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On **May 10, 2018**, SymBio Pharmaceuticals Ltd. announced earnings results for Q1 FY12/18.

Cumulative	FY12/17				FY12/18				FY12/18	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	870	1,786	2,417	3,444	888				21.1%	4,201
YoY	350.2%	47.5%	71.7%	45.4%	2.1%					22.0%
Gross profit	239	510	675	1,031	250					
YoY	323.0%	26.0%	41.0%	14.1%	4.4%					
GPM	27.5%	28.5%	27.9%	29.9%	28.1%					
SG&A expenses	764	1,746	4,183	4,978	964					
YoY	32.9%	42.5%	108.0%	64.2%	26.1%					
SG&A ratio	87.9%	97.7%	173.1%	144.5%	108.5%					
Operating profit	-525	-1,236	-3,508	-3,947	-715				-	-2,981
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					-
Recurring profit	-583	-1,268	-3,547	-3,977	-749				-	-3,044
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					-
Net income	-583	-1,266	-3,546	-3,978	-760				-	-3,056
YoY	-	-	-	-	-					-
Net margin	-	-	-	-	-					-

Quarterly	FY12/17				FY12/18			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	870	916	631	1,028	888			
YoY	350.2%	-9.9%	220.3%	7.0%	2.1%			
Gross profit	239	271	165	357	250			
YoY	323.0%	-22.2%	123.8%	-16.2%	4.4%			
GPM	27.5%	29.6%	26.1%	34.7%	28.1%			
SG&A expenses	764	982	2,437	795	964			
YoY	32.9%	51.1%	210.1%	-22.1%	26.1%			
SG&A ratio	87.9%	107.1%	386.5%	77.4%	108.5%			
Operating profit	-525	-711	-2,272	-439	-715			
YoY	-	-	-	-	-			
OPM	-	-	-	-	-			
Recurring profit	-583	-685	-2,279	-430	-749			
YoY	-	-	-	-	-			
RPM	-	-	-	-	-			
Net income	-583	-684	-2,280	-432	-760			
YoY	-	-	-	-	-			
Net margin	-	-	-	-	-			

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

Q1 FY12/18 sales totaled JPY888mn (+2.1% YoY) mainly owing to domestic sales of Treakisym®.

Due to the sales increase, gross profit came to JPY250mn (+4.4% YoY). Gross profit margin was 28.1% (+0.6pp).

SG&A expenses rose 26.1% YoY to JPY964mn. R&D expenses increased 5.3% to JPY416mn. There were expenses for clinical trials for intravenous and oral formulations of Treakisym® and rigosertib. SG&A expenses excluding R&D expenses were up 48.4% at JPY548mn.

As a result, operating loss totaled JPY715mn (loss of JPY525mn in Q1 FY12/17). The company also reported a recurring loss of JPY749mn (loss of JPY583mn in Q1 FY12/17) partly due to non-operating expenses of JPY35mn (mainly on forex losses). Net loss was JPY760mn (loss of JPY583mn in Q1 FY12/17).

Domestic

Treakisym® (SyB L-0501/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 refractory or relapsed low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL), untreated low-grade NHL and MCL, and chronic lymphocytic leukemia (CLL).

As a result of additional indications, Treakisym® is steadily increasing its market share in the area of first-line treatment by replacing R-CHOP, the conventional standard treatment, and sales of Treakisym® based on the National Health Insurance (NHI) drug price grew significantly by 32.4% YoY. Product sales to Eisai is also progressing in line with plan.

In addition to the above three approved indications, the company has started Phase III clinical trials for the fourth indication of relapsed or refractory diffuse large B-cell lymphoma (DLBCL, or aggressive NHL) and is currently enrolling patients for the trial with an aim to obtain approval. In response to strong medical needs, the company finished consultation with the Pharmaceuticals and Medical Devices Agency (PMDA) and began phase III clinical trials toward the addition of an indication in August 2017, enrolling the first patient in January 2018.

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 to patients and healthcare professionals, and extend Treakisym®'s product life cycle until 2031. For the RTD formulation, the company completed consultation with PMDA and is preparing for approval. For the RI formulation, it is in the process of preparing for a clinical trial, including consultation with PMDA.

SymBio is exploring further expansion of the Treakisym® business by developing an oral formulation in addition to the injection currently under development or on sale to treat solid tumors and autoimmune diseases. In this context, 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. 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 to conduct 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 (30 patients enrolled so far). The global Phase III trial addresses higher-risk myelodysplastic syndrome (MDS) patients who do not respond to treatment or relapsed after treatment with hypomethylating agents (HMAs), the current standard of care ("Primary HMA Failure") and is under way at clinical trial sites in more than 20 countries worldwide. Patient enrollments are smoothly accumulating. Based on the results of an interim analysis performed in January 2018, SymBio decided to continue the trial, increasing the number of patient enrollment in accordance with a pre-determined statistical criteria. Based on these results, the company plans to apply for approval in Japan at the same time as in the U.S. and Europe.

Regarding the oral formulation of rigosertib, Onconova is conducting 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 U.S. 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 steadily enrolling patients. After completing the Phase I trials, the company plans to promptly start clinical trials for rigosertib used in combination with azacytidine, participate in international Phase III clinical trials of the drug used in combination with azacytidine as first-line treatment for higher-risk MDS Onconova is planning, and apply for approval of the oral formulation of the drug in Japan at the same time as in the U.S. and Europe. 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.

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 Korea, Taiwan, and Singapore, and sales were in line with plans.

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

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