This PDF document is an updated note on the company. A comprehensive version of the report on the company, including this latest update, is available on our website and various professional platforms.

On **August 7, 2019**, SymBio Pharmaceuticals Ltd. announced earnings results for 1H FY12/19.

Cumulative	FY12/18				FY12/19				FY12/19	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Sales	888	1,928	3,032	3,836	1,611	2,005			64.8%	3,092
YoY	2.1%	8.0%	25.5%	11.4%	81.4%	4.0%				-19.4%
Gross profit	250	573	924	1,173	609	529				
YoY	4.4%	12.4%	37.0%	13.7%	144.0%	-7.7%				
GPM	28.1%	29.7%	30.5%	30.6%	37.8%	26.4%				
SG&A expenses	964	1,898	2,832	3,829	1,205	2,545				
YoY	26.1%	8.7%	-32.3%	-23.1%	25.0%	34.1%				
SG&A ratio	108.5%	98.4%	93.4%	99.8%	74.8%	126.9%				
Operating profit	-715	-1,325	-1,908	-2,656	-596	-2,015			-	-3,780
YoY	-	-	-	-	-	-				-
OPM	-	-	-	-	-	-				-
Recurring profit	-749	-1,378	-1,938	-2,749	-616	-2,069			-	-3,856
YoY	-	-	-	-	-	-				-
RPM	-	-	-	-	-	-				-
Net income	-760	-1,389	-1,941	-2,753	-617	-2,070			-	-3,859
YoY	-	-	-	-	-	-				-
Net margin	-	-	-	-	-	-				-

Quarterly	FY12/18				FY12/19			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	888	1,040	1,104	803	1,611	394		
YoY	2.1%	13.5%	75.1%	-21.8%	81.4%	-62.2%		
Gross profit	250	324	351	249	609	-79		
YoY	4.4%	19.5%	113.0%	-30.3%	144.0%	-124.5%		
GPM	28.1%	31.1%	31.8%	31.0%	37.8%	-		
SG&A expenses	964	934	934	997	1,205	1,340		
YoY	26.1%	-4.9%	-61.7%	25.4%	25.0%	43.4%		
SG&A ratio	108.5%	89.8%	84.6%	124.2%	74.8%	340.4%		
Operating profit	-715	-610	-583	-749	-596	-1,419		
YoY	-	-	-	-	-	-		
OPM	-	-	-	-	-	-		
Recurring profit	-749	-629	-560	-811	-616	-1,453		
YoY	-	-	-	-	-	-		
RPM	-	-	-	-	-	-		
Net income	-760	-629	-552	-812	-617	-1,453		
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	FY12/18				FY12/19			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	964	1,898	2,832	3,829	1,205	2,545		
YoY	26.1%	8.7%	-32.3%	-23.1%	25.0%	34.1%		
R&D expenses	416	839	1,293	1,833	472	963		
YoY	5.3%	-0.1%	-52.3%	-39.3%	13.4%	14.8%		
SG&A expenses excl. R&D	548	1,059	1,539	1,996	733	1,582		
YoY	48.5%	16.9%	4.6%	1.8%	33.8%	49.3%		

Quarterly	FY12/18				FY12/19			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	964	934	934	997	1,205	1,340		
YoY	26.1%	-4.9%	-61.7%	25.4%	25.0%	43.4%		
R&D expenses	416	423	454	540	472	491		
YoY	5.3%	-4.9%	-75.7%	76.0%	13.4%	16.2%		
SG&A expenses excl. R&D	548	511	479	458	733	849		
YoY	48.5%	-4.8%	-15.2%	-6.4%	33.8%	66.0%		

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

1H FY12/19 results

- Sales: JPY2.0bn (+4.0% YoY)
- Operating loss: JPY2.0bn (loss of JPY1.3bn in 1H FY12/18)
- Recurring loss: JPY2.1bn (loss of JPY1.4bn in 1H FY12/18)
- Net loss: JPY2.1bn (loss of JPY1.4bn in 1H FY12/18)

Sales rose on domestic product sales of Treakisym®.

SG&A expenses rose 34.1% YoY to JPY2.5bn and R&D expenses increased 14.8% YoY to JPY963mn, which included expenses for conducting clinical trials of intravenous and oral formulations of Treakisym® and rigosertib. Excluding R&D expenses, SG&A expenses increased by 49.3% YoY to JPY1.6bn.

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

Domestic

Preparations for in-house sales organization begin

The business alliance agreement between SymBio and Eisai Co., Ltd. under which Eisai acts as a sales agent expires in December 2020. SymBio started to build an in-house sales organization for Treakisym® in the domestic market in October 2018. Key management priority is to move into the black in FY12/21 and ongoing profit growth thereafter. The company is therefore laying the groundwork for a shift to an internal sales organization to drive future business development.

Twenty Treakisym® managers are to form the core of the marketing team in the internal sales organization. The company conducted the necessary recruitment and training activities, and prepared for deployment to each region of responsibility as planned by the end of 1H. It also made steady progress with preparation of infrastructure such as logistics, distribution, and information systems.

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, which applies to all of the approved indications. This has seen Treakisym® establish its position as a standard treatment for lymphatic cancer. According to the company, market share in the area of first-line treatment increased to 55%.

In addition to the above three approved indications, the company is conducting Phase III clinical trials for the fourth indication of relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) and these are progressing well 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. The company has made steady progress in enrollments following the first patient in January 2018, completing enrollments in April 2019. Going forward, after completing the follow-up period for enrolled cases, it will prepare to file an application for regulatory approval.

