SymBio Pharmaceuticals | 4582 |

On **November 11**, SymBio Pharmaceuticals announced earnings results for Q3 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	1,408		60.2%	2,339
YoY	135.0%	0.1%	-1.2%	-1.1%	-52.7%	24.0%	5.6%			21.0%
Gross profit	120	283	395	583	57	405	478			
YoY	272.1%	14.3%	11.8%	10.7%	-53.1%	43.2%	21.1%			
GPM	29.5%	28.9%	29.7%	30.2%	29.2%	33.4%	34.0%			
SG&A expenses	453	931	1,383	3,135	575	1,225	2,011			
YoY	1.1%	4.2%	4.7%	71.3%	27.0%	31.6%	45.4%			
SG&A-to-sales ratio	110.9%	95.3%	103.8%	162.1%	297.6%	101.2%	142.8%			
Operating profit	-332	-648	-988	-2,552	-518	-820	-1,532		-	-2,778
YoY	-	-	-	-	-	-	-			-
OPM	-	-	-	-	-	-	-			-
Recurring profit	-419	-674	-1,056	-2,630	-655	-1,177	-1,917		-	-2,811
YoY	-	-	-	-	-	-	-			-
RPM	-	-	-	-	-	-	-			-
Net income	-420	-676	-1,059	-2,632	-653	-1,175	-1,916		-	-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	197	
YoY	135.0%	-29.2%	-4.5%	-1.0%	-52.7%	79.2%	-44.7%	
Gross profit	120	162	113	188	57	348	74	
YoY	272.1%	-24.5%	5.8%	8.5%	-53.1%	114.8%	-34.6%	
GPM	29.5%	28.6%	31.6%	31.3%	29.2%	34.2%	37.4%	
SG&A expenses	453	478	452	1,752	575	650	786	
YoY	1.1%	7.3%	6.0%	243.7%	27.0%	36.0%	73.8%	
SG&A-to-sales ratio	110.9%	84.1%	127.0%	291.6%	297.6%	63.9%	399.2%	
Operating profit	-332	-316	-340	-1,564	-518	-302	-712	
YoY	-	-	-	-	-	-	-	
OPM	-	-	-	-	-	-	-	
Recurring profit	-419	-255	-382	-1,574	-655	-522	-740	
YoY	-	-	-	-	-	-	-	
RPM	-	-	-	-	-	-	-	
Net income	-420	-256	-383	-1,573	-653	-523	-741	
YoY	-	-	-	-	-	-	-	
Net margin	-	-	-	-	-	-	-	

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

Q3 FY12/16 sales totaled JPY1.4bn (+5.6% YoY) thanks to domestic sales of Treakisym. Product sales through Eisai were largely in line with forecasts, and products sales rose 3.3%. It also booked a non-recurring revenue resulting from achieving the sales milestone of SyB L-0501 in Taiwan.

SG&A expenses rose 45.4% YoY to JPY2.0bn. R&D expenses rose to JPY981mn (+64.1% YoY) primarily due to expenses associated with obtaining the approval for the additional indications of TREAKISYM®, the clinical trial for the intravenous and oral formulations of Rigosertib Sodium, and preparations for the clinical trial of SyB P-1501. SG&A expenses excluding R&D expenses were up 31.2% at JPY1.0bn 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 JPY1.5bn (loss of JPY988mn in Q3 FY12/15). The company also reported a recurring loss of JPY1.9bn (loss of JPY1.1bn last year) due to non-operating expenses of JPY391mn (mainly on forex losses of JPY356mn). Net loss was JPY1.9bn (loss of JPY1.1bn).

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 Q3, 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 obtained approval for the additional indication in August 2016. The company developed and applied for this indication upon request of the Ministry of Health, Labour and Welfare in Japan as one of the "Unapproved or Off-Labeled Drugs with High Medical Needs." This is the second approval after the approval of an sNDA for the indication of refractory/relapsed low-grade NHL and mantle cell lymphoma which the company has already received in October 2010.

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

Regarding these agents, for which a licensing agreement was entered into in July 2011, the company changed their generic name from "Rigosertib" to "Rigosertib Sodium" in accordance with the notice of decision on its Japanese Accepted Names for Pharmaceuticals (JAN) received in October 2016. 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. Enrollments are currently accumulating.

SymBio started domestic Phase I clinical trials for the oral (IV) 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, patient enrollment has not started as of November 11, 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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