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On **February 7, 2019**, SymBio Pharmaceuticals Ltd. announced earnings results for Full-year 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	3,836	91.3%	4,201
YoY	350.2%	47.5%	71.7%	45.4%	2.1%	8.0%	25.5%	11.4%		22.0%
Gross profit	239	510	675	1,031	250	573	924	1,173		
YoY	323.0%	26.0%	41.0%	14.1%	4.4%	12.4%	37.0%	13.7%		
GPM	27.5%	28.5%	27.9%	29.9%	28.1%	29.7%	30.5%	30.6%		
SG&A expenses	764	1,746	4,183	4,978	964	1,898	2,832	3,829		
YoY	32.9%	42.5%	108.0%	64.2%	26.1%	8.7%	-32.3%	-23.1%		
SG&A ratio	87.9%	97.7%	173.1%	144.5%	108.5%	98.4%	93.4%	99.8%		
Operating profit	-525	-1,236	-3,508	-3,947	-715	-1,325	-1,908	-2,656	-	-2,981
YoY	-	-	-	-	-	-	-	-		-
OPM	-	-	-	-	-	-	-	-		-
Recurring profit	-583	-1,268	-3,547	-3,977	-749	-1,378	-1,938	-2,749	-	-3,044
YoY	-	-	-	-	-	-	-	-		-
RPM	-	-	-	-	-	-	-	-		-
Net income	-583	-1,266	-3,546	-3,978	-760	-1,389	-1,941	-2,753	-	-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	803
YoY	350.2%	-9.9%	220.3%	7.0%	2.1%	13.5%	75.1%	-21.8%
Gross profit	239	271	165	357	250	324	351	249
YoY	323.0%	-22.2%	123.8%	-16.2%	4.4%	19.5%	113.0%	-30.3%
GPM	27.5%	29.6%	26.1%	34.7%	28.1%	31.1%	31.8%	31.0%
SG&A expenses	764	982	2,437	795	964	934	934	997
YoY	32.9%	51.1%	210.1%	-22.1%	26.1%	-4.9%	-61.7%	25.4%
SG&A ratio	87.9%	107.1%	386.5%	77.4%	108.5%	89.8%	84.6%	124.2%
Operating profit	-525	-711	-2,272	-439	-715	-610	-583	-749
YoY	-	-	-	-	-	-	-	-
OPM	-	-	-	-	-	-	-	-
Recurring profit	-583	-685	-2,279	-430	-749	-629	-560	-811
YoY	-	-	-	-	-	-	-	-
RPM	-	-	-	-	-	-	-	-
Net income	-583	-684	-2,280	-432	-760	-629	-552	-812
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	3,829
YoY	32.9%	42.5%	108.0%	64.2%	26.1%	8.7%	-32.3%	-23.1%
R&D expenses	395	840	2,711	3,018	416	839	1,293	1,833
YoY	76.8%	62.0%	176.3%	81.0%	5.3%	-0.1%	-52.3%	-39.3%
SG&A expenses excl. R&D	369	906	1,472	1,961	548	1,059	1,539	1,996
YoY	5.0%	28.3%	42.9%	43.7%	48.5%	16.9%	4.6%	1.8%

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	997
YoY	32.9%	51.1%	210.1%	-22.1%	26.1%	-4.9%	-61.7%	25.4%
R&D expenses	395	445	1,872	307	416	423	454	540
YoY	76.8%	50.8%	304.4%	-55.3%	5.3%	-4.9%	-75.7%	76.0%
SG&A expenses excl. R&D	369	537	566	489	548	511	479	458
YoY	5.0%	51.3%	75.0%	46.1%	48.5%	-4.8%	-15.2%	-6.4%

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

Full-year FY12/18 results

▷ Sales: JPY3.8bn (+11.4% YoY)

- ▷ Operating loss: JPY2.7bn (loss of JPY3.9bn)
- ▷ Recurring loss: JPY2.7bn (loss of JPY4.0bn)
- ▷ Net loss: JPY2.8bn (loss of JPY4.0bn)

Sales rose as product sales totaled JPY3.8bn (+10.6% YoY) mainly owing to domestic sales of Treakisym®.

