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SymBio Pharmaceuticals (4582)

On **May 7, 2015**, SymBio Pharmaceuticals announced earnings results for Q1 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				21.8%	1,870
YoY	-64.5%	20.3%	1.9%	27.6%	135.0%					122.1%
Gross profit	32	247	353	527	120					
YoY	-78.6%	34.1%	29.4%	65.6%	272.1%					
GPM	18.6%	25.3%	26.2%	26.9%	29.5%					
SG&A expenses	448	893	1,320	1,830	453					
YoY	-9.0%	-9.9%	-10.0%	-8.4%	1.1%					
SG&A / sales	257.9%	91.6%	97.9%	93.6%	110.9%					
Operating profit	-416	-646	-967	-1,303	-332					-2,452
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					-
Recurring profit	-454	-713	-941	-1,110	-419					-2,481
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					-
Net income	-455	-715	-944	-1,116	-420					-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			
YoY	-64.5%	149.1%	-27.3%	191.0%	135.0%			
Gross profit	32	215	106	173	120			
YoY	-78.6%	543.6%	19.8%	286.1%	272.1%			
GPM	18.6%	26.8%	28.5%	28.5%	29.5%			
SG&A expenses	448	445	427	510	453			
YoY	-9.0%	-10.8%	-10.1%	-4.3%	1.1%			
SG&A / sales	257.9%	55.6%	114.5%	84.0%	110.9%			
Operating profit	-416	-231	-320	-337	-332			
YoY	-	-	-	-	-			
OPM	-	-	-	-	-			
Recurring profit	-454	-259	-228	-170	-419			
YoY	-	-	-	-	-			
RPM	-	-	-	-	-			
Net income	-455	-261	-228	-172	-420			
YoY	-	-	-	-	-			
NPM	-	-	-	-	-			

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

Source: Company data

Sales for Q1 FY12/15 totaled JPY408mn (+135.0% YoY) due to domestic and overseas shipments of Treakisym.

Domestic sales of Treakisym were up 2.1x YoY, owing to a favorable year-on-year comparison, as last year the company faced adjustments to distribution inventory.

SG&A expenses were JPY453mn (+1.1% YoY), including R&D expenses of JPY206mn (+15.2% YoY) owing to clinical trial expenses for Treakisym and the oral and IV forms of rigosertib. Other SG&A expenses totaled JPY247mn (-8.3% YoY).

As a result, operating loss totaled JPY332mn (Q1 FY12/14: loss of JPY416mn). The company also reported

a recurring loss of JPY419mn (Q1 FY12/14: loss of JPY454mn), owing to non-operating expenses of JPY91mn, mainly from forex losses of JPY89mn. Net loss totaled JPY420mn (Q1 FY12/14: loss of JPY455mn).

Domestic

Treakisym (SyB L-0501; anticancer agent; generic name: bendamustine hydrochloride)

SymBio completed the phrase II clinical trial of Treakisym for the first-line treatment of low-grade NHL and MCL in February 2014. The company is analyzing and evaluating data from the trial as it prepares to file a supplemental new drug application (sNDA) for marketing approval. The company plans to build on Astellas Pharma GmbH ("Astellas"; European subsidiary of Astellas Pharma Inc.; TSE1: 4503)'s ongoing application for approval in Europe as it files a domestic sNDA.

The company completed patient enrollment for a phase II clinical trial for CLL in October 2014. It plans to complete the trial and file an sNDA for marketing approval as soon as possible. Treakisym was designated as an orphan drug (drug for the treatment of rare diseases) for CLL in June 2012.

The company 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). Patient enrollment was completed in January 2015.

In February 2014, licensor Onconova Therapeutics, Inc. ("Onconova"; Nasdaq: ONTX) announced the results of its phase III ONTIME clinical trial in patients with higher-risk MDS. Compared with best supportive care (BSC), the clinical trial did not show a statistically significant improvement in the overall survival period (primary outcome measures). However, group analysis showed a statistically significant difference in the survival period for patients whose condition had deteriorated or those who had not responded to previous treatment using hypomethylating agents (HMAs).

Onconova held discussions with regulatory agencies in the US and Europe regarding the possibility of seeking approval based on the results of the phase III trial. The regulators have confirmed that patients who had not responded to HMAs would require a new treatment. In response, the company announced that it would develop the new treatment. SymBio will continue with procedures to complete the current phase I clinical trials in Japan. Post-phase I development in Japan will depend on the development in the US and Europe.

A domestic phase I clinical trial using the oral form of rigosertib is also underway in Japan for the treatment of high-risk MDS patients. The patient enrollment for the trial was completed in August 2014, and the company worked toward the end of the clinical trials. It plans to complete the trials as soon as possible and continuing developing the drug for the indications of high-risk MDS (in combination with azacitidine) and blood transfusion-dependent low-risk MDS.

Overseas

The company marketed Treakisym in Korea, Taiwan, and Singapore. Product sales were mostly in line with targets.

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

Shared Research Inc.

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