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On February 4, 2021, SymBio Pharmaceuticals Ltd. announced earnings results for full-year FY12/20.

Cumulative	FY12/19				FY12/20				FY12/20	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of Est.	FY Est.
Sales	1,611	2,005	2,008	2,838	551	1,361	2,333	2,987	98.2%	3,043
YoY	81.4%	4.0%	-33.8%	-26.0%	-65.8%	-32.1%	16.2%	5.3%		7.2%
Gross profit	609	529	563	865	128	330	611	867		
YoY	144.0%	-7.7%	-39.1%	-26.3%	-79.0%	-37.7%	8.5%	0.2%		
GPM	37.8%	26.4%	28.0%	30.5%	23.2%	24.2%	26.2%	29.0%		
SG&A expenses	1,205	2,545	4,099	5,166	1,090	2,170	3,753	5,373		
YoY	25.0%	34.1%	44.8%	34.9%	-9.6%	-14.7%	-8.4%	4.0%		
SG&A ratio	74.8%	126.9%	204.1%	182.1%	197.6%	159.5%	160.9%	179.9%		
Operating profit	-596	-2,015	-3,536	-4,302	-962	-1,840	-3,142	-4,506	-	-4,592
YoY	-	-	-	-	-	-	-	-		-
OPM	-	-	-	-	-	-	-	-		-
Recurring profit	-616	-2,069	-3,642	-4,377	-991	-1,883	-3,221	-4,616	-	-4,656
YoY	-	-	-	-	-	-	-	-		-
RPM	-	-	-	-	-	-	-	-		-
Net income	-617	-2,070	-3,641	-4,376	-992	-1,885	-2,694	-4,090	-	-3,796
YoY	-	-	-	-	-	-	-	-		-
Net margin	-	-	-	-	-	-	-	-		-

Quarterly	FY12/19				FY12/20			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	1,611	394	3	830	551	809	972	654
YoY	81.4%	-62.2%	-99.7%	3.3%	-65.8%	105.7%	-	-21.1%
Gross profit	609	-79	33	302	128	202	281	256
YoY	144.0%	-	-90.5%	21.4%	-79.0%	-	738.4%	-15.2%
GPM	37.8%	-	-	36.4%	23.2%	25.0%	28.9%	39.1%
SG&A expenses	1,205	1,340	1,555	1,067	1,090	1,080	1,583	1,620
YoY	25.0%	43.4%	66.5%	7.0%	-9.6%	-19.4%	1.8%	51.8%
SG&A ratio	74.8%	340.4%	-	128.6%	197.6%	133.5%	162.9%	247.5%
Operating profit	-596	-1,419	-1,521	-765	-962	-878	-1,302	-1,364
YoY	-	-	-	-	-	-	-	-
OPM	-	-	-	-	-	-	-	-
Recurring profit	-616	-1,453	-1,573	-735	-991	-892	-1,338	-1,395
YoY	-	-	-	-	-	-	-	-
RPM	-	-	-	-	-	-	-	-
Net income	-617	-1,453	-1,571	-736	-992	-893	-809	-1,396
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	FY12/19				FY12/20			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	1,205	2,545	4,099	5,166	1,090	2,170	3,753	5,373
YoY	25.0%	34.1%	44.8%	34.9%	-9.6%	-14.7%	-8.4%	4.0%
R&D expenses	472	963	1,972	2,442	438	834	1,745	2,267
YoY	13.4%	14.8%	52.5%	33.2%	-7.1%	-13.4%	-11.5%	-7.2%
SG&A expenses excl. R&D	733	1,582	2,127	2,725	651	1,336	2,008	3,107
YoY	33.8%	49.3%	38.3%	36.5%	-11.1%	-15.5%	-5.6%	14.0%

Quarterly	FY12/19				FY12/20			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	1,205	1,340	1,555	1,067	1,090	1,080	1,583	1,620
YoY	25.0%	43.4%	66.5%	7.0%	-9.6%	-19.4%	1.8%	51.8%
R&D expenses	472	491	1,009	470	438	396	911	522
YoY	13.4%	16.2%	122.1%	-13.0%	-7.1%	-19.4%	-9.7%	11.0%
SG&A expenses excl. R&D	733	849	546	597	651	685	672	1,098
YoY	33.8%	66.0%	13.8%	30.6%	-11.1%	-19.3%	23.2%	83.9%

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

Full-year FY12/20 results

- Sales: JPY3.0bn (+5.3% YoY)
- Operating loss: JPY4.5bn (loss of JPY4.3bn in FY12/19)
- Recurring loss: JPY4.6bn (loss of JPY4.4bn in FY12/19)
- Net loss: JPY4.1bn (loss of JPY4.4bn in FY12/19)

Sales increased YoY, as the company booked sales of Treakisym®.

