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On **May 12, 2020**, SymBio Pharmaceuticals Ltd. announced earnings results for Q1 FY12/20.

Cumulative	FY12/19				FY12/20				FY12/20	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	1,611	2,005	2,008	2,838	551				16.2%	3,404
YoY	81.4%	4.0%	-33.8%	-26.0%	-65.8%					20.0%
Gross profit	609	529	563	865	128					
YoY	144.0%	-7.7%	-39.1%	-26.3%	-79.0%					
GPM	37.8%	26.4%	28.0%	30.5%	23.2%					
SG&A expenses	1,205	2,545	4,099	5,166	1,090					
YoY	25.0%	34.1%	44.8%	34.9%	-9.6%					
SG&A ratio	74.8%	126.9%	204.1%	182.1%	197.6%					
Operating profit	-596	-2,015	-3,536	-4,302	-962				-	-5,090
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					-
Recurring profit	-616	-2,069	-3,642	-4,377	-991				-	-5,134
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					-
Net income	-617	-2,070	-3,641	-4,376	-992				-	-4,803
YoY	-	-	-	-	-					-
Net margin	-	-	-	-	-					-

Quarterly	FY12/19				FY12/20			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	1,611	394	3	830	551			
YoY	81.4%	-62.2%	-99.7%	3.3%	-65.8%			
Gross profit	609	-79	33	302	128			
YoY	144.0%	-	-90.5%	21.4%	-79.0%			
GPM	37.8%	-	-	36.4%	23.2%			
SG&A expenses	1,205	1,340	1,555	1,067	1,090			
YoY	25.0%	43.4%	66.5%	7.0%	-9.6%			
SG&A ratio	74.8%	340.4%	-	128.6%	197.6%			
Operating profit	-596	-1,419	-1,521	-765	-962			
YoY	-	-	-	-	-			
OPM	-	-	-	-	-			
Recurring profit	-616	-1,453	-1,573	-735	-991			
YoY	-	-	-	-	-			
RPM	-	-	-	-	-			
Net income	-617	-1,453	-1,571	-736	-992			
YoY	-	-	-	-	-			
Net margin	-	-	-	-	-			

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

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			
YoY	25.0%	34.1%	44.8%	34.9%	-9.6%			
R&D expenses	472	963	1,972	2,442	438			
YoY	13.4%	14.8%	52.5%	33.2%	-7.1%			
SG&A expenses excl. R&D	733	1,582	2,127	2,725	651			
YoY	33.8%	49.3%	38.3%	36.5%	-11.1%			

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			
YoY	25.0%	43.4%	66.5%	7.0%	-9.6%			
R&D expenses	472	491	1,009	470	438			
YoY	13.4%	16.2%	122.1%	-13.0%	-7.1%			
SG&A expenses excl. R&D	733	849	546	597	651			
YoY	33.8%	66.0%	13.8%	30.6%	-11.1%			

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

Q1 FY12/20 results

- Sales: JPY551mn (-65.8% YoY)
- Operating loss: JPY962mn (loss of JPY596mn in Q1 FY12/19)
- Recurring loss: JPY991mn (loss of JPY616mn in Q1 FY12/19)
- Net loss: JPY992mn (loss of JPY617mn in Q1 FY12/19)

Sales fell YoY. The company booked sales of Treakisym®.

SG&A expenses fell 9.6% YoY to JPY1.1bn and R&D expenses declined 7.1% YoY to JPY438mn. This included expenses for conducting clinical trials of intravenous and oral formulations of Treakisym® and rigosertib. Excluding R&D expenses, SG&A expenses fell by 11.1% YoY to JPY651mn. The company incurred development costs for its in-house sales organization.

As a result, operating loss, recurring loss, and net loss widened YoY. The difference between operating loss and recurring loss was accounted for largely by JPY30mn in non-operating expenses: mainly JPY16mn in forex losses and JPY13mn in stock issuance costs.

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 expires in December 2020. The company plans to transition to its in-house sales organization in January 2021. This should facilitate a move into the black from FY12/21 and ongoing profit growth thereafter and lay the groundwork for future business development.

In Q1, the company hired and trained additional Treakisym® sales representatives and regional sales managers who will form the core of its in-house marketing network. This set the stage to complete the nationwide sales structure in 1H FY12/20. SymBio continued building its distribution and logistics capabilities with logistics centers in East and West Japan and in-house infrastructure including a new IT system with ERP.

Substandard products

SymBio imports lyophilized Treakisym® for injection from Astellas Deutschland (consolidated subsidiary of Astellas Pharma). Some batches of Treakisym® 100mg vials imported from Astellas Deutschland for domestic sales in FY12/19 had impurities and appearance defects in a significantly higher percentage than stipulated in the supply agreement. In order to prevent a recurrence of such product quality issues, the company objected to Astellas Deutschland, and demanded steps such as corrective and preventive action (CAPA) processes to fulfil its responsibilities as the supplier. Nonetheless, there was no improvement in Q1, with persistent supply issues. Several batches from Astellas Deutschland had high defect ratios and deliveries were irregular. Sales fell YoY as Treakisym® inventory levels were low compared with Q1 FY12/19.

