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 5, 2020**, SymBio Pharmaceuticals Ltd. announced earnings results for 1H FY12/20

Cumulative	FY12/19				FY12/20				FY12/20	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of Est.	FY Est.
Sales	1,611	2,005	2,008	2,838	551	1,361			40.0%	3,404
YoY	81.4%	4.0%	-33.8%	-26.0%	-65.8%	-32.1%				20.0%
Gross profit	609	529	563	865	128	330				
YoY	144.0%	-7.7%	-39.1%	-26.3%	-79.0%	-37.7%				
GPM	37.8%	26.4%	28.0%	30.5%	23.2%	24.2%				
SG&A expenses	1,205	2,545	4,099	5,166	1,090	2,170				
YoY	25.0%	34.1%	44.8%	34.9%	-9.6%	-14.7%				
SG&A ratio	74.8%	126.9%	204.1%	182.1%	197.6%	159.5%				
Operating profit	-596	-2,015	-3,536	-4,302	-962	-1,840			-	-5,090
YoY	-	-	-	-	-	-				-
OPM	-	-	-	-	-	-				-
Recurring profit	-616	-2,069	-3,642	-4,377	-991	-1,883			-	-5,134
YoY	-	-	-	-	-	-				-
RPM	-	-	-	-	-	-				-
Net income	-617	-2,070	-3,641	-4,376	-992	-1,885			-	-4,803
YoY	-	-	-	-	-	-				-
Net margin	-	-	-	-	-	-				-

Quarterly	FY12/19				FY12/20			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales	1,611	394	3	830	551	809		
YoY	81.4%	-62.2%	-99.7%	3.3%	-65.8%	105.7%		
Gross profit	609	-79	33	302	128	202		
YoY	144.0%	-	-90.5%	21.4%	-79.0%	-		
GPM	37.8%	-	-	36.4%	23.2%	25.0%		
SG&A expenses	1,205	1,340	1,555	1,067	1,090	1,080		
YoY	25.0%	43.4%	66.5%	7.0%	-9.6%	-19.4%		
SG&A ratio	74.8%	340.4%	-	128.6%	197.6%	133.5%		
Operating profit	-596	-1,419	-1,521	-765	-962	-878		
YoY	-	-	-	-	-	-		
OPM	-	-	-	-	-	-		
Recurring profit	-616	-1,453	-1,573	-735	-991	-892		
YoY	-	-	-	-	-	-		
RPM	-	-	-	-	-	-		
Net income	-617	-1,453	-1,571	-736	-992	-893		
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	FY12/19				FY12/20			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	1,205	2,545	4,099	5,166	1,090	2,170		
YoY	25.0%	34.1%	44.8%	34.9%	-9.6%	-14.7%		
R&D expenses	472	963	1,972	2,442	438	834		
YoY	13.4%	14.8%	52.5%	33.2%	-7.1%	-13.4%		
SG&A expenses excl. R&D	733	1,582	2,127	2,725	651	1,336		
YoY	33.8%	49.3%	38.3%	36.5%	-11.1%	-15.5%		

Quarterly	FY12/19				FY12/20			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
SG&A expenses	1,205	1,340	1,555	1,067	1,090	1,080		
YoY	25.0%	43.4%	66.5%	7.0%	-9.6%	-19.4%		
R&D expenses	472	491	1,009	470	438	396		
YoY	13.4%	16.2%	122.1%	-13.0%	-7.1%	-19.4%		
SG&A expenses excl. R&D	733	849	546	597	651	685		
YoY	33.8%	66.0%	13.8%	30.6%	-11.1%	-19.3%		

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

1H FY12/20 results

- Sales: JPY1.4bn (-32.1% YoY)
- Operating loss: JPY1.8bn (loss of JPY2.0bn in 1H FY12/19)
- Recurring loss: JPY1.9bn (loss of JPY2.1bn in 1H FY12/19)
- Net loss: JPY1.9bn (loss of JPY2.1bn in 1H FY12/19)

Sales fell YoY. The company booked sales of Treakisym®.

SG&A expenses fell 14.7% YoY to JPY2.2bn and R&D expenses declined 13.4% YoY to JPY834mn. This included expenses for conducting clinical trials of intravenous and oral formulations of Treakisym® and rigosertib. Excluding R&D expenses, SG&A expenses fell by 15.5% YoY to JPY1.3bn. The company incurred development costs for its in-house sales organization.

