SymBio Pharmaceuticals | 4582 |

On **February 10, 2016**, SymBio Pharmaceuticals announced earnings results for full-year 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	1,933	103.4%	1,870
YoY	-64.5%	20.3%	1.9%	27.6%	135.0%	0.1%	-1.2%	-1.1%		122.1%
Gross profit	32	247	353	527	120	283	395	583		
YoY	-78.6%	34.1%	29.4%	65.6%	272.1%	14.3%	11.8%	10.7%		
GPM	18.6%	25.3%	26.2%	26.9%	29.5%	28.9%	29.7%	30.2%		
SG&A expenses	448	893	1,320	1,830	453	931	1,383	3,135		
YoY	-9.0%	-9.9%	-10.0%	-8.4%	1.1%	4.2%	4.7%	71.3%		
SG&A / sales	257.9%	91.6%	97.9%	93.6%	110.9%	95.3%	103.8%	162.1%		
Operating profit	-416	-646	-967	-1,303	-332	-648	-988	-2,552		-2,452
YoY	-	-	-	-	-	-	-	-		-
OPM	-	-	-	-	-	-	-	-		-
Recurring profit	-454	-713	-941	-1,110	-419	-674	-1,056	-2,630		-2,481
YoY	-	-	-	-	-	-	-	-		-
RPM	-	-	-	-	-	-	-	-		-
Net income	-455	-715	-944	-1,116	-420	-676	-1,059	-2,632		-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	601
YoY	-64.5%	149.1%	-27.3%	191.0%	135.0%	-29.2%	-4.5%	-1.0%
Gross profit	32	215	106	173	120	162	113	188
YoY	-78.6%	543.6%	19.8%	286.1%	272.1%	-24.5%	5.8%	8.5%
GPM	18.6%	26.8%	28.5%	28.5%	29.5%	28.6%	31.6%	31.3%
SG&A expenses	448	445	427	510	453	478	452	1,752
YoY	-9.0%	-10.8%	-10.1%	-4.3%	1.1%	7.3%	6.0%	243.7%
SG&A / sales	257.9%	55.6%	114.5%	84.0%	110.9%	84.1%	127.0%	291.6%
Operating profit	-416	-231	-320	-337	-332	-316	-340	-1,564
YoY	-	-	-	-	-	-	-	-
OPM	-	-	-	-	-	-	-	-
Recurring profit	-454	-259	-228	-170	-419	-255	-382	-1,574
YoY	-	-	-	-	-	-	-	-
RPM	-	-	-	-	-	-	-	-
Net income	-455	-261	-228	-172	-420	-256	-383	-1,573
YoY	-	-	-	-	-	-	-	-
NPM	-	-	-	-	-	-	-	-

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

FY12/15 sales totaled JPY1.9bn (-1.1% YoY) due to domestic and overseas sales of SyB L-0501 (Treakisym).

Treakisym domestic sales rose 24.0% YoY, but overseas sales fell 76.1% on factors including the earlier booking of orders in Korea in FY12/14.

SG&A expenses rose 71.3% YoY to JPY3.1bn due to expenses incurred for clinical trials for oral and intravenous rigosertib and Treakisym, and the booking of R&D expenses of JPY2.0bn (+162.8%) in conjunction with the in-licensing expenses for SyB P-1501 (IONSYS for post-operative patient-controlled analgesia) and “other” SG&A expenses of JPY1.1bn (+4.2%).

As a result, operating loss totaled JPY2.6bn (versus a loss of JPY1.3bn the preceding year). The company also reported a recurring loss of JPY2.6bn (JPY1.1bn loss) due to non-operating expenses of JPY96mn (mainly on forex losses of JPY86mn). Net loss totaled JPY2.6bn (JPY1.1bn loss the preceding year).

Progress towards FY12/16 targets is as follows.

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. NHI price-based sales rose 10.3% YoY.

Phase II clinical trial of Treakisym for the first-line treatment of low-grade NHL and MCL had already been completed and the company submitted a new drug application (NDA) to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) in December 2015. Meanwhile, in Europe, review of the application by Astellas Pharma is under way by European authorities.

Regarding the phase II clinical trial for chronic lymphocytic leukemia (CLL), the company filed an NDA in December 2015. 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.

In addition to the 100mg dosage of Treakisym, SymBio Pharmaceuticals also filed in December 2015 for approval of a smaller 25mg dosage as an amount that could actually be used at medical facilities.

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 the trial was completed in October 2015.

Onconova Therapeutics, Inc., the U.S. 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 MDS patients who do not respond to 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.

SyB P-1501, a post-operative patient-controlled analgesia
In October 2015 SymBio reached an in-licensing agreement with The Medicines Company (through its wholly owned subsidiary Incline Therapeutics) for the development and commercialization of SyB P-1501, a post-operative patient-controlled analgesia known as IONSYS in the US. SymBio acquired exclusive development and marketing rights for Japan. Preparations are under way to start a domestic phase III clinical trial in 2016.

Overseas

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

Full-year company forecasts

FY12/16 Forecasts (JPYmn)	FY12/15 FY Act.	FY12/16 FY Est.
Sales	**1,933**	**2,339**
CoGS	1,350	
Gross Profit	**583**	
GPM	30.2%	
SG&A	3,135	
SG&A / Sales	162.1%	
R&D expenses	2,035	
Operating Profit	**-2,552**	**-2,778**
OPM	-	
Recurring Profit	**-2,630**	**-2,811**
RPM	-	
Net Income	**-2,632**	**-2,815**
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 JPY2.3bn (+21.0% YoY), with an operating loss of JPY2.8bn, a recurring loss of JPY2.8bn and a net loss of JPY2.8bn.

R&D expense is expected to total JPY2.2bn (up from JPY2.0bn in FY12/15), while total SG&A expense–including R&D–is projected to reach JPY3.6bn (up from JPY3.1bn).

R&D spending targets additional indications for Treakisym and development toward NDA applications for 1) intravenous and oral rigosertib and 2) SyB P-1501, which was in-licensed in FY12/15. The company will also work jointly with Teikyo Heisei University on the development of an anti-cancer drug using the TTR1 nano-agonist molecule.

Pipeline

Treakisym

Supplemental NDAs were filed in FY12/15 for indications as a first-line treatment for refractory/relapsed low-grade NHL, MCL and CLL. Work is under way to respond to matters raised by the PMDA and speed up the approvals.

Intravenous and oral rigosertib

The company is moving ahead with the Japan edition of the global Phase III trial for the intravenous version of rigosertib, and hopes to quickly begin initial patient enrollment. Similarly, SymBio aims to quickly start initial patient enrollment for 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. Preparations are under way to start a domestic phase III clinical trial in 3Q FY3/17.

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

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