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On **February 7, 2018**, SymBio Pharmaceuticals Ltd. announced earnings results for Full-year 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	1,786	2,417	3,444	96.1%	3,583
YoY	-52.7%	24.0%	5.6%	22.5%	350.2%	47.5%	71.7%	45.4%		51.3%
Gross profit	57	405	478	904	239	510	675	1,031		
YoY	-53.1%	43.2%	21.1%	55.1%	323.0%	26.0%	41.0%	14.1%		
GPM	29.2%	33.4%	34.0%	38.2%	27.5%	28.5%	27.9%	29.9%		
SG&A expenses	575	1,225	2,011	3,031	764	1,746	4,183	4,978		
YoY	27.0%	31.6%	45.4%	-3.3%	32.9%	42.5%	108.0%	64.2%		
SG&A ratio	297.6%	101.2%	142.8%	128.0%	87.9%	97.7%	173.1%	144.5%		
Operating profit	-518	-820	-1,532	-2,127	-525	-1,236	-3,508	-3,947	-	-3,932
YoY	-	-	-	-	-	-	-	-		-
OPM	-	-	-	-	-	-	-	-		-
Recurring profit	-655	-1,177	-1,917	-2,317	-583	-1,268	-3,547	-3,977	-	-4,009
YoY	-	-	-	-	-	-	-	-		-
RPM	-	-	-	-	-	-	-	-		-
Net income	-653	-1,175	-1,916	-2,313	-583	-1,266	-3,546	-3,978	-	-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	1,028
YoY	-52.7%	79.2%	-44.7%	59.9%	350.2%	-9.9%	220.3%	7.0%
Gross profit	57	348	74	426	239	271	165	357
YoY	-53.1%	114.8%	-34.6%	126.6%	323.0%	-22.2%	123.8%	-16.2%
GPM	29.2%	34.2%	37.4%	44.3%	27.5%	29.6%	26.1%	34.7%
SG&A expenses	575	650	786	1,021	764	982	2,437	795
YoY	27.0%	36.0%	73.8%	-41.7%	32.9%	51.1%	210.1%	-22.1%
SG&A ratio	297.6%	63.9%	399.2%	106.2%	87.9%	107.1%	386.5%	77.4%
Operating profit	-518	-302	-712	-595	-525	-711	-2,272	-439
YoY	-	-	-	-	-	-	-	-
OPM	-	-	-	-	-	-	-	-
Recurring profit	-655	-522	-740	-400	-583	-685	-2,279	-430
YoY	-	-	-	-	-	-	-	-
RPM	-	-	-	-	-	-	-	-
Net income	-653	-523	-741	-397	-583	-684	-2,280	-432
YoY	-	-	-	-	-	-	-	-
Net margin	-	-	-	-	-	-	-	-

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

FY12/17 sales totaled JPY3.4bn (+45.4% YoY) thanks to domestic sales of Treakisym®.

Due to the sales increase, gross profit came to JPY1.0bn (+14.1% YoY). Gross profit margin was 29.9% (-8.2pp).

SG&A expenses rose 64.2% YoY to JPY5.0bn. R&D expenses increased 81.0% to JPY3.0bn. There were expenses for clinical trials for Treakisym®, the intravenous and oral formulations of Rigosertib Sodium and SyB P-1501, and the cost of in-licensing liquid formulation products of Treakisym® (RTD and RI formulations). SG&A expenses excluding R&D expenses were up 43.7% at JPY2.0bn.

As a result, operating loss totaled JPY4.0bn (loss of JPY2.1bn in FY12/16). The company also reported a recurring loss of JPY4.0bn (loss of JPY2.3bn in FY12/16) partly due to non-operating expenses of JPY34mn (mainly on share issue expenses of JPY14mn, forex losses of JPY10mn, and fees and commissions paid of JPY9mn). Net loss was JPY4.0bn (loss of JPY2.3bn in FY12/16).

Domestic

Treakisym® (SyB L-0501/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).

As a result of additional indications, sales of Treakisym® based on the National Health Insurance (NHI) drug price grew 60.9% YoY, and accordingly product sales to Eisai increased 62.7%.

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, enrolling the first patient in January 2018.

In addition to ongoing efforts to add 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 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. In this context, 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.

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 (30 patients enrolled so far). 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 20 countries worldwide. The company completed the first patient enrollment in July 2016 and enrollments are smoothly accumulating. Based on the results of an interim analysis performed in January 2018, SymBio decided to continue the trial, increasing the number of patient enrollment in accordance with a pre-determined statistical criteria.

SymBio planned to start domestic Phase I clinical trials for the oral form of Rigosertib (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. The license agreement with Incline Therapeutics, Inc. was terminated in November 2017.

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.

In conjunction with the termination of the license agreement, the Company will terminate the development of SyB P-1501, a process that the Company expects to complete by March 2018.

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, 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 Treakisym® in Korea, Taiwan, and Singapore, and overseas sales were ahead of target.

Full-year company forecasts

(JPYmn)	FY12/17 FY Act.	FY12/18 FY Est.
Sales	3,444	4,201
SG&A expensees	4,978	4,350
SG&A ratio	144.5%	103.5%
R&D expenses	3,017	2,311
SG&A excluding R&D	1,961	2,039
Operating profit	-3,947	-2,981
OPM		
Recurring profit	-3,977	-3,044
RPM		
Net income	-3,978	-3,056
Net margin		

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

Earnings outlook

The company forecasts sales of JPY4.2bn (+22.0% YoY) on sales growth of Treakisym®.

