SymBio Pharmaceuticals | 4582 |

On **August 4, 2016**, SymBio Pharmaceuticals announced earnings results for Q2 FY12/16.

Quarterly performance (cumulative)	FY12/15				FY12/16				FY12/16	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	408	976	1,332	1,933	193	1,211			51.8%	2,339
YoY	135.0%	0.1%	-1.2%	-1.1%	-52.7%	24.0%				21.0%
Gross profit	120	283	395	583	57	405				
YoY	272.1%	14.3%	11.8%	10.7%	-53.1%	43.2%				
GPM	29.5%	28.9%	29.7%	30.2%	29.2%	33.4%				
SG&A expenses	453	931	1,383	3,135	575	1,225				
YoY	1.1%	4.2%	4.7%	71.3%	27.0%	31.6%				
SG&A / sales	110.9%	95.3%	103.8%	162.1%	297.6%	101.2%				
Operating profit	-332	-648	-988	-2,552	-518	-820			-	-2,778
YoY	-	-	-	-	-	-				-
OPM	-	-	-	-	-	-				-
Recurring profit	-419	-674	-1,056	-2,630	-655	-1,177			-	-2,811
YoY	-	-	-	-	-	-				-
RPM	-	-	-	-	-	-				-
Net income	-420	-676	-1,059	-2,632	-653	-1,175			-	-2,815
YoY	-	-	-	-	-	-				-
Net margin	-	-	-	-	-	-				-

Quarterly performance	FY12/15				FY12/16			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	408	568	356	601	193	1,018		
YoY	135.0%	-29.2%	-4.5%	-1.0%	-52.7%	79.2%		
Gross profit	120	162	113	188	57	348		
YoY	272.1%	-24.5%	5.8%	8.5%	-53.1%	114.8%		
GPM	29.5%	28.6%	31.6%	31.3%	29.2%	34.2%		
SG&A expenses	453	478	452	1,752	575	650		
YoY	1.1%	7.3%	6.0%	243.7%	27.0%	36.0%		
SG&A / sales	110.9%	84.1%	127.0%	291.6%	297.6%	63.9%		
Operating profit	-332	-316	-340	-1,564	-518	-302		
YoY	-	-	-	-	-	-		
OPM	-	-	-	-	-	-		
Recurring profit	-419	-255	-382	-1,574	-655	-522		
YoY	-	-	-	-	-	-		
RPM	-	-	-	-	-	-		
Net income	-420	-256	-383	-1,573	-653	-523		
YoY	-	-	-	-	-	-		
Net margin	-	-	-	-	-	-		

Source: Shared Research based on company data.

Note: Figures may differ from company materials due to differences in rounding methods.

1H FY12/16 results

1H FY12/16 sales totaled JPY1.2bn (+24.0% YoY) thanks to domestic sales of Treakisym.

Product sales were up 20.9% YoY. Further, the company booked royalty revenue from a milestone payment on the sales of SyB L-0501 in Taiwan.

SG&A expenses rose 31.6% YoY to JPY1.2bn. R&D expenses rose to JPY518mn (+28.4% YoY) on expenses for clinical trials for the intravenous and oral versions of rigosertib and expenses related to preparations for clinical trials for SyB P-1501.

SG&A expenses excluding R&D expenses were up 34.1% at JPY706mn on expenses for the introduction of new development candidates and expenses for acquisition of companies that own the rights to new drug candidates.

As a result, operating loss totaled JPY820mn (loss of JPY648mn in 1H FY12/15). The company also reported a recurring loss of JPY1.2bn (loss of JPY674mn last year) due to non-operating expenses of JPY360mn (mainly on forex losses of JPY330mn). Net loss was JPY1.2bn (loss of JPY676mn).

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). In 1H, product sales to Eisai were largely in line with plan.

In Japan, the company submitted a new drug application (NDA) to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) in December 2015 for a first-line treatment of low-grade NHL and MCL. Meanwhile, in Europe, though the company received notification on January 2016 from Astellas Pharma that its application had been withdrawn, it plans to continue with the domestic approval process upon consulting with the PMDA.

Regarding chronic lymphocytic leukemia (CLL), the company filed an NDA in December 2015. In June 2016, the PMDA held a discussion of experts. The company continues to look for quick approval as the process proceeds. Treakisym was designated as an orphan drug (drug for the treatment of rare diseases) for CLL in June 2012, and the Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Need has also submitted a development request to the company.

SymBio is still considering applying for approval for use of the drug for relapsed or refractory aggressive NHL.

Rigosertib (SyB L-1101 [IV]/SyB C-1101 [oral]; anticancer agent)

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 has taken steps to register patients, and completed the first patient enrollment in July 2016, after the close of 1H FY12/16.

SymBio started domestic Phase I clinical trials for the oral (IV) form of rigosertib (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, patient enrollment has not started as of August 4, 2016. The company is looking to start patient registration upon resolution of this issue, and complete joint trials in line with its plans. SymBio is considering participating in the global clinical trial to be conducted by Onconova.

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 is looking to complete the Phase III clinical trial quickly, and obtain regulatory approval in 2019.

New drug candidates

From a long-term perspective, SymBio will continue to search for and evaluate promising drug candidates, and acquire global rights for these drugs to become a sustainable and profitable pharmaceutical company with growth potential and profitability. 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 accelerate the process of turning into a global specialty pharmaceutical company.

Overseas

The company marketed Treakisym in Korea, Taiwan, and Singapore, and saw overseas sales progress largely in line with plans in Q1 because shipments to overseas clients are planned from Q2 and after.

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

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