SG&A expenses fell 23.1% YoY to JPY3.8bn due to a 39.3% YoY drop in R&D expenses to JPY1.8bn, 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 1.8% YoY to JPY2.0bn.

As a result, operating loss, recurring loss, and net loss shrank YoY.

Domestic

Preparations for in-house sales organization begin

In October 2018, SymBio announced that it had started preparing to build an in-house sales organization for Treakisym® in the domestic market. The business alliance agreement the company reached with Eisai in 2008 regarding the sale of Treakisym® will expire in December 2020. The company considered all of its business development options including business alliances with other companies, but concluded that it was best to move to its own sales organization to better look after its patients' interests and maximize the business value. SymBio is considering the organizational structure and personnel requirements ahead of the shift to its own sales organization from early FY12/21, and planning appropriate investments in building systems and creating the necessary logistics infrastructure. These initiatives will help it engage in sophisticated marketing and enable a quality product supply structure. The company aims to move into the black in FY12/21 and post ongoing profit growth thereafter.

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 untreated low-grade non-Hodgkin's lymphoma and mantle cell lymphoma (marketing approval obtained in December 2016), refractory or relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma (October 2010), and chronic lymphocytic leukemia (August 2016).

As a result of additional indications, Treakisym® is steadily increasing its market share in the area of first-line treatment in medical settings 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. This has seen Treakisym® establish its position as a standard treatment for lymphatic cancer. Sales of Treakisym® based on the National Health Insurance (NHI) drug price grew steadily by 11.6% YoY.

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 (r/r 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 (reduced burden) to patients and healthcare professionals, and extend Treakisym®'s product life cycle until 2031. The company has already consulted with PMDA and is preparing to file for approval of the RTD formulation. SymBio launched clinical trials for the RI formulation in November 2018 primarily to confirm safety.

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 (40 patients enrolled as of end-December 2018). 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 product sales exceeded the company's plans.

Full-year company forecasts

	FY12/18			FY12/19
(JPYmn)	1H Act.	2H Act.	FY Act.	FY Est.
Sales	1,928	1,907	3,836	4,465
Gross profit	573	600	1,173	1,466
GPM	29.7%	31.4%	30.6%	32.8%
SG&A expenses	1,898	1,931	3,829	5,053
SG&A ratio	98.4%	101.3%	99.8%	113.2%
R&D expenses	1,059	774	1,833	2,508
Excluding R&D expenses	839	1,157	1,996	2,545
Operating profit	-1,325	-1,331	-2,656	-3,587
OPM	-	-	-	-
Recurring profit	-1,378	-1,371	-2,749	-3,612
RPM	-	-	-	-
Net income	-1,389	-1,364	-2,753	-3,616
Net margin	-	-	-	-

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

Earnings outlook

▷ Sales: JPY4.5bn (+16.4% YoY)

▷ Operating loss: JPY3.6bn (loss of JPY2.7bn)

▷ Recurring loss: JPY3.6bn (loss of JPY2.7bn)

▷ Net loss: JPY3.6bn (loss of JPY2.8bn)

SymBio expects sales growth primarily on rising domestic product sales for Treakisym®.

It forecasts SG&A expenses of JPY5.1bn (+32.0% YoY) and R&D expenses of JPY2.5bn (+36.8% YoY). SymBio plans to continue developing Treakisym® for relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) and liquid formulations of Treakisym® (RTD and RI formulations), Treakisym® (oral), and oral and intravenous rigosertib products. The company forecasts SG&A expenses excluding R&D at JPY2.5bn (+27.5% YoY).

The main pipeline development plans are as follows.

