of Treakisym® RTD liquid formulation for use in BR and Pola-BR therapy as treatment for r/r DLBCL.

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 lyophilized powder formulation.

SymBio imports lyophilized Treakisym® for injection from Astellas Deutschland (consolidated subsidiary of Astellas Pharma) and Treakisym® RTD formulation from Eagle Pharmaceuticals Inc. In Q1, secondary packaging and quality tests were applied to imported batches, resulting in stable quality, and as of May 2021, inventories had maintained proper levels to enable stable product supply.

On the supply front, the company is aiming for 91% completion of the switchover from the lyophilized injectable formulation to the RTD formulation of Treakisym®.

Treakisym® (SyB L-0501[lyophilized injection]/SyB L-1701 [RTD]/SyB L-1702 [RI]/SyB C-0501 [oral]; anticancer agent; generic name: bendamustine hydrochloride)

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 Pola-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 Pola-BR therapy and obtained approval in March 2021. With the approvals obtained by Chugai and SymBio, once polatuzumab vedotin is added to the NHI drug price list, Treakisym® will be able to be used in Pola-BR therapy. At present there are no effective treatments for the additional indication of r/r DLBCL, which is usually treated by a combination of anticancer agents as salvage chemotherapy, so development of a highly effective but safe new drug would be ideal. Since BR therapy is already being used in the West to treat r/r DLBCL, patient organizations and related academic societies have petitioned MHLW so that it can 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 applies for approval in May

2021. Unlike the current lyophilized powder 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 lyophilized injection and RTD formulation. This reduces the burden on patients and healthcare professionals, providing significant value added. Multiple patent protections in the form of a liquid product license will enable the extension of the product life of Treakisym® to 2031.

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 of the high-dose oral formulation of rigosertib as an initial treatment for higher-risk MDS among Japanese patients, SymBio began a phase I clinical trial in Japan in June 2017 and completed patient enrollment in June 2019.

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.

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. The FDA has approved priority review for BCV under the Prescription Drug User Fee Act (PDUFA) and set the date for completing the review (PDUFA date) at July 7, 2021.

Overseas
The company marketed SyB L-0501 in China and Hong Kong, and product sales were in line with the company's plans.

In-licensing of drug candidates

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

This note is the most recent addition to the full report.

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