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On **May 14, 2019**, SymBio Pharmaceuticals Ltd. announced earnings results for Q1 FY12/19

Cumulative	FY12/18				FY12/19				FY12/19	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	888	1,928	3,032	3,836	1,611				38.4%	4,201
YoY	2.1%	8.0%	25.5%	11.4%	81.4%					9.5%
Gross profit	250	573	924	1,173	609					
YoY	4.4%	12.4%	37.0%	13.7%	144.0%					
GPM	28.1%	29.7%	30.5%	30.6%	37.8%					
SG&A expenses	964	1,898	2,832	3,829	1,205					
YoY	26.1%	8.7%	-32.3%	-23.1%	25.0%					
SG&A ratio	108.5%	98.4%	93.4%	99.8%	74.8%					
Operating profit	-715	-1,325	-1,908	-2,656	-596				-	-2,981
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					-
Recurring profit	-749	-1,378	-1,938	-2,749	-616				-	-3,044
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					-
Net income	-760	-1,389	-1,941	-2,753	-617				-	-3,056
YoY	-	-	-	-	-					-
Net margin	-	-	-	-	-					-

Quarterly	FY12/18				FY12/19			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	888	1,040	1,104	803	1,611			
YoY	2.1%	13.5%	75.1%	-21.8%	81.4%			
Gross profit	250	324	351	249	609			
YoY	4.4%	19.5%	113.0%	-30.3%	144.0%			
GPM	28.1%	31.1%	31.8%	31.0%	37.8%			
SG&A expenses	964	934	934	997	1,205			
YoY	26.1%	-4.9%	-61.7%	25.4%	25.0%			
SG&A ratio	108.5%	89.8%	84.6%	124.2%	74.8%			
Operating profit	-715	-610	-583	-749	-596			
YoY	-	-	-	-	-			
OPM	-	-	-	-	-			
Recurring profit	-749	-629	-560	-811	-616			
YoY	-	-	-	-	-			
RPM	-	-	-	-	-			
Net income	-760	-629	-552	-812	-617			
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	FY12/18				FY12/19			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	964	1,898	2,832	3,829	1,205			
YoY	26.1%	8.7%	-32.3%	-23.1%	25.0%			
R&D expenses	416	839	1,293	1,833	472			
YoY	5.3%	-0.1%	-52.3%	-39.3%	13.4%			
SG&A expenses excl. R&D	548	1,059	1,539	1,996	733			
YoY	48.5%	16.9%	4.6%	1.8%	33.8%			

Quarterly	FY12/18				FY12/19			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	964	934	934	997	1,205			
YoY	26.1%	-4.9%	-61.7%	25.4%	25.0%			
R&D expenses	416	423	454	540	472			
YoY	5.3%	-4.9%	-75.7%	76.0%	13.4%			
SG&A expenses excl. R&D	548	511	479	458	733			
YoY	48.5%	-4.8%	-15.2%	-6.4%	33.8%			

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

Q1 FY12/19 results

- ▷ Sales: JPY1.6bn (+81.4% YoY)
- ▷ Operating loss: JPY596mn (loss of JPY715mn in Q1 FY12/18)
- ▷ Recurring loss: JPY616mn (loss of JPY749mn in Q1 FY12/18)
- ▷ Net loss: JPY617mn (loss of JPY760mn in Q1 FY12/18)

Sales rose on domestic product sales of Treakisym®.

SG&A expenses rose 25.0% YoY to JPY1.2bn and R&D expenses increased 13.4% YoY to JP472mn, which included expenses for conducting clinical trials of intravenous and oral formulations of Treakisym® and rigosertib. Excluding the climb in R&D expenses, SG&A expenses increased by 33.8% YoY to JPY733mn.

As a result, operating loss, recurring loss, and net loss shrank YoY.

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. SymBio started to build an in-house sales organization for Treakisym® in the domestic market in October 2018. Key management priority is to move into the black in FY12/21 and ongoing profit growth thereafter. The company is therefore laying the groundwork for a shift to an internal sales organization to drive future business development.

Twenty Treakisym® managers are to form the core of the marketing team in the internal sales organization. The company conducted the necessary recruitment activities as planned by the end of Q1. It also started readying the infrastructure such as logistics, distribution, and information systems.

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 company markets the anticancer agent Treakisym® in Japan through its business partner, Eisai Co., Ltd. (TSE1: 4523) 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).

As a result of additional indications, Treakisym® is steadily increasing its market share in the area of first-line treatment in medical settings by replacing R-CHOP, the conventional standard treatment. 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. Sales of Treakisym® based on the National Health Insurance (NHI) drug price grew steadily by 11.0% YoY.

