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On **November 10, 2017**, SymBio Pharmaceuticals Ltd. announced earnings results for Q3 FY12/17 and that it had recorded non-operating profit.

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	1,786	2,417		67.4%	3,583
YoY	-52.7%	24.0%	5.6%	22.5%	350.2%	47.5%	71.7%			51.3%
Gross profit	57	405	478	904	239	510	675			
YoY	-53.1%	43.2%	21.1%	55.1%	323.0%	26.0%	41.0%			
GPM	29.2%	33.4%	34.0%	38.2%	27.5%	28.5%	27.9%			
SG&A expenses	575	1,225	2,011	3,031	764	1,746	4,183			
YoY	27.0%	31.6%	45.4%	-3.3%	32.9%	42.5%	108.0%			
SG&A-to-sales ratio	297.6%	101.2%	142.8%	128.0%	87.9%	97.7%	173.1%			
Operating profit	-518	-820	-1,532	-2,127	-525	-1,236	-3,508		-	-3,932
YoY	-	-	-	-	-	-	-			-
OPM	-	-	-	-	-	-	-			-
Recurring profit	-655	-1,177	-1,917	-2,317	-583	-1,268	-3,547		-	-4,009
YoY	-	-	-	-	-	-	-			-
RPM	-	-	-	-	-	-	-			-
Net income	-653	-1,175	-1,916	-2,313	-583	-1,266	-3,546		-	-4,009
YoY	-	-	-	-	-	-	-			-
Net margin	-	-	-	-	-	-	-			-

Quarterly	FY12/16				FY12/17			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	193	1,018	197	960	870	916	631	
YoY	-52.7%	79.2%	-44.7%	59.9%	350.2%	-9.9%	220.3%	
Gross profit	57	348	74	426	239	271	165	
YoY	-53.1%	114.8%	-34.6%	126.6%	323.0%	-22.2%	123.8%	
GPM	29.2%	34.2%	37.4%	44.3%	27.5%	29.6%	26.1%	
SG&A expenses	575	650	786	1,021	764	982	2,437	
YoY	27.0%	36.0%	73.8%	-41.7%	32.9%	51.1%	210.1%	
SG&A-to-sales ratio	297.6%	63.9%	399.2%	106.2%	87.9%	107.1%	386.5%	
Operating profit	-518	-302	-712	-595	-525	-711	-2,272	
YoY	-	-	-	-	-	-	-	
OPM	-	-	-	-	-	-	-	
Recurring profit	-655	-522	-740	-400	-583	-685	-2,279	
YoY	-	-	-	-	-	-	-	
RPM	-	-	-	-	-	-	-	
Net income	-653	-523	-741	-397	-583	-684	-2,280	
YoY	-	-	-	-	-	-	-	
Net margin	-	-	-	-	-	-	-	

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

Cumulative Q3 FY12/17 sales totaled JPY2.4bn (+71.7% YoY) thanks to sales of Treakisym.

Due to the sales increase, gross profit came to JPY675mn (+41.0% YoY). Gross profit margin was 27.9% (-6.1pp).

SG&A expenses rose 108.0% YoY to JPY4.2bn. R&D expenses increased 176.3% to JPY2.7bn. There were expenses for clinical trials for the intravenous and oral formulations of Rigosertib Sodium and SyB P-1501, and the cost of in-licensing liquid formulation products of bendamustine hydrochloride (RTD and RI products). SG&A expenses excluding R&D expenses were up 42.9% at JPY1.5bn.

As a result, operating loss totaled JPY3.5bn (loss of JPY1.5bn in Q3 FY12/16). The company also reported a recurring loss of JPY3.5bn (loss of JPY1.9bn in Q3 FY12/16) partly due to non-operating expenses of JPY43mn (mainly on forex losses of JPY24mn). Net loss was JPY3.5bn (loss of JPY1.9bn in Q3 FY12/16).

Progress made in Q3 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), untreated low-grade NHL and MCL, and chronic lymphocytic leukemia (CLL).

As a result of additional indications, sales of Treakisym based on the National Health Insurance (NHI) drug price grew 53.4% YoY, and accordingly product sales to Eisai increased 68.0%.

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). In response to strong medical needs, the company finished consultation with the Pharmaceuticals and Medical Devices Agency and began phase III clinical trials toward the addition of an indication in August 2017.

In addition to ongoing efforts to add new indications, in September 2017, the company concluded an agreement with Eagle Pharmaceuticals (based in New Jersey, US) that licenses to SymBio rights to develop, market, and sell Eagle's bendamustine hydrochloride RTD and RI injection products in Japan for Treakisym's product life cycle management. The RTD and RI products offer significant value added to patients and healthcare professionals, and extends Treakisym's product life cycle until 2031.

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)

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 completed the first patient enrollment in July 2016 and enrollments are smoothly accumulating.

SymBio planned to start domestic Phase I clinical trials for the oral form of Rigosertib Sodium (used in combination with azacitidine) for higher-risk myelodysplastic syndrome (MDS), however, due to delays in the supply of drugs by Onconova for the trials, patient enrollment did not make progress. Since Onconova resumed the supply of clinical trial materials, SymBio initiated a phase I clinical trial in Japan in June 2017 and enrolled the first patient in October. The purpose of the Japanese phase I study is to confirm the safety of high-dose oral rigosertib, which was added to the ongoing US phase II study by Onconova in untreated or relapsed/refractory patients with higher-risk MDS. After demonstrating the safety of high-dose oral rigosertib, SymBio intends to immediately recommence an oral rigosertib/azacitidine combination trial in Japan, and participate in the global phase III study in untreated higher-risk MDS patients that Onconova is planning.

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, SymBio later found a fact that raises concerns about the continuity of The Medicines Company's SyB P-1501 business. In the interests of patient welfare, SymBio has suspended further patient enrollment since April 2017 and is in talks with The Medicines Company regarding how the SyB P-1501 clinical trial and commercialization in Japan would be affected.

New drug candidates

From a long-term perspective, SymBio continues to search for and evaluate promising drug candidates, in a bid to acquire global licensing rights for these drugs and grow into a sustainable and profitable biopharmaceutical company with growth potential and profitability. At present, talks are underway regarding licensing rights for several drug candidates. 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 are trending ahead of target.

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

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