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. The company plans to transition to its in-house sales organization for domestic sales of Treakisym® in January 2021. This should facilitate a move into the black from FY12/21 and ongoing profit growth thereafter and lay the groundwork for future business development.

In Q2, the company completed setting up its nationwide internal sales organization as planned, hiring and training additional Treakisym® sales representatives and regional sales managers who will form the core of its nationwide in-house marketing network. In addition, SymBio continued building its distribution and logistics capabilities with logistics centers in East and West Japan and in-house infrastructure including a new IT system with ERP, which is also now in the final stages.

Substandard products

SymBio imports lyophilized Treakisym® for injection from Astellas Deutschland (consolidated subsidiary of Astellas Pharma). Some batches of Treakisym® 100mg vials imported from Astellas Deutschland for domestic sales in FY12/19 had impurities and appearance defects in a significantly higher percentage than stipulated in the supply agreement. In order to prevent a recurrence of such product quality issues, the company objected to Astellas Deutschland, and demanded steps such as corrective and preventive action (CAPA) processes to fulfil its responsibilities as the supplier. Nonetheless, there was no improvement in 1H, with persistent supply issues. Several batches from Astellas Deutschland had high defect ratios and deliveries were irregular. Q2 sales fell YoY as Treakisym® inventory levels were low compared with Q2 FY12/19.

In Q3, the company is persisting with its efforts to restore Treakisym® inventory levels by continuing discussions with its supplier to reduce defect rates, and stabilize supply .

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 anticancer agent Treakisym® is used 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).

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.

Also, SymBio obtained approval for the partial revision to the marketing authorization of Treakisym® in July 2018. Treakisym® can now be used in combination with new anti-CD20 antibodies and not just rituximab for the treatment of CD20-positive follicular

lymphoma, the most common histological type of low-grade NHL. This allows the company to provide patients a new treatment option: combination therapy with obinutuzumab (launched in August 2018). In March 2019, SymBio obtained approval for the partial revision to its application to use Treakisym® as a pretreatment agent in tumor-specific T cell infusion therapy. This allows Treakisym® to be used as a pretreatment agent for Kymriah® intravenous infusion, which was the first chimeric antigen receptor T-cell (CAR-T) therapy approved in Japan and on the NHI drug price list from May 2019.

Following on from the above approved indications, the company conducted a phase III clinical study for the fourth indication of relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL), with Treakisym® administered in combination with rituximab (BR therapy). The response rate (primary endpoint) in the test results released in November 2019 was better than expected. In May 2020, the company applied for a partial revision to manufacture and marketing approval. After Chugai Pharmaceutical Co., Ltd. applied for manufacture and marketing approval of polatuzumab vedotin-piiq in combination with BR therapy to treat r/r DLBCL in June 2020, the company made a partial change to its application for approval of Treakisym® in combination with polatuzumab vedotin-piiq and rituximab therapy. If the new drug applications by Chugai and SymBio are approved and polatuzumab vedotin-piiq is added to the NHI drug price list, Treakisym® can be used with polatuzumab vedotin-piiq in combination with BR therapy. At present there are no effective treatments for the additional indication of r/r DLBCL, which is usually treated by a combination of anticancer agents as salvage chemotherapy. An effective new drug with few side effects is sought, however, because salvage chemotherapy produces severe adverse effects. Since BR therapy is already being used in the West to treat r/r DLBCL, patient organizations and related academic societies have petitioned MHLW so that it can be used in Japan as soon as possible.

The company concluded an exclusive licensing agreement in Japan with Eagle Pharmaceuticals (based in New Jersey, US) in September 2017 for the RTD and RI formulations of Treakisym®. The company filed for approval of the RTD formulation in September 2019, and plans to launch it in Q1 FY12/21. SymBio launched clinical trials for the RI formulation in November 2018 primarily to confirm safety and completed patient enrollment in March 2020. The company will apply for approval without delay after the end of the clinical trials of the RI formulation and aims to begin sales in 2H FY12/22. The RI formulation can be administered in just 10 minutes versus 60 minutes for the current lyophilized injection and RTD formulation. This reduces the burden on patients and healthcare professionals, providing significant value added. Multiple patent protections in the form of a liquid product license will enable the extension of the product life of Treakisym® to 2031.

