SymBio Pharmaceuticals | 4582 |

On **November 6, 2015**, SymBio Pharmaceuticals announced earnings results for Q3 FY12/15.

Quarterly Performance (cumulative)	FY12/14				FY12/15				FY12/15	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	174	975	1,348	1,955	408	976	1,332		71.3%	1,870
YoY	-64.5%	20.3%	1.9%	27.6%	135.0%	0.1%	-1.2%			122.1%
Gross profit	32	247	353	527	120	283	395			
YoY	-78.6%	34.1%	29.4%	65.6%	272.1%	14.3%	11.8%			
GPM	18.6%	25.3%	26.2%	26.9%	29.5%	28.9%	29.7%			
SG&A expenses	448	893	1,320	1,830	453	931	1,383			
YoY	-9.0%	-9.9%	-10.0%	-8.4%	1.1%	4.2%	4.7%			
SG&A / sales	257.9%	91.6%	97.9%	93.6%	110.9%	95.3%	103.8%			
Operating profit	-416	-646	-967	-1,303	-332	-648	-988			-2,452
YoY	-	-	-	-	-	-	-			-
OPM	-	-	-	-	-	-	-			-
Recurring profit	-454	-713	-941	-1,110	-419	-674	-1,056			-2,481
YoY	-	-	-	-	-	-	-			-
RPM	-	-	-	-	-	-	-			-
Net income	-455	-715	-944	-1,116	-420	-676	-1,059			-2,485
YoY	-	-	-	-	-	-	-			-
NPM	-	-	-	-	-	-	-			-

Quarterly Performance	FY12/14				FY12/15			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	174	802	373	607	408	568	356	
YoY	-64.5%	149.1%	-27.3%	191.0%	135.0%	-29.2%	-4.5%	
Gross profit	32	215	106	173	120	162	113	
YoY	-78.6%	543.6%	19.8%	286.1%	272.1%	-24.5%	5.8%	
GPM	18.6%	26.8%	28.5%	28.5%	29.5%	28.6%	31.6%	
SG&A expenses	448	445	427	510	453	478	452	
YoY	-9.0%	-10.8%	-10.1%	-4.3%	1.1%	7.3%	6.0%	
SG&A / sales	257.9%	55.6%	114.5%	84.0%	110.9%	84.1%	127.0%	
Operating profit	-416	-231	-320	-337	-332	-316	-340	
YoY	-	-	-	-	-	-	-	
OPM	-	-	-	-	-	-	-	
Recurring profit	-454	-259	-228	-170	-419	-255	-382	
YoY	-	-	-	-	-	-	-	
RPM	-	-	-	-	-	-	-	
Net income	-455	-261	-228	-172	-420	-256	-383	
YoY	-	-	-	-	-	-	-	
NPM	-	-	-	-	-	-	-	

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

Sales for Q3 FY12/15 totaled JPY1.3bn (-1.2% YoY) due to domestic and overseas sales of SyB L-0501 (Treakisym).

Overall Treakisym sales fell 1.2% YoY. Though domestic sales of Treakisym increased 6.1% YoY, overseas sales declined due to shipments having been frontloaded in FY12/14.

SG&A expenses came to JPY1.4bn (+4.7% YoY), including research and development expenses worth JPY598mn (+9.7%). These expenses mainly covered clinical trials for additional SyB L-0501 indications and costs pertaining to preparing the New Drug Application (NDA) for submission, as well as clinical trials for SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation), and preparation for the next phase of clinical trials. Other SG&A expenses came to JPY785mn (+1.3%).

As a result, operating loss totaled JPY988mn (Q3 FY12/14: loss of JPY967mn). The company also reported a recurring loss of JPY1.1bn (Q3 FY12/14: loss of JPY941mn), owing to non-operating expenses of JPY82mn, mainly from forex losses of JPY74mn. Net loss totaled JPY1.1bn (Q3 FY12/14: loss of JPY944mn)

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). Sales through Eisai increased as expected.

SymBio completed the phase II clinical trial of Treakisym for the first-line treatment of low-grade NHL and MCL in February 2014.. Along with the regulatory approval process for the application submitted by Astellas Pharma Europe Ltd. (a European subsidiary of Astellas Pharma Inc.; TSE1: 4503) in the European Union, the company is also continuing to prepare the New Drug Application (NDA) for submission in Japan, having entered preliminary consultations with the Pharmaceuticals and Medical Devices Agency (PMDA).

The company completed patient enrollment for a phase II clinical trial for chronic lymphocytic leukemia (CLL) in October 2014, and completed the trial in October 2015. It plans to file a Supplemental New Drug Application (sNDA) for marketing approval in Q1 FY12/16.. 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)
The company is conducting a domestic phase I clinical trial for the intravenous (IV) form of rigosertib in relapsed or refractory higher-risk myelodysplastic syndromes (MDS), a hematological malignancy. Patient enrollment was completed in January 2015, and tests were completed in October 2015.

Onconova Therapeutics, Inc., the U.S. licensor, is currently conducting a global Phase III trial for higher risk MDS patients who do not respond to treatment with hypomethylating agents (HMAs), the current standard of care ("Primary HMA Failure"), at clinical trial sites in more than ten countries worldwide. Following its completion of the domestic Phase I clinical trial, SymBio also decided to participate in the global clinical trial in October 2015.

As for SyB C-1101 (oral formulation, or Oral rigosertib), the company's domestic Phase I clinical trial for the target indication of higher risk MDS was completed in June, 2015. The company plans to continue clinical trials for the development of Oral rigosertib in combination with azacitidine for higher risk MDS, as well as for lower risk transfusiondependent MDS, and is considering participating in the global clinical trial to be conducted by Onconova.

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

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