SymBio Pharmaceuticals (4582)

On **February 10, 2015**, SymBio Pharmaceuticals announced full-year FY12/14 results and a medium-term management plan.

Quarterly Performance	FY12/13				FY12/14				FY12/14	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	489	322	513	209	174	802	373	607	98.2%	1,990
YoY	-15.8%	-32.0%	10.5%	-52.3%	-64.5%	149.1%	-27.3%	191.0%		29.9%
GP	151	33	89	45	32	215	106	173		
YoY	17.6%	-75.7%	-59.5%	-58.5%	-78.6%	543.6%	19.8%	286.1%		
GPM	30.9%	10.4%	17.3%	21.5%	18.6%	26.8%	28.5%	28.5%		
SG&A	492	500	475	532	448	445	427	510		
YoY	-19.2%	-5.9%	-18.7%	-6.5%	-9.0%	-10.8%	-10.1%	-4.3%		
SG&A / Sales	100.6%	155.2%	92.6%	255.3%	257.9%	55.6%	114.5%	84.0%		
OP	-341	-466	-386	-488	-416	-231	-320	-337		-1,311
YoY	-	-	-	-	-	-	-	-		-
OPM	-	-	-	-	-	-	-	-		-
RP	-352	-460	-376	-414	-454	-259	-228	-170		-1,308
YoY	-	-	-	-	-	-	-	-		-
RPM	-	-	-	-	-	-	-	-		-
NI	-353	-461	-377	-414	-455	-261	-228	-172		-1,311
YoY	-	-	-	-	-	-	-	-		-
NPM	-	-	-	-	-	-	-	-		-

Figures may differ from company materials due to differences in rounding methods
Source: Company data

Sales for FY12/14 totaled JPY2.0bn (+27.6% YoY) due to domestic and overseas shipments of SyB L-0501.

Domestic sales of Treakisym rose 12.9% YoY. Overseas sales increased by 3.6x after the company added one year of inventory in South Korea following a factory alignment. Milestone revenues declined 85.0% YoY.

SG&A expenses were JPY1.8bn (-8.4% YoY), including R&D expenses of JPY774mn (-26.5% YoY) associated with SyB L-0501、SyB L-1101, and SyBC-1101.

As a result, operating loss totaled JPY1.3bn (FY12/13: loss of JPY1.7bn). The company also had a recurring loss of JPY1.1bn (FY12/13: loss of JPY1.6bn). The recurring loss was narrowed because the company had a JPY189mn in currency gain, received JPY16mn in interest payments, and earned JPY8mn from securities holdings. Net loss totaled JPY1.1bn (FY12/13: loss of 1.6bn).

Domestic

Treakisym

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. Astellas Pharma GmbH (“Astellas”; European subsidiary of Astellas Pharma Inc.; TSE1: 4503) has already applied for approval in Europe.

The company completed the patient enrollment for a phase II clinical trial for CLL in October 2014. 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

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).

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 its 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.

Overseas

SyB L-0501 was approved in South Korea for the additional indication of relapsed or refractory low-grade NHL in June 2014. The product is now sold by Eisai's Eisai Korea Inc. unit. The subsidiary also sells the drug for two other indications—CLL and multiple myeloma (MM).

In Taiwan, the drug is being marketed by InnoPharmax Inc. In Singapore, Eisai (Singapore) Pte. Ltd. markets the drug. Overseas sales increased by 2.2 times the estimate after the company added one year of inventory in South Korea in connection with a factory alignment.

Overseas capital procurement

The company in November 2014 announced that it would issue No. 2 unsecured convertible bonds with subscription rights to new shares, and No. 34 subscription rights to new shares in a third-party allocation to Oak Capital Corporation. Oak in December 2014 paid JPY510mn to SymBio for the purchase. All the bonds were converted to shares by the end of the month.

Full-year (FY12/15) outlook

FY12/14 Forecasts (JPYmn)	FY12/14 1H Act.	FY12/14 2H Act.	FY12/14 FY Act.	FY12/15 FY Est.
Sales	**975**	**980**	**1,955**	**1,870**
CoGS	626	802	1,428	
Gross Profit	247	280	527	
GPM	25.3%	28.5%	26.9%	
SG&A	893	937	1,830	
SG&A / Sales	91.6%	95.6%	93.6%	
R&D expenses	370	404	774	
Operating Profit	**-646**	**-657**	**-1,303**	**-2,452**
OPM	-	-	-	-
Recurring Profit	**-713**	**-397**	**-1,110**	**-2,481**
RPM	-	-	-	-
Net Income	**-715**	**-401**	**-1,116**	**-2,485**
Net Margin	-	-	-	-

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

Source: Company data

Earnings outlook

The company expects sales of JPY1.9bn (-4.3% YoY), operating loss of JPY2.5bn, recurring loss of JPY2.5bn, and net loss of JPY2.5bn.

Sales

Sales of Treakisym are expected to surge. However, overseas sales may decline from FY12/14, when shipments surged after the company added one year of inventory in South Korea following a factory alignment.

SG&A

The company will expand the application of cancer agents SyBL-0501, SyB-L-1101, and SyB C-1101 while acquiring new drug candidates. For this purpose, SymBio will seek to conclude more licensing agreements with other companies. As a result, SG&A expenses may reach JPY3.0bn (FY12/14: JPY1.8bn), with JPY1.9bn in R&D costs (FY12/14: JPY774mn).

Long-term outlook

When it released its FY12/14 results, SymBio also announced a mid-term plan for FY12/15 through FY12/17.

Midterm Plan (JPYmn)	FY12/14 Act.	FY12/15 Est.	FY12/16 Target	FY12/17 Target
Sales	1,955	1,870	2919～2,148	3,754～2,160
Operating Profit	-1,303	-2,452	-2,390～-3,005	-2,525～-3,492
Recurring Profit	-1,110	-2,481	-2,419～-3,034	-2,554～-3,521
Net Income	-1,115	-2,485	-2,422～-3,038	-2,557～-3,524

Source: Company data

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

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