Treakisym®

▷ For r/r DLBCL, the company plans to continue enrolling patients for phase III clinical trials already underway

▷ SymBio is preparing to file for approval of the RTD formulation and progressing with clinical trials of the RI formulation mainly to confirm safety for Treakisym® in-licensed from Eagle Pharmaceuticals

▷ The company has already launched phase I clinical trials for Treakisym® (oral)

Oral and intravenous rigosertib products

- ▷ SymBio is continuing to develop intravenous rigosertib formulation, and is enrolling patients in Japan as part of global phase III clinical trials
- ▷ For oral rigosertib, following confirmation of safety in domestic phase I clinical trials for single drug applications which is currently enrolling patients, SymBio is preparing for early participation in global phase III trials of rigosertib azacitidine combination therapy that Onconova Therapeutics is planning

On **the same day**, the company announced a medium-term plan covering FY12/19–FY12/22.

Medium-term plan targets

(JPYmn)	FY12/18 Act.	FY12/19 Est.	FY12/20 MTP	FY12/21 MTP	FY12/21 MTP
Sales	3,810	4,465	3,282	9,132	11,282–11,809
Operating profit (losses)	-2,656	-3,587	-5,180	1,225	2,084–2,464
Recurring profit (losses)	-2,749	-3,612	-5,224	1,181	2,040–2,420
Net income (losses)	-2,753	-3,616	-5,228	1,005	1,736–2,060

Source: Shared Research based on company data

Targets in medium-term plan (FY12/19–FY12/22)

Sales

SymBio expects product sales of Treakisym® to account for the bulk of sales. Product sales targets reflect the recent pace of market penetration and sales trends, which feed into the company's revised sales growth rates calculated over the medium-term plan period. Currently sales are booked based on product shipment sales to the sales distributor, Eisai. From FY12/21 onward, sales will be booked on product shipment sales to pharmaceutical wholesalers from the company's own in-house sales organization.

The company plans to shift to its own sales organization and switch product shipments from Eisai to pharmaceutical wholesalers in FY12/21. In the run-up to this it will be necessary to reduce Eisai's inventories toward the end of FY12/20. Sales of Treakisym® based on the National Health Insurance (NHI) drug price should remain solid, reflecting actual market demand, but SymBio plans to stop shipping to Eisai with a target date of end-1H FY12/20. It expects FY12/20 sales to decline by a commensurate amount.

SymBio forecasts increased product sales of Treakisym® from FY12/21 onward as it expects to gain approval of the drug as a treatment for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in Q2 FY12/21. The company said that its sales target range for FY12/22 is based on an estimated market penetration rate due to the additional indication.

SG&A expenses

The company has broken down SG&A expenses into primarily R&D spending and other SG&A expenses.

- ▷ The company calculated R&D expenses based on the latest development plans for its existing pipeline comprising Treakisym® and rigosertib IV and oral formulations
- ▷ The company has not factored in in-licensing or development costs for drug candidates outside its existing pipeline, although it will continue to evaluate and investigate them
- ▷ Other SG&A expenses comprise primarily Treakisym® marketing, production and distribution, business development, and management related costs. SymBio is factoring in costs associated with building and operating its own sales organization from FY12/19 onward ahead of the move to sell Treakisym® in-house from FY12/21. It forecasts an increase primarily in personnel costs due to a higher medical representative headcount and higher costs due to more activities

Personnel plans

SymBio assumes it will increase the number of medical representatives to as many as 60 to prepare for in-house sales from FY12/21 and subsequent launch of rigosertib IV. It plans to allocate the bare minimum of necessary personnel in other parts of the organization and is budgeting for personnel expenses accordingly.

Funding plans

In April 2018, the company decided to issue its 45th through 47th stock acquisition rights to secure funds needed to operate until it moves into the black in FY12/21. The proceeds were basically sufficient for its already in-licensed drug development pipeline, creation of an in-house sales structure, and new in-licensing or M&A activity necessary to take advantage of long-term growth opportunities.

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

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