In addition to the above three approved indications, the company is conducting Phase III clinical trials for the fourth indication of relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) and these are progressing well with an aim to obtain approval. In response to strong medical needs, the company began phase III clinical trials in August 2017, and with the enrollment of the first patient in January 2018, is working on enrolling patients. The company has made steady progress in enrollments following the first patient in January 2018, completing enrollments in April 2019. Going forward, after completing the follow-up period for enrolled cases, it will prepare to file an application for regulatory approval.

In addition to efforts for new indications, in September 2017, the company concluded an exclusive licensing agreement with Eagle Pharmaceuticals (based in New Jersey, US) to develop, market, and sell liquid formulations of Treakisym® (RTD and RI formulations) in Japan for Treakisym®'s product life cycle management. The RTD and RI products offer significant value added

(reduced burden) to patients and healthcare professionals, and liquid formulation patent protection extends Treakisym®'s product life until 2031. The company has already consulted with PMDA and is preparing to file for approval of the RTD formulation. SymBio launched clinical trials for the RI formulation in November 2018 primarily to confirm safety, and finished enrolling the first patient in April 2019.

In July 2018, SymBio obtained approval for the partial revision to the marketing authorization of Treakisym®. As a result, Treakisym® can now be used in combination with not only rituximab but new anti-CD20 antibodies as well. One of these is obinutuzumab (launched in August 2018) for the treatment of CD 20-positive follicular lymphoma (FL), the most common histological type of low-grade NHL, enabling the company to provide patients with a new treatment therapy. In March 2019, the company obtained approval for the partial revision to the marketing authorization allowing the use of Treakisym® as a pretreatment agent in tumor-specific T cell infusion therapy. The first chimeric antigen receptor T-cell (CAR-T) therapy CTL019 (Kymriah® intravenous infusion) was approved for use in Japan in the same month. Once this goes on sale Treakisym® will be able to be used as a pretreatment agent.

To reinforce the position of Treakisym® at the core of its business to strengthen its business foundation, SymBio is developing an oral formulation of the drug in addition to the injection currently under development or on sale. The company commenced a phase I clinical trial for progressive solid tumors in January 2018, with the aim of examining the recommended dosage and schedule as well as tolerability and safety of the oral formulation of Treakisym®, and narrowing down the types of potential target tumors. With the enrollment of the first patient in May 2018, the company is currently working on enrolling more patients for the trial. To evaluate the effect of oral administration of Treakisym® on the immune system, the company concluded a joint research agreement with Keio University in May 2018 and began a preclinical study to verify the efficacy of the oral form of Treakisym® in treating systemic lupus erythematosus (SLE), a form of autoimmune disease.

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 (43 patients enrolled as of May 2019). 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. As of March 2019, the company had reached 75% of its target of enrolling 360 patients worldwide. 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 has completed Phase I/II clinical trials for the drug used in combination with azacytidine as first-line treatment for higher-risk MDS and Phase II clinical trials for transfusion-dependent lower-risk MDS in the US. 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 is making steady progress with the clinical trial after enrolling the first patients in October 2017. After completing the Phase I trials, the company plans to start Phase I clinical trials for rigosertib used in combination with azacytidine, participate in global Phase III clinical trials of the drug used in combination with azacytidine as first-line treatment for higher-risk MDS currently planned by Onconova, and apply for approval of the oral formulation of the drug in Japan at the same time as in the US and Europe. In December 2018, Onconova submitted a Special Protocol Assessment (SPA) request to the US Food and Drug Administration (FDA) to speed up the approval review for the global trials, and expects an outcome of the discussions in 1H 2019. In regards to development of rigosertib for transfusion-dependent lower-risk MDS, the company is considering participating from Japan while monitoring Onconova's development progress.

SyB P-1501, a post-operative patient-controlled analgesia
Regarding SyB P-1501 licensed by the Medicines Company (through its wholly owned subsidiary Incline Therapeutics, Inc.) in October 2015, SymBio found a fact that raised concerns about the continuity of its business, and in the interests of patient welfare, it suspended further patient enrollment in April 2017. The license agreement was terminated in November 2017, and the development of the drug was terminated in February 2018.

The Company initiated an arbitration against The Medicines Company in October 2017, 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. Arbitration proceedings against The Medicines Company are still ongoing.

New drug candidates

From a long-term perspective, SymBio continues to search for and evaluate promising drug candidates, in a bid to acquire global licensing rights for these drugs and grow into a sustainable and profitable biopharmaceutical company with growth potential and profitability. The company is considering licensing rights for several drug candidates. Further, in May 2016, the company established SymBio Pharma USA, Inc., a wholly owned US-based subsidiary, as a strategic base for overseas business development. The company looks to leverage this subsidiary to actively acquire rights over new drug development candidates globally, and engage in development and commercialization in major markets including the US, Japan, and Europe to transition to a global specialty pharmaceutical 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.

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

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Contact Details

Shared Research Inc.
3-31-12 Sendagi Bunkyo-ku Tokyo, Japan
https://sharedresearch.jp
Phone: +81 (0)3 5834-8787
Email: info@sharedresearch.jp