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On **November 9, 2018**, SymBio Pharmaceuticals Ltd. announced earnings results for Q3 FY12/18.

Cumulative	FY12/17				FY12/18				FY12/18	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	870	1,786	2,417	3,444	888	1,928	3,032		72.2%	4,201
YoY	350.2%	47.5%	71.7%	45.4%	2.1%	8.0%	25.5%			22.0%
Gross profit	239	510	675	1,031	250	573	924			
YoY	323.0%	26.0%	41.0%	14.1%	4.4%	12.4%	37.0%			
GPM	27.5%	28.5%	27.9%	29.9%	28.1%	29.7%	30.5%			
SG&A expenses	764	1,746	4,183	4,978	964	1,898	2,832			
YoY	32.9%	42.5%	108.0%	64.2%	26.1%	8.7%	-32.3%			
SG&A ratio	87.9%	97.7%	173.1%	144.5%	108.5%	98.4%	93.4%			
Operating profit	-525	-1,236	-3,508	-3,947	-715	-1,325	-1,908		-	-2,981
YoY	-	-	-	-	-	-	-			-
OPM	-	-	-	-	-	-	-			-
Recurring profit	-583	-1,268	-3,547	-3,977	-749	-1,378	-1,938		-	-3,044
YoY	-	-	-	-	-	-	-			-
RPM	-	-	-	-	-	-	-			-
Net income	-583	-1,266	-3,546	-3,978	-760	-1,389	-1,941		-	-3,056
YoY	-	-	-	-	-	-	-			-
Net margin	-	-	-	-	-	-	-			-

Quarterly	FY12/17				FY12/18			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	870	916	631	1,028	888	1,040	1,104	
YoY	350.2%	-9.9%	220.3%	7.0%	2.1%	13.5%	75.1%	
Gross profit	239	271	165	357	250	324	351	
YoY	323.0%	-22.2%	123.8%	-16.2%	4.4%	19.5%	113.0%	
GPM	27.5%	29.6%	26.1%	34.7%	28.1%	31.1%	31.8%	
SG&A expenses	764	982	2,437	795	964	934	934	
YoY	32.9%	51.1%	210.1%	-22.1%	26.1%	-4.9%	-61.7%	
SG&A ratio	87.9%	107.1%	386.5%	77.4%	108.5%	89.8%	84.6%	
Operating profit	-525	-711	-2,272	-439	-715	-610	-583	
YoY	-	-	-	-	-	-	-	
OPM	-	-	-	-	-	-	-	
Recurring profit	-583	-685	-2,279	-430	-749	-629	-560	
YoY	-	-	-	-	-	-	-	
RPM	-	-	-	-	-	-	-	
Net income	-583	-684	-2,280	-432	-760	-629	-552	
YoY	-	-	-	-	-	-	-	
Net margin	-	-	-	-	-	-	-	

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

Breakdown of SG&A expenses

Cumulative	FY12/17				FY12/18			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	764	1,746	4,183	4,978	964	1,898	2,832	
YoY	32.9%	42.5%	108.0%	64.2%	26.1%	8.7%	-32.3%	
R&D expenses	395	840	2,711	3,018	416	839	1,293	
YoY	76.8%	62.0%	176.3%	81.0%	5.3%	-0.1%	-52.3%	
SG&A expenses excl. R&D	369	906	1,472	1,961	548	1,059	1,539	
YoY	5.0%	28.3%	42.9%	43.7%	48.5%	16.9%	4.6%	

Quarterly	FY12/17				FY12/18			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	764	982	2,437	795	964	934	934	
YoY	32.9%	51.1%	210.1%	-22.1%	26.1%	-4.9%	-61.7%	
R&D expenses	395	445	1,872	307	416	423	454	
YoY	76.8%	50.8%	304.4%	-55.3%	5.3%	-4.9%	-75.7%	
SG&A expenses excl. R&D	369	537	566	489	548	511	479	
YoY	5.0%	51.3%	75.0%	46.1%	48.5%	-4.8%	-15.2%	

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

Q3 FY12/18 results

Cumulative Q3 FY12/18 sales totaled JPY3.0bn (+25.5% YoY) mainly owing to domestic sales of Treakisym®.

Due to sales growth, gross profit rose 37.0% YoY to JPY924mn with the gross profit margin increasing 2.6pp YoY to 30.5%. SG&A expenses fell 32.3% YoY to JPY2.8bn due to a 52.3% YoY drop in R&D expenses to JPY1.3bn, which included expenses for conducting clinical trials of intravenous and oral formulations of Treakisym® and rigosertib. Excluding the drop in R&D expenses, SG&A expenses would have risen by 4.6% YoY to JPY1.5bn.

As a result, operating loss narrowed to JPY1.9bn (versus a loss of JPY3.5bn in Q3 FY12/17). Recurring loss was JPY1.9bn (versus a loss of JPY3.5bn in Q3 FY12/17) due in part to the booking of non-operating expenses of JPY34mn (mainly on share issuance costs). Net loss was JPY1.9bn (versus a loss of JPY3.5bn in Q3 FY12/17).