The company forecasts R&D expenses of JPY2.3bn (JPY3.0bn in FY12/17) and total SG&A expenses including R&D expenses of JPY4.4bn (JPY5.0bn).

The company's R&D program comprises development of Treakisym® for the additional indication of relapsed or refractory DLBCL (aggressive NHL), oral and liquid formulations of Treakisym® (RTD and RI formulations), and oral and intravenous Rigosertib products.

The company forecasts an operating loss of JPY3.0bn (operating loss of JPY4.0bn in FY12/17), recurring loss of JPY3.0bn (JPY4.0bn loss), and net loss of JPY3.0bn (JPY4.0bn loss).

Pipeline

Treakisym®

Enrolments are currently accumulating for the phase III trial for relapsed or refractory DLBCL (aggressive NHL) that is under way. The company will progress development of liquid formulations (RTD and RI formulations) of Treakisym® in-licensed from Eagle Pharmaceuticals after finalizing development plans for the two products. The company aims to enroll the first patient for its phase I clinical trial of oral Treakisym®, which has already started, as soon as possible.

Intravenous and oral rigosertib

The company is moving ahead with the accumulation of cases in Japan in the global phase III trial for the intravenous version of rigosertib. Clinical trials of the oral version of rigosertib for use in combination with azacitidine are to begin after safety of azacitidine monotherapy is confirmed in a domestic phase I study for which the company is still enrolling patients.

Long-term outlook

Medium-term plan (FY12/18–FY12/21)

When it released its FY12/17 results, SymBio also announced a four year medium-term plan for FY12/18 through FY12/21.

Medium-term plan

(JPYmn)	FY12/17 Act.	FY12/18 Est.	FY12/19 Target	FY12/20 Target	FY12/21 Target
Sales	3,444	4,201	4,238	4,413	11,624–10,325
Operating profit (losses)	-3,947	-2,981	-3,786	-3,709	1,777–878
Recurring profit (losses)	-3,977	-3,044	-3,849	-3,772	1,724–825
Net income (losses)	-3,978	-3,056	-3,853	-3,776	1,467–702

Source: Shared Research based on company data.

Main pipeline schedule

	FY12/17	FY12/18	FY12/19	FY12/20	FY12/21
Treakisym® (relapsed or refractory low-grade NHL and MCL)	Obtained approval (Oct-10)				
Treakisym® (first-line treatment of low-grade NHL and MCL)	Obtained approval (Dec-16)				
Treakisym® (CLL)	Obtained approval (Aug-16)				
Treakisym® (relapsed or refractory moderate- and high-grade NHL)	Phase III clinical trials underway		Complete phase III clinical trials	Apply for approval	Obtain approval
Treakisym®RTD (all indications)				Apply for approval	Obtain approval
Treakisym®RI (all indications)			Initiate phase III clinical trials	Complete phase III clinical trials	Apply for approval
Treakisym® (oral) (progressive solid tumors)		Phase I clinical trials			
Rigosertib (IV) (relapsed and refractory high-risk MDS)		Global phase III clinical trials underway			Apply for approval
Rigosertib (oral) (high-risk MDS [in combination with azacitidine])	Phase I clinical trials underway	Complete phase I clinical trials			
Rigosertib (oral) (high-risk MDS [in combination with azacitidine])			Initiate phase I clinical trials	Complete phase I clinical trials	

Source: Shared Research based on company data

Earnings targets of medium-term plan (FY12/18–FY12/21)

Sales

Sales of Treakisym® accounts for the bulk of overall sales. The company set the performance targets for drug sales after analysis and discussions on market size projections (derived from estimated number of patients), competitive positioning and advantages compared with existing therapies, and sales performance after commencement of sales. The company's forecast for FY12/21 is based on sales of Treakisym® through its own sales force.

The company forecasts sales growth of Treakisym® in FY12/21 onward following approval of an additional indication of relapsed or refractory diffuse large-B-cell lymphoma (DLBCL), which is expected in 1H FY12/21. Its sales target is calculated using an estimated market penetration rate range for the indication.

CoGS

CoGS is based on the terms and conditions of licensing and supply agreements with Astellas Deutschland GmbH (German subsidiary of Astellas Pharma Inc.) and Eagle Pharmaceuticals, Inc.

SG&A expenses

SG&A expenses are broken down into R&D expenses and other SG&A expenses. In the new medium-term plan, R&D expenses are broken down as follows:

- ▷ Expenses associated with phase III clinical trials of Treakisym®, targeting indication for refractory or relapsed DLBCL (trials started in August 2017)
- ▷ Expenses associated with the filing and development of Treakisym® liquid formulations (RTD and RI), in-licensed from Eagle Pharmaceuticals after signing an exclusive licensing agreement in September 2017
- ▷ Expenses associated with phase I clinical trials of oral Treakisym®, targeting indication for progressive solid tumors (trials commenced in January 2018)

In regard to SyB L-1101 (Rigosertib IV), based on the results of an interim analysis performed in January 2018 the company plans to continue its clinical trial, increasing patient enrollment in Japan. Milestone payments that arise at the time of obtaining approval have not been factored into the forecasts.

In-licensing or development costs on new drug candidates other than those listed in the current pipeline are not accounted for, although the company plans to continue evaluation and discussion of these agents.

Other SG&A expenses are mainly associated with the marketing, production and distribution, business development, and administrative operations for Treakisym®. The company expects to begin sales of Treakisym® through its own sales force from 2021 onward, because the business alliance agreement with Eisai comes to an end in December 2020. As such, expenses for establishing and running its own sales force are accounted for from 2019 onward.

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

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