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 (INSPIRE trial), with SymBio performing the Japan trial. 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. Onconova announced that it had reached its target of enrolling 360 patients worldwide as of March 2020 and achieved the required number of survival events in July 2020. Onconova said the primary endpoint results would become clear in Q3 2020, and that it planned to announce trial results at an academic conference by the end of the year. 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 completed phase I/II clinical trials for the drug used in combination with azacytidine, whose results suggested the efficacy and safety of the combination therapy. 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 completed patient enrollment in June 2019. After completing the phase I trials, the company will participate in global clinical trials of the drug used in combination with azacitidine as first-line treatment for higher-risk MDS currently planned by Onconova. In December 2019, Onconova announced that it was considering the design of a Phase II/III adaptive trial with untreated higher risk MDS patients based on the data presented at the 61st American Society of Hematology (ASH) Annual Meeting in December 2019.

Antiviral drug for the treatment of infections SyB V-1901 (generic name: Brincidofovir)
In September 2019, SymBio concluded an exclusive global license agreement with Chimerix Inc. (hereafter Chimerix) for brincidofovir (SyB V-1901, hereafter BCV IV and BCV Oral), an antiviral drug for the treatment of infections in intravenous and oral forms). The company acquired exclusive global rights to develop, manufacture, and market BCV for all diseases except smallpox.

After concluding the exclusive global license agreement, SymBio held discussions with Japanese and overseas infectious disease experts to examine the scientific and medical validity of BCV and progress its feasibility study. The company concluded that it would prioritize global development of BCV IV (mainly in Japan, the US, and Europe) to treat adenovirus (AdV) infections in patients receiving hematopoietic stem cell transplantation to address an unmet medical need. Based on safety and efficacy data acquired from its study, the company plans to extend its target disease area to multivirus infections in patients receiving hematopoietic stem cell transplantation. By exploring the potential for expanding target disease areas to organ transplants (including kidney transplants) to grow the market for, and maximize the business value of BCV, the company aims to transform itself into a global specialty pharmaceutical company with an integrated structure to supply quality pharmaceutical products. Clinical trials by Chimerix have demonstrated superior, broad-spectrum antivirus activity of BCV Oral against dsDNA viruses, raising expectations for its potential as a safe and effective therapy to prevent and treat a range of viral infections in patients receiving hematopoietic stem cell transplantation.

SyB P-1501, a post-operative patient-controlled analgesia
Regarding SyB P-1501 licensed by The Medicines Company, the company initiated an arbitration against The Medicines Company (MDCO), under the rules of the International Chamber of Commerce, seeking damages of USD82mn (approximately JPY9.0bn) arising from MDCO's repudiation of the license agreement. SymBio argued that MDCO'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. In August 2020, SymBio announced that it had received the arbitration judgment. The Court of Arbitration did not award damages sought by the company, but ordered MDCO to pay 50% of all arbitration costs as sought by the company. Counterclaims and claims for costs by MDCO were rejected. The above costs are under close examination and expected to take several weeks to finalize. The company commented that it would examine the arbitration judgment in detail to assess carefully its impact on FY12/20 earnings forecasts.

Overseas
The company marketed SyB L-0501 in South Korea, Taiwan, and Singapore, and product sales were in line with the company's plans.

In-licensing of drug candidates
The company is currently focusing on producing and unrolling development plans for antiviral drug brincidofovir it in-licensed in September 2019. It is constantly looking into multiple licensing deals and looking for and evaluating promising in-licensing drug candidates.

Full-year company forecasts

	FY12/19			FY12/20		
(JPYmn)	1H Act.	2H Act.	FY Act.	1H Act.	2H Est.	FY Est.
Sales	2,005	833	2,838	1,361	2,043	3,404
Gross profit	529	335	865	330	816	1,146
GPM	26.4%	40.3%	30.5%	24.2%	39.9%	33.7%
SG&A expenses	2,545	2,622	5,166	2,170	4,066	6,236
SG&A ratio	126.9%	314.8%	182.1%	159.5%	199.0%	183.2%
Operating profit	-2,015	-2,287	-4,302	-1,840	-3,250	-5,090
OPM	-	-	-	-	-	-
Recurring profit	-2,069	-2,307	-4,377	-1,883	-3,251	-5,134
RPM	-	-	-	-	-	-
Net income	-2,070	-2,306	-4,376	-1,885	-2,918	-4,803
Net margin	-	-	-	-	-	-

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

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 https://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 from us that could influence investment decisions in the company, such an 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