SymBio is targeting a transition to Treakisym® liquid formulation (RTD and RI formulations), for which it concluded an exclusive licensing agreement in Japan with Eagle Pharmaceuticals (based in New Jersey, US) in September 2017. 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, and has made steady progress with patient enrollments since enrolling the first patient in April 2019. Liquid formulations of Treakisym® will offer significant value added (reduced burden) to patients and healthcare professionals, and liquid formula patent protection makes it possible to extend the product life of Treakisym® until 2031.

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 new anti-CD20 antibodies as well. This will allow combination therapy with 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 March 2019, the company obtained approval for the partial revision to its application concerning the use of Treakisym® as a pretreatment agent in tumor-specific T cell infusion therapy. This will allow Treakisym® to be used as a pretreatment agent for Kymriah® intravenous infusion, which was approved as the first chimeric antigen receptor T-cell (CAR-T) therapy in Japan and listed on the NHI drug price list in May 2019.

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 performed a preclinical study to verify the efficacy of the oral formulation of Treakisym® in treating systemic lupus erythematosus (SLE), a form of autoimmune disease. The company will consider the next stage of this research project (including clinical trials) after evaluating the results of the preclinical study.

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 (44 patients enrolled as of July 2019). 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. As of March 2019, the company had reached 75% of its target of enrolling 360 patients worldwide. Based on these trial 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 has completed 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, enrolled the first patients in October 2017, and completed patient enrollment in June 2019. After completing the Phase I trials, the company plans to start Phase I clinical trials for rigosertib used in combination with azacytidine, participate in global Phase III clinical trials of the drug used in combination with azacytidine as first-line treatment for higher-risk MDS currently planned by Onconova, and apply for approval of the oral formulation of the drug in Japan at the same time as in the US and Europe. In December 2018, Onconova submitted a Special Protocol Assessment (SPA) request to the US Food and Drug Administration (FDA) to speed up the approval review for the global trials, and plans to begin Phase III clinical trials as soon as it receives approval from the FDA. 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 learned of an event 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, 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. SymBio argued that The Medicine Company's failure to provide sufficient assurance to the company regarding the performance of obligations under on the license agreement in light of its decision to suspend and withdraw from business activities relating to SyB P-1501in the European and US markets was a material breach 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 licensing 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 South Korea, Taiwan, and Singapore, and product sales were in line with 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	3,092
Gross profit	573	600	1,173	980
GPM	29.7%	31.4%	30.6%	31.7%
SG&A expenses	1,898	1,931	3,829	4,760
SG&A ratio	98.4%	101.3%	99.8%	153.9%
Operating profit	-1,325	-1,331	-2,656	-3,780
OPM	-	-	-	-
Recurring profit	-1,378	-1,371	-2,749	-3,856
RPM	-	-	-	-
Net income	-1,389	-1,364	-2,753	-3,859
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: JPY3.1bn (+16.4% YoY)
- ▷ Operating loss: JPY3.8bn (loss of JPY2.7bn in FY12/18)
- ▷ Recurring loss: JPY3.9bn (loss of JPY2.7bn in FY12/18)
- ▷ Net loss: JPY3.9bn (loss of JPY2.8bn in FY12/18)

In August 2019, SymBio announced a revision to its FY12/19 earnings forecast, with downward revisions of JPY1.4bn for sales, JPY193mn for operating loss, JPY244mn for recurring loss, and JPY243mn for net loss.

Reasons for revision

SymBio imports lyophilized Treakisym® for injection from Astellas Deutschland GmBH (consolidated subsidiary of Astellas Pharma Inc.), which it supplies to the market for sale in Japan through its business partner, Eisai Co., Ltd. after quality inspection and packaging. In Q2 FY12/19, impurities and appearance defects were found in Treakisym® 100mg vials imported from Astellas Deutschland, which led to the company returning the whole batch. Thus only a fraction of the batches scheduled for shipment in 2Q FY12/19 onward can be shipped by the end of the year, with shipments possibly being delayed until Q1 FY12/20. The company therefore revised down its FY12/19 earnings forecast. Lower operating profit stems from the sales decline, but the impact on operating profit is mitigated by SG&A expenses (including R&D expenses) being revised down by JPY294mn from JPY5.1bn to JPY4.8bn.

The following is a discussion of the company's previous earnings forecast. Share Research plans to update the report after interviews with the company.

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

We offer corporate clients comprehensive report coverage, a service that allows them to better inform investors and other stakeholders by presenting a continuously updated third-party view of business fundamentals, independent of investment biases. Shared Research can be found on the web at http://www.sharedresearch.jp.

Disclaimer

This document is provided for informational purposes only. No investment opinion or advice is provided, intended, or solicited. Shared Research Inc. offers no warranty, either expressed or implied, regarding the veracity of data or interpretations of data included in this report. We shall not be held responsible for any damage caused by the use of this report.

 Our officers and employees may currently, or in the future, have a position in securities of the companies mentioned in this report, which may affect this report's objectivity.

Japanese Financial Instruments and Exchange Law (FIEL) Disclaimer

The report has been prepared by Shared Research under a contract with the company described in this report ("the company"). Opinions and views presented are ours where so stated. Such opinions and views attributed to the company are interpretations made by Shared Research. We represent that if this report is deemed to include an opinion by us that could influence investment decisions in the company, such opinion may be in exchange for consideration or promise of consideration from the company to Shared Research.

Contact Details

Shared Research Inc.
3-31-12 Sendagi Bunkyo-ku Tokyo, Japan
https://sharedresearch.jp
Phone: +81 (0)3 5834-8787
Email: info@sharedresearch.jp