On **May 11, 2017**, SymBio Pharmaceuticals announced earnings results for Q1 FY12/17.

Cumulative	FY12/16				FY12/17				FY12/17	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	193	1,211	1,408	2,368	870				81.6%	2,903
YoY	-52.7%	24.0%	5.6%	22.5%	350.2%					22.6%
Gross profit	57	405	478	904	239					
YoY	-53.1%	43.2%	21.1%	55.1%	323.0%					
GPM	29.2%	33.4%	34.0%	38.2%	27.5%					
SG&A expenses	575	1,225	2,011	3,031	764					
YoY	27.0%	31.6%	45.4%	-3.3%	32.9%					
SG&A-to-sales ratio	297.6%	101.2%	142.8%	128.0%	87.9%					
Operating profit	-518	-820	-1,532	-2,127	-525				-	-3,238
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					-
Recurring profit	-655	-1,177	-1,917	-2,317	-583				-	-3,303
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					-
Net income	-653	-1,175	-1,916	-2,313	-583				-	-3,306
YoY	-	-	-	-	-					-
Net margin	-	-	-	-	-					-

Quarterly	FY12/15				FY12/17			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	193	1,018	197	960	870			
YoY	-52.7%	79.2%	-44.7%	59.9%	350.2%			
Gross profit	57	348	74	426	239			
YoY	-53.1%	114.8%	-34.6%	126.6%	323.0%			
GPM	29.2%	34.2%	37.4%	44.3%	27.5%			
SG&A expenses	575	650	786	1,021	764			
YoY	27.0%	36.0%	73.8%	-41.7%	32.9%			
SG&A-to-sales ratio	297.6%	63.9%	399.2%	106.2%	87.9%			
Operating profit	-518	-302	-712	-595	-525			
YoY	-	-	-	-	-			
OPM	-	-	-	-	-			
Recurring profit	-655	-522	-740	-400	-583			
YoY	-	-	-	-	-			
RPM	-	-	-	-	-			
Net income	-653	-523	-741	-397	-583			
YoY	-	-	-	-	-			
Net margin	-	-	-	-	-			

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

Q1 FY12/17 sales totaled JPY870mn (+350.2% YoY) thanks to sales of Treakisym.

SG&A expenses rose 32.9% YoY to JPY764mn. R&D expenses increased 76.8% to JPY395mn. There were expenses for clinical trials for the intravenous and oral formulations of Rigosertib Sodium and SyB P-1501. SG&A expenses excluding R&D expenses were up 5.0% at JPY369mn.

As a result, operating loss totaled JPY525mn (loss of JPY518mn in Q1 FY12/16). The company also reported a recurring loss of JPY583mn (loss of JPY655mn in Q1 FY012/16) partly due to non-operating expenses of JPY59mn (mainly on forex losses of JPY55mn). Net loss was JPY583mn (loss of JPY653mn).

Progress in Q1 FY12/17 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). Product sales based on the National Health Insurance (NHI) drug price grew 28.0% YoY, and accordingly product sales to Eisai increased 312.4%.

In addition to the above three approved indications, the company has filed an NDA for a fourth indication to help patients who need new treatments and maximize the value of the product. The company has completed phase III clinical trials for relapsed or refractory diffuse large B-cell lymphoma (DLBCL, or aggressive NHL) and is in talks with the PMDA regarding approval of a new indication given the high medical need. Symbio is exploring further expansion of the Treakisym business by developing an oral formulation in addition to the injection currently under development or on sale to treat solid tumors and autoimmune diseases.

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 May 11, 2017. 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 enrolled the first patient in November 2016 and was making progress with case accumulation. However, in the interests of patient welfare, the company suspended further patient enrollment on April 21, 2017 because concerns were raised about the continuity of The Medicines Company's SyB P-1501 business.

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 transition to a global specialty pharmaceutical company.

Overseas

The company marketed Treakisym in Korea, Taiwan, and Singapore, and overseas sales were steady.

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

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