Losses expanded across the board despite higher sales due to an increase in SG&A expenses. SG&A expenses increased 4.0% YoY to JPY5.4bn and R&D expenses declined 7.4% YoY to JPY2.3bn. This included expenses for conducting clinical trials of intravenous formulations of Treakisym® and rigosertib. Excluding R&D expenses, SG&A rose 14.0% YoY to JPY3.1bn. The company incurred development costs for its in-house sales organization. The difference between recurring loss and net loss is attributable to a JPY525mn settlement payment booked as extraordinary income.

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. The company therefore began preparations to build an in-house sales organization for domestic sales of Treakisym®.

In FY12/21, the company has deployed a nationwide network of 53 marketing representatives as well as nine 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.

To establish a nationwide distribution structure, in September 2020, the company concluded a basic agreement with Suzuken Co., Ltd (Suzuken Group) and Toho Pharmaceutical Co., Ltd (a consolidated subsidiary of Toho Holdings Co., Ltd.; Kyoso Mirai Group) for the procurement and sale of pharmaceuticals. SymBio is using Suzuken Group and Kyoso Mirai Group as its sole distributors after the marketing agreement with Eisai expired. 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.

SymBio has thus completed building its in-house sales organization, and transitioned to in-house sales of Treakisym® in December 2020 after expiry of the business alliance agreement with Eisai.

Stable product supply

SymBio imports lyophilized Treakisym® for injection from Astellas Deutschland (consolidated subsidiary of Astellas Pharma). Treakisym® inventories were substantially depleted in 1H relative to year-ago levels, but inventory levels recovered in 2H as secondary packaging and quality tests were applied to some batches of Treakisym® 100mg vials imported from Astellas Deutschland.

In September 2020, the company obtained manufacturing and marketing approval for liquid formulations of Treakisym® (RTD formulation) under license from Eagle Pharmaceuticals with plans to begin sales in January 2021. Import and shipments to the sole distributors of the Treakisym® (RTD formulation) began in Q4 FY12/20 (October–December 2020).

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 and on the NHI drug price list from May 2019. 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 combination with rituximab (BR therapy) targeting relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL), an additional indication following the above approved ones, results showed that the response rate (primary endpoint) was better than expected. Based on this, the company filed for approval for partial revision to manufacturing and marketing approval in May 2020. It is currently conducting 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 combination with rituximab is crucial for establishing Treakisym® as a treatment for DLBCL. 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 made a partial change to its application for approval for Treakisym® in combination with polatuzumab vedotin and rituximab. If the new drug applications by Chugai and SymBio are approved and polatuzumab vedotin is added to the NHI drug price list, Treakisym® can be used with polatuzumab vedotin in combination with 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 RI formulations of Treakisym®. Manufacturing and marketing approval of the RTD formulation was obtained in September 2020, and the company plans to launch it in January 2021. The company is conducting clinical trials to confirm safety of the RI formulation and plans to apply for approval in FY12/21. 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.

After a review at the global advisory board held in February 2020, the company 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. 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. The company is presently in preparation to initiate a dose-finding study of the liquid formulation of BCV in pediatric patients slated to begin in December 2021.

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 April 7, 2021.

SyB P-1501, a post-operative patient-controlled analgesia
Regarding SyB P-1501 licensed by The Medicines Company (marketed as IONSYS in the US), the company initiated an arbitration against The Medicines Company (MDCO), under the rules of the International Chamber of Commerce, seeking damages of USD82mn arising from MDCO's repudiation of the license agreement. SymBio argued that MDCO's failure to provide sufficient assurance to the company regarding the performance of obligations under the license agreement in light of its decision to withdraw from business activities relating to SyB P-1501 in the European and US markets was a material breach of the license agreement. In September 2020, SymBio announced it had received the arbitration judgment and although the Court of Arbitration did not award damages sought by the company, it did order MDCO to pay 50% of legal costs (about USD5mn) sought by the company.

Overseas
The company marketed SyB L-0501 in South Korea, Taiwan, and Singapore, 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.

Full-year company forecast

	FY12/20			FY12/21
(JPYmn)	1H Act.	2H Act.	FY Act.	FY Est.
Sales	1,361	1,626	2,987	9,151
Gross profit	330	537	867	6,957
Gross profit margin	24.2%	33.0%	29.0%	76.0%
SG&A expenses	2,170	3,203	5,373	5,596
SG&A ratio	159.5%	197.0%	179.9%	61.2%
R&D expenses	834	1,433	2,267	2,019
Excluding R&D expenses	1,336	1,770	3,107	3,577
Operating profit	-1,840	-2,666	-4,506	1,361
Operating profit margin	-	-	-	14.9%
Recurring profit	-1,883	-2,733	-4,616	1,350
Recurring profit margin	-	-	-	14.8%
Net income	-1,885	-2,205	-4,090	1,149
Net margin	-	-	-	12.6%

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

Earnings outlook

The company's FY12/21 forecast calls for sales of JPY9.2bn (+206.4% YoY), operating profit of JPY1.4bn (operating loss of JPY4.5bn in FY12/20), recurring profit of JPY1.4bn (recurring loss of JPY4.6bn), and a net profit of JPY1.1bn (net loss of JPY4.1bn).

