SymBio Pharmaceuticals | 4582 |

On **May 10, 2016**, SymBio Pharmaceuticals announced earnings results for Q1 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				8.3%	2,339
YoY	135.0%	0.1%	-1.2%	-1.1%	-52.7%					21.0%
Gross profit	120	283	395	583	57					
YoY	272.1%	14.3%	11.8%	10.7%	-53.1%					
GPM	29.5%	28.9%	29.7%	30.2%	29.2%					
SG&A expenses	453	931	1,383	3,135	575					
YoY	1.1%	4.2%	4.7%	71.3%	27.0%					
SG&A / sales	110.9%	95.3%	103.8%	162.1%	297.6%					
Operating profit	-332	-648	-988	-2,552	-518					-2,778
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					-
Recurring profit	-419	-674	-1,056	-2,630	-655					-2,811
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					-
Net income	-420	-676	-1,059	-2,632	-653					-2,815
YoY	-	-	-	-	-					-
NPM	-	-	-	-	-					-

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

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

Q1 FY12/16 sales totaled JPY193mn (-52.7% YoY) due to domestic and overseas sales of SyB L-0501 (Treakisym).

Treakisym domestic sales declined, as shipments to Eisai Co., Ltd. (TSE1: 4523) are expected to be focused in Q2 and sales of overseas products are planned from Q2.

SG&A expenses rose 27.0% YoY to JPY575mn. R&D expenses rose to JPY224mn (+8.4%) on expenses for clinical trials in Japan that are part of global Phase III trials for the intravenous version of rigosertib; expenses for domestic phase I trials for the oral version of rigosertib for use in combination with azacitidine; and expenses related to preparations for domestic Phase III trials for SyB P-1501.

As a result, operating loss totaled JPY518mn (versus a loss of JPY332mn the preceding year). The company also reported a recurring loss of JPY655mn (JPY419mn loss) due to non-operating expenses of JPY139mn (mainly on forex losses of JP134mn). Net loss was JPY653mn (loss of JPY420mn in the previous year).

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 Q1, 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 and is looking 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 is currently preparing to begin patient enrollment.

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, and was preparing to begin patient enrollment. The company is looking to quickly complete joint trials, and is considering participating in the global clinical trial to be conducted by Onconova.

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

In October 2015 SymBio reached an in-licensing agreement with The Medicines Company (through its wholly owned subsidiary Incline Therapeutics) for the development and commercialization of SyB P-1501, a post-operative patient-controlled analgesia known as IONSYS in the US. SymBio acquired exclusive development and marketing rights for Japan. Preparations are under way for domestic phase III clinical trials.

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 ensure its long-term growth and become a sustainable and profitable pharmaceutical company.

Overseas

The company marketed Treakisym in Korea, Taiwan, and Singapore, but did not book sales for 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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