SymBio Pharmaceuticals | 4582 |

On**February 9 2017**, SymBio Pharmaceuticals announced earnings results for full-year FY12/16.

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	2,368	101.2%	2,339
YoY	135.0%	0.1%	-1.2%	-1.1%	-52.7%	24.0%	5.6%	22.5%		21.0%
Gross profit	120	283	395	583	57	405	478	904		
YoY	272.1%	14.3%	11.8%	10.7%	-53.1%	43.2%	21.1%	55.1%		
GPM	29.5%	28.9%	29.7%	30.2%	29.2%	33.4%	34.0%	38.2%		
SG&A expenses	453	931	1,383	3,135	575	1,225	2,011	3,031		
YoY	1.1%	4.2%	4.7%	71.3%	27.0%	31.6%	45.4%	-3.3%		
SG&A-to-sales ratio	110.9%	95.3%	103.8%	162.1%	297.6%	101.2%	142.8%	128.0%		
Operating profit	-332	-648	-988	-2,552	-518	-820	-1,532	-2,127	-	-2,778
YoY	-	-	-	-	-	-	-	-		-
OPM	-	-	-	-	-	-	-	-		-
Recurring profit	-419	-674	-1,056	-2,630	-655	-1,177	-1,917	-2,317	-	-2,811
YoY	-	-	-	-	-	-	-	-		-
RPM	-	-	-	-	-	-	-	-		-
Net income	-420	-676	-1,059	-2,632	-653	-1,175	-1,916	-2,313	-	-2,815
YoY	-	-	-	-	-	-	-	-		-
Net margin	-	-	-	-	-	-	-	-		-

Quarterly	FY12/15				FY12/16			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	408	568	356	601	193	1,018	197	960
YoY	135.0%	-29.2%	-4.5%	-1.0%	-52.7%	79.2%	-44.7%	59.9%
Gross profit	120	162	113	188	57	348	74	426
YoY	272.1%	-24.5%	5.8%	8.5%	-53.1%	114.8%	-34.6%	126.6%
GPM	29.5%	28.6%	31.6%	31.3%	29.2%	34.2%	37.4%	44.3%
SG&A expenses	453	478	452	1,752	575	650	786	1,021
YoY	1.1%	7.3%	6.0%	243.7%	27.0%	36.0%	73.8%	-41.7%
SG&A-to-sales ratio	110.9%	84.1%	127.0%	291.6%	297.6%	63.9%	399.2%	106.2%
Operating profit	-332	-316	-340	-1,564	-518	-302	-712	-595
YoY	-	-	-	-	-	-	-	-
OPM	-	-	-	-	-	-	-	-
Recurring profit	-419	-255	-382	-1,574	-655	-522	-740	-400
YoY	-	-	-	-	-	-	-	-
RPM	-	-	-	-	-	-	-	-
Net income	-420	-256	-383	-1,573	-653	-523	-741	-397
YoY	-	-	-	-	-	-	-	-
Net margin	-	-	-	-	-	-	-	-

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

FY12/16 sales totaled JPY2.4bn (+22.5% YoY) thanks to domestic sales of Treakisym. Products sales rose 10.6%. It also booked a non-recurring revenue resulting from achieving the sales milestone of SyB L-0501 in Taiwan.

SG&A expenses fell 3.3% YoY to JPY3.0bn. R&D expenses fell to JPY1.7bn (-18.1% YoY). There were expenses for clinical trials for TREAKISYM®, the intravenous and oral formulations of Rigosertib Sodium, and SyB P-1501. SG&A expenses excluding R&D expenses were up 24.0% at JPY1.4bn.

As a result, operating loss totaled JPY2.1bn (loss of JPY2.6bn in FY12/15). The company also reported a recurring loss of JPY2.3bn (loss of JPY2.6bn last year) partly due to non-operating expenses of JPY196mn (mainly on forex losses of JPY159mn). Net loss was JPY2.3bn (loss of JPY2.6bn).

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). Though product sales based on the National Health Insurance (NHI) drug price declined slightly to 99.2% of the previous year's result, product sales to Eisai were largely in line with plan.

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.

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 and obtained approval for the additional indication in December 2016. Meanwhile, in Europe, though the company received notification on January 2016 from Astellas Pharma that its application had been withdrawn, it continued with the domestic approval process upon consulting with the PMDA, resulting in the approval of the additional indication.

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 overseas sales were steady.

Full-year company forecasts

FY12/16 Forecasts (JPYmn)	FY12/16 FY Act.	FY12/17 FY Est.
Sales	**2,368**	**2,903**
CoGS	1,464	
Gross profit	**904**	
GPM	38.2%	
SG&A expenses	3,031	
SG&A-to-sales ratio	128.0%	
R&D expenses	1,667	
Operating profit	**-2,127**	**-3,238**
OPM	-	-
Recurring profit	**-2,317**	**-3,303**
RPM	-	-
Net Income	**-2,313**	**-3,306**
Net margin	-	-

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

Earnings outlook

Sales are expected to reach JPY2.9bn (+22.6% YoY), attributable to higher sales from Treakisym.

R&D expense is expected to total JPY2.3bn (up from JPY1.7bn in FY12/16), while total SG&A expense–including R&D–is projected to reach JPY4.1bn (up from JPY3.0bn).

R&D spending is slated to increase with the development for approvals of the manufacture and sale of 1) intravenous and oral rigosertib and 2) SyB P-1501. The company will consider expanding indications of Treakisym. In a bid to boost its enterprise value for the long term, SymBio plans to consider introducing candidates for newly developed drug products and enhancing the overall value of its pipeline.

As a result, SymBio forecasts an operating loss of JPY3.2bn (operating loss of JPY2.1bn in FY12/16), a recurring loss of JPY3.3bn (recurring loss of JPY2.3bn in FY12/16), and a net loss of JPY3.3bn (net loss of JPY2.3bn in FY12/16).

Pipeline

Treakisym

The company has finished the phase II trial for relapsed or refractory moderate to high-grade non-Hodgkin lymphoma (NHL) and continues considering expansion of indications.

Intravenous and oral rigosertib

The company is moving ahead with the accumulation of cases in Japan in the global phase III trial for the intravenous version of rigosertib Similarly, SymBio aims to quickly start initial patient enrollment by resuming the domestic phase I trial of the oral version of rigosertib for use in combination with azacitidine. Regarding development with low-risk MDS as the target efficacy, SymBio will consider it while watching development progress at Onconova Therapeutics.

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

SymBio reached an in-licensing agreement for SyB P-1501 in FY12/15. The company plans to register as many cases as possible to finish its domestic phase III clinical trial.

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

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