The problems with defective products and irregular deliveries are likely to persist through the rest of 1H, and SymBio expects sales from shipments to its Treakisym® sales agent, Eisai, to be down YoY. The company is persisting with its efforts to restore Treakisym® inventory levels, reduce defect rates, and stabilize supply through discussions with its supplier.

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 for the indications of untreated low-grade non-Hodgkin's lymphoma and mantle cell lymphoma (marketing approval obtained in December 2016), refractory or relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma (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 edited and 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 (launched in August 2018). 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.

Following on from the above approved indications, the company conducted a phase III clinical study for the fourth indication of relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL), with Treakisym® administered in combination with rituximab (BR therapy). The response rate (primary endpoint) in the test results released in November 2019 was better than expected. In May 2020, the company applied for a partial revision to manufacture and marketing approval.

The company concluded an exclusive licensing agreement in Japan with Eagle Pharmaceuticals (based in New Jersey, US) in September 2017. Following consultations with the PMDA, the company filed for approval of the RTD formulation in September 2019, and plans to launch it in Q1 FY12/21. SymBio launched clinical trials for the RI formulation in November 2018 primarily to confirm safety and completed patient enrollment in March 2020. The company will apply for approval without delay after the end of the clinical trials of the RI formulation and aims to begin sales in 2H FY12/22. 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 extended 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, is currently conducting a global phase III trial and SymBio Pharmaceuticals started the Japan trial in December 2015 (50 patients enrolled as of April 2020). The global phase III trial addresses higher-risk myelodysplastic syndromes (higher-risk MDS), which do not respond to the current standard treatment with hypomethylating agents, which relapse after treatment under the current standard of care, or which are intolerant to hypomethylating agents, and is under way at clinical trial sites in more than 20 countries worldwide. Onconova announced that it had reached its target of enrolling 360 patients worldwide as of March 2020. Onconova said the primary endpoint results would become clear in 2H 2020, and that it planned to announce trial results at an academic conference by the end of the year. Based on these trial results, the company plans to apply for approval in Japan at the same time as in the US and Europe.

Regarding the oral formulation of rigosertib, Onconova completed phase I/II clinical trials 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 oral formulation of rigosertib among Japanese patients, SymBio began phase I clinical trials in Japan in June 2017 and completed patient enrollment in June 2019. After completing the phase I trials, the company will participate in global phase III clinical trials of the drug used in combination with azacitidine as first-line treatment for higher-risk MDS currently planned by Onconova. In December 2019, Onconova announced that it was considering the design of a Phase II/III adaptive trial with untreated higher risk MDS patients based on the data presented at the 61st American Society of Hematology (ASH) Annual Meeting in December 2019.

Antiviral drug for the treatment of infections 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 for the treatment of infections in intravenous and oral forms). The company acquired exclusive global rights to develop, manufacture, and market BCV for all diseases except smallpox.

BCV Oral has demonstrated a strong, broad-spectrum antiviral effect in clinical trials in Europe and the US by Chimerix. The company will design a global clinical trial based on these findings.

The company will initially develop BCV-IV for treatment of viral hemorrhagic cystitis (vHC) occurring after hematopoietic stem cell transplantation for the domestic market, which has high unmet medical needs. It plans to conduct clinical studies and gain approval in Japan first so it can offer it to patients there. It also plans to market BCV IV globally after conducting international joint clinical trials in countries including the US and Europe. As well, the company plans clinical development of BCV IV as an antiviral treatment of infections after kidney transplants, because it is likely to be effective for transplants other than hematopoietic stem cell transplants, including organ transplants. The company looks to expand its business in Europe, the US and Asia (including China), where organ transplant markets are larger than Japan's. It is also looking for partnerships that take advantage of regional characteristics of these target diseases.

SyB P-1501, a post-operative patient-controlled analgesia

Regarding SyB P-1501 licensed by The Medicines Company, the company initiated an arbitration against The Medicines Company, under the rules of the International Chamber of Commerce, seeking damages of USD82mn (approximately JPY9.0bn) arising from The Medicines Company's repudiation of the license agreement. SymBio argued that The Medicine Company's failure to provide sufficient assurance to the company regarding the performance of obligations under on the license agreement in light of its decision to suspend and withdraw from business activities relating to SyB P-1501in the European and US markets was a material breach of the license agreement. On November 30, 2017, the license agreement was terminated as the breach was not corrected within the contract period and development of the product ceased in February 2018. Arbitration proceedings against The Medicines Company are still ongoing. In January, 2020, Swiss company Novartis AG announced that it had acquired The Medicines Company. SymBio expects an arbitration judgment in 1H 2020.

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 producing and unrolling 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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