Domestic

Treakisym® (SyB L-0501[lyophilized injection]/SyB L-1701 [RTD]/SyB L-1702 [RI]/SyB C-0501 [oral]; 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). (The company obtained marketing approval for refractory or relapsed low-grade NHL and MCL in October 2010, for untreated low-grade NHL and MCL in December 2016, and for CLL in August 2016.)

As a result of additional indications, Treakisym® is steadily increasing its market share in the area of first-line treatment by replacing R-CHOP, the conventional standard treatment. The combination therapy of Treakisym® and rituximab (BR therapy) was newly included in the Practical Guidelines for Hematological Malignancies 2018 edited and published by Japanese Society of Hematology as a standard treatment option. Sales of Treakisym® based on the National Health Insurance (NHI) drug price grew steadily by 15.2% YoY, and product sales to Eisai also progressed in line with plan.

In addition to the above three approved indications, the company has started Phase III clinical trials for the fourth indication of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and is currently enrolling patients for the trial with an aim to obtain approval. In response to strong medical needs, the company began phase III clinical trials in August 2017, and with the enrollment of the first patient in January 2018, is working on enrolling patients.

In addition to efforts for new indications, in September 2017, the company concluded an exclusive licensing agreement with Eagle Pharmaceuticals (based in New Jersey, US) to develop, market, and sell liquid formulations of Treakisym® (RTD and RI formulations) in Japan for Treakisym®'s product life cycle management. The RTD and RI products offer significant value added to patients and healthcare professionals, and extend Treakisym®'s product life cycle until 2031. The company has already consulted with PMDA on the details of the application for approval of the RTD formulation and clinical trial design for the RI formulation, and is preparing for obtaining approval and launching Treakisym® liquid formulation in 2021 or later.

In July 2018, Symbio obtained approval for the partial revision to the marketing authorization of Treakisym®. As a result, Treakisym® can now be used in combination with not only rituximab but also obinutuzumab (launched in August 2018) for the treatment of CD 20-positive follicular lymphoma (FL), the most common histological type of low-grade NHL, enabling the company to provide patients with a new treatment therapy. In September 2018, the company applied for approval of a partial revision to the marketing authorization of Treakisym® to enable its use as a pretreatment agent for regenerative medical products.

To reinforce the position of Treakisym® at the core of its business to strengthen its business foundation, SymBio is developing an oral formulation of the drug in addition to the injection currently under development or on sale. The company commenced a phase I clinical trial for progressive solid tumors in January 2018, with the aim of examining the recommended dosage and schedule as well as tolerability and safety of the oral formulation of Treakisym®, and narrowing down the types of potential target tumors. With the enrollment of the first patient in May 2018, the company is currently working on enrolling more patients for the trial. To evaluate the effect of oral administration of Treakisym® on the immune system, the company concluded a joint research agreement with Keio University in May 2018 and began a preclinical study to verify the efficacy of the oral form of Treakisym® in treating systemic lupus erythematosus (SLE), a form of autoimmune disease.

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 (37 patients enrolled so far). The global Phase III trial addresses higher-risk myelodysplastic syndromes (higher-risk MDS), which do not respond to the current standard treatment with hypomethylating agents, which relapse after treatment under the current standard of care, or which are intolerant to hypomethylating agents, and is under way at clinical trial sites in more than 20 countries worldwide. Patient enrollments are smoothly accumulating. Based on the results of an interim analysis performed in January 2018, SymBio decided to continue the trial in an adoptive design agreed upon in advance with the US Food and Drug Administration (FDA), increasing the number of patient enrollment in accordance with pre-determined statistical criteria. Based on these results, the company plans to apply for approval in Japan at the same time as in the US and Europe.

Regarding the oral formulation of rigosertib, Onconova is conducting Phase I/II clinical trials for the drug used in combination with azacytidine as first-line treatment for higher-risk MDS and Phase II clinical trials for transfusion-dependent lower-risk MDS in the US. To verify the tolerability and safety of the oral formulation of rigosertib among Japanese patients, SymBio began Phase I clinical trials in Japan in June 2017 and is steadily enrolling patients. After completing the Phase I trials, the company plans to promptly start clinical trials for rigosertib used in combination with azacytidine, participate in international Phase III clinical trials of the drug used in combination with azacytidine as first-line treatment for higher-risk MDS Onconova is planning, and apply for approval of the oral formulation of the drug in Japan at the same time as in the US and Europe. In regards to development of rigosertib for transfusion-dependent lower-risk MDS, the company is considering participating from Japan while monitoring Onconova's development progress.

SyB P-1501, a post-operative patient-controlled analgesia
Regarding SyB P-1501 licensed by the Medicines Company (through its wholly owned subsidiary Incline Therapeutics, Inc.) in October 2015, SymBio found a fact that raised concerns about the continuity of its business, and in the interests of patient welfare, it suspended further patient enrollment in April 2017. The license agreement was terminated in November 2017, and the development of the drug was terminated in February 2018.

The Company initiated an arbitration against The Medicines Company in October 2017, under the rules of the International Chamber of Commerce, seeking damages of USD82mn (approximately JPY9.0bn) arising from The Medicines Company's repudiation of the license agreement. Arbitration proceedings against The Medicines Company are still ongoing.

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. The company is considering 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 SyB L-0501 in Korea, Taiwan, and Singapore, and sales were largely in line with plans.

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

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