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On **August 3, 2017**, SymBio Pharmaceuticals Ltd. announced earnings results for 1H FY12/17.

Cumulative	FY12/16				FY12/17				FY12/17	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	193	1,211	1,408	2,368	870	1,786			61.5%	2,903
YoY	-52.7%	24.0%	5.6%	22.5%	350.2%	47.5%				22.6%
Gross profit	57	405	478	904	239	510				
YoY	-53.1%	43.2%	21.1%	55.1%	323.0%	26.0%				
GPM	29.2%	33.4%	34.0%	38.2%	27.5%	28.5%				
SG&A expenses	575	1,225	2,011	3,031	764	1,746				
YoY	27.0%	31.6%	45.4%	-3.3%	32.9%	42.5%				
SG&A-to-sales ratio	297.6%	101.2%	142.8%	128.0%	87.9%	97.7%				
Operating profit	-518	-820	-1,532	-2,127	-525	-1,236			-	-3,238
YoY	-	-	-	-	-	-				-
OPM	-	-	-	-	-	-				-
Recurring profit	-655	-1,177	-1,917	-2,317	-583	-1,268			-	-3,303
YoY	-	-	-	-	-	-				-
RPM	-	-	-	-	-	-				-
Net income	-653	-1,175	-1,916	-2,313	-583	-1,266			-	-3,306
YoY	-	-	-	-	-	-				-
Net margin	-	-	-	-	-	-				-

Quarterly	FY12/16				FY12/17			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	193	1,018	197	960	870	916		
YoY	-52.7%	79.2%	-44.7%	59.9%	350.2%	-9.9%		
Gross profit	57	348	74	426	239	271		
YoY	-53.1%	114.8%	-34.6%	126.6%	323.0%	-22.2%		
GPM	29.2%	34.2%	37.4%	44.3%	27.5%	29.6%		
SG&A expenses	575	650	786	1,021	764	982		
YoY	27.0%	36.0%	73.8%	-41.7%	32.9%	51.1%		
SG&A-to-sales ratio	297.6%	63.9%	399.2%	106.2%	87.9%	107.1%		
Operating profit	-518	-302	-712	-595	-525	-711		
YoY	-	-	-	-	-	-		
OPM	-	-	-	-	-	-		
Recurring profit	-655	-522	-740	-400	-583	-685		
YoY	-	-	-	-	-	-		
RPM	-	-	-	-	-	-		
Net income	-653	-523	-741	-397	-583	-684		
YoY	-	-	-	-	-	-		
Net margin	-	-	-	-	-	-		

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

1H FY12/17 sales totaled JPY1.8bn (+47.5% YoY) thanks to sales of Treakisym.

Due to the sales increase, gross profit came to JPY510mn (+26.0% YoY). Gross profit margin was 28.5% (-4.9pp).

SG&A expenses rose 42.5% YoY to JPY1.7bn. R&D expenses increased 62.0% to JPY840mn. There were expenses for clinical trials for the intravenous and oral formulations of Rigosertib Sodium and SyB P-1501. SG&A expenses excluding R&D expenses were up 28.3% at JPY906mn.

As a result, operating loss totaled JPY1.2bn (loss of JPY820mn in 1H FY12/16). The company also reported a recurring loss of JPY1.3bn (loss of JPY1.2bn in 1H FY12/16) partly due to non-operating expenses of JPY34mn (mainly on forex losses of JPY27mn). Net loss was JPY1.3bn (loss of JPY1.2bn in 1H FY12/16).

Progress made in 1H FY12/17 is as follows.

Domestic

Treakisym (SyB L-0501; 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).

In 1H FY12/17, sales of Treakisym based on the National Health Insurance (NHI) drug price grew 42.9% YoY, and accordingly product sales to Eisai increased 44.6%.

In addition to the above three approved indications, the company has filed an NDA for a fourth indication to help patients who need new treatments and maximize the value of the product. The company has completed phase III clinical trials for relapsed or refractory diffuse large B-cell lymphoma (DLBCL, or aggressive NHL). In response to strong medical needs, the company has finished consultation with the Pharmaceuticals and Medical Devices Agency and is preparing for phase III clinical trials toward the addition of an indication.

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.

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. 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 ten countries worldwide. The company completed the first patient enrollment in July 2016 and enrollments are smoothly accumulating.

SymBio started domestic Phase I clinical trials for the oral form of Rigosertib Sodium (used in combination with azacitidine) for higher-risk myelodysplastic syndrome (MDS) in December 2015. Due to delays in the supply of drugs for the joint trials, however, patient enrollment did not make progress. Since Onconova resumed the supply of clinical trial materials, SymBio initiated a phase I clinical trial in Japan. The purpose of the Japanese phase I study is to confirm the safety of high-dose oral rigosertib, which was added to the ongoing US phase II study by Onconova in untreated or relapsed/refractory patients with higher-risk MDS. After demonstrating the safety of high-dose oral rigosertib, SymBio intends to immediately recommence an oral rigosertib/azacytidine combination trial in Japan, and participate in the global phase III study in untreated higher-risk MDS patients that Onconova is planning.

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

The company started a domestic phase III clinical trial for SyB P-1501—licensed by the Medicines Company (through its wholly owned subsidiary Incline Therapeutics)—for the short-term management of acute post-operative pain during hospitalization in June 2016. The company enrolled the first patient in November 2016 and was making progress with case accumulation. However, SymBio later found a fact that raises concerns about the continuity of The Medicines Company's SyB P-1501 business. In the interests of patient welfare, SymBio has suspended further patient enrollment since April 2017.

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. At present, talks are underway regarding 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 Treakisym in Korea, Taiwan, and Singapore, and overseas sales were steady.

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

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