The company expects increased product sales in Japan due to the move to sell Treakisym® in-house, and to turn profitable at all levels on the back of sales growth.

The company forecasts SG&A expenses of JPY5.6bn (+4.1% YoY) and R&D expenses of JPY2.0bn (-10.9% YoY). It will proceed with development of Treakisym® to treat r/r DLBCL, Treakisym® liquid formulations, and rigosertib, as well as antiviral drug brincidofovir. SG&A expenses excluding R&D expenses are an estimated JPY3.6bn (+15.1% YoY). The company will prepare to establish its in-house sales structure and expand its business overseas so that it can turn profitable in FY12/21 and sustain earnings expansion thereafter.

The main pipeline development plans are as follows.

Treakisym®

- For r/r DLBCL, in May 2020, the company filed partial revisions for the manufacturing and marketing approval for Treakisym®.
- SymBio is preparing to begin sales of the RTD formulation in-licensed from Eagle Pharmaceuticals, which was approved in September 2020, with plans to begin sales in January 2021, and progressing with clinical trials of the RI formulation mainly to confirm safety.

Oral and intravenous rigosertib products

- SymBio is continuing to develop intravenous rigosertib formulation. Onconova, the licensor of anticancer drug rigosertib, announced in August 2020 that its global phase III trial (INSPIRE study) addressing higher-risk myelodysplastic syndromes (higher-risk MDS) intolerant of treatment with hypomethylating agents failed to meet its primary endpoints. SymBio engages in clinical development of rigosertib in Japan, and plans to use the knowledge obtained from genomic analysis of the INSPIRE study in future development of rigosertib.

Antiviral drug brincidofovir

Regarding the intravenous formulation of brincidofovir (BCV IV), after a review at the global advisory board held in February 2020, the company 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. The

company will continue to work with specialist researchers to design international clinical trials for BCV IV and BCV Oral to promote global development of the two formulations.

On February 4, 2021, the company announced a three-year medium-term plan covering FY12/21–FY12/23.

Medium-term plan targets

(JPYmn)	FY12/21 Est.	FY12/22 Target	FY12/23 Target
Sales	9,151	10,985	12,369
YoY	206.4%	20.0%	12.6%
Operating profit	1,361	1,738	2,099
YoY	-	27.7%	20.8%
Operating profit margin	14.9%	15.8%	17.0%
Recurring profit	1,350	1,727	2,088
YoY	-	27.9%	20.9%
Recurring profit margin	14.8%	15.7%	16.9%
Net income	1,149	1,470	1,778
YoY	-	27.9%	21.0%
Net margin	12.6%	13.4%	14.4%

Source: Shared Research based on company data

Targets in medium-term plan (FY12/21–FY12/23)

Sales

SymBio expects product sales of Treakisym® to account for the bulk of sales. Product sales targets reflect the recent pace of market penetration and sales trends, which feed into the company's revised sales growth rates calculated over the medium-term plan period. Sales through FY12/20 were booked based on product shipment sales to the sales distributor, Eisai. From FY12/21 onward, sales will be booked on product shipment sales to pharmaceutical wholesalers from the company's own in-house sales organization.

In estimating sales from FY12/21 onward, SymBio disclosed targets assuming increased product sales of Treakisym® as it expects to gain approval of the drug as a treatment for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in Q2 FY12/21.

SG&A expenses

The company has broken down SG&A expenses into primarily R&D spending and other SG&A expenses.

- ▷ The company calculated R&D expenses based on the latest development plans for its existing pipeline comprising Treakisym®, rigosertib, and brincidofovir, an antiviral drug.
- ▷ The company does not assume any upfront payments for in-licensing drug candidates outside its existing pipeline after brincidofovir, an antiviral drug, although it will continue to evaluate and investigate them.
- ▷ Other SG&A expenses comprise primarily Treakisym® sales and marketing, production and distribution, business development, and management related costs. From FY12/21, SymBio assumes costs associated with operating its own sales organization for sales of Treakisym®. It forecasts an increase primarily in personnel costs due to a higher medical representative headcount and higher costs due to more activities.

Net income

In the previous medium-term plan announced in February 2020, the company forecast net income exceeding recurring profit in FY12/21 and FY20/22 to reflect the reduction in loss carried forward from FY12/21 onward on tax effect accounting. Heeding the advice of accounting auditors, the new medium-term plan was formulated by removing income taxes adjustment factors for FY12/21 onward.

Personnel plans

SymBio completed the formation of its 62-member nationwide sales structure in FY12/20. It plans to allocate the bare minimum of necessary personnel in other parts of the organization and is budgeting for personnel expenses accordingly. The company plans to increase personnel expenses for global expansion of brincidofovir, an antiviral drug, and reflected this in personnel expenses.

Funding plans

Regarding funding plans, the company will work toward strengthening its financial base so that it can respond in a flexible and nimble way to the need for funds according to business developments.

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

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