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On November 10, 2020, SymBio Pharmaceuticals Ltd. announced earnings results for Q3 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 | 2,333 | | 76.7% | 3,043 |
| YoY | 81.4% | 4.0% | -33.8% | -26.0% | -65.8% | -32.1% | 16.2% | | | 7.2% |
| Gross profit | 609 | 529 | 563 | 865 | 128 | 330 | 611 | | | |
| YoY | 144.0% | -7.7% | -39.1% | -26.3% | -79.0% | -37.7% | 8.5% | | | |
| GPM | 37.8% | 26.4% | 28.0% | 30.5% | 23.2% | 24.2% | 26.2% | | | |
| SG&A expenses | 1,205 | 2,545 | 4,099 | 5,166 | 1,090 | 2,170 | 3,753 | | | |
| YoY | 25.0% | 34.1% | 44.8% | 34.9% | -9.6% | -14.7% | -8.4% | | | |
| SG&A ratio | 74.8% | 126.9% | 204.1% | 182.1% | 197.6% | 159.5% | 160.9% | | | |
| Operating profit | -596 | -2,015 | -3,536 | -4,302 | -962 | -1,840 | -3,142 | | - | -4,592 |
| YoY | - | - | - | - | - | - | - | | | - |
| OPM | - | - | - | - | - | - | - | | | - |
| Recurring profit | -616 | -2,069 | -3,642 | -4,377 | -991 | -1,883 | -3,221 | | - | -4,656 |
| YoY | - | - | - | - | - | - | - | | | - |
| RPM | - | - | - | - | - | - | - | | | - |
| Net income | -617 | -2,070 | -3,641 | -4,376 | -992 | -1,885 | -2,694 | | - | -3,796 |
| 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 | 972 | |
| YoY | 81.4% | -62.2% | -99.7% | 3.3% | -65.8% | 105.7% | 31539.1% | |
| Gross profit | 609 | -79 | 33 | 302 | 128 | 202 | 281 | |
| YoY | 144.0% | - | -90.5% | 21.4% | -79.0% | - | 738.4% | |
| GPM | 37.8% | - | - | 36.4% | 23.2% | 25.0% | 28.9% | |
| SG&A expenses | 1,205 | 1,340 | 1,555 | 1,067 | 1,090 | 1,080 | 1,583 | |
| YoY | 25.0% | 43.4% | 66.5% | 7.0% | -9.6% | -19.4% | 1.8% | |
| SG&A ratio | 74.8% | 340.4% | - | 128.6% | 197.6% | 133.5% | 162.9% | |
| Operating profit | -596 | -1,419 | -1,521 | -765 | -962 | -878 | -1,302 | |
| YoY | - | - | - | - | - | - | - | |
| OPM | - | - | - | - | - | - | - | |
| Recurring profit | -616 | -1,453 | -1,573 | -735 | -991 | -892 | -1,338 | |
| YoY | - | - | - | - | - | - | - | |
| RPM | - | - | - | - | - | - | - | |
| Net income | -617 | -1,453 | -1,571 | -736 | -992 | -893 | -809 | |
| 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 | 3,753 | |
| YoY | 25.0% | 34.1% | 44.8% | 34.9% | -9.6% | -14.7% | -8.4% | |
| R&D expenses | 472 | 963 | 1,972 | 2,442 | 438 | 834 | 1,745 | |
| YoY | 13.4% | 14.8% | 52.5% | 33.2% | -7.1% | -13.4% | -11.5% | |
| SG&A expenses excl. R&D | 733 | 1,582 | 2,127 | 2,725 | 651 | 1,336 | 2,008 | |
| YoY | 33.8% | 49.3% | 38.3% | 36.5% | -11.1% | -15.5% | -5.6% | |

| 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 | 1,583 | |
| YoY | 25.0% | 43.4% | 66.5% | 7.0% | -9.6% | -19.4% | 1.8% | |
| R&D expenses | 472 | 491 | 1,009 | 470 | 438 | 396 | 911 | |
| YoY | 13.4% | 16.2% | 122.1% | -13.0% | -7.1% | -19.4% | -9.7% | |
| SG&A expenses excl. R&D | 733 | 849 | 546 | 597 | 651 | 685 | 672 | |
| YoY | 33.8% | 66.0% | 13.8% | 30.6% | -11.1% | -19.3% | 23.2% | |

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

## Cumulative Q3 FY12/20 results

- ▷ Sales: JPY2.3bn (+16.2% YoY)
- ▷ Operating loss: JPY3.1bn (loss of JPY3.5bn in Q3 FY12/19)
- ▷ Recurring loss: JPY3.2bn (loss of JPY3.6bn in Q3 FY12/19)
- ▷ Net loss: JPY2.7bn (loss of JPY3.6bn in Q3 FY12/19)

Sales increased YoY, as the company booked sales of Treakisym®.

Losses narrowed across the board on higher sales and lower SG&A expenses. SG&A expenses declined 8.4% YoY to JPY3.8bn and R&D expenses declined 11.5% YoY to JPY1.7bn. This included expenses for conducting clinical trials of intravenous formulations of Treakisym® and rigosertib. Excluding R&D expenses, SG&A expenses fell by 5.6% YoY to JPY2.0bn. The company incurred development costs for its in-house sales organization. The difference between recurring and net losses is attributable to a JPY525mn settlement payment booked as extraordinary income.

### 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 Q3, the company has started work on transferring marketing operations from Eisai, and as planned, has deployed a nationwide network of 51 marketing representatives as well as six hematology experts to cover each region.

In September 2020, the company concluded a basic agreement with Suzuken Co., Ltd (hereafter, Suzuken Group) and Toho Pharmaceutical Co., Ltd (a consolidated subsidiary of Toho Holdings Co., Ltd., hereafter Kyoso Mirai Group) for the procurement and sale of pharmaceuticals. SymBio will use Suzuken Group and Kyoso Mirai Group as its sole distributors once the marketing agreement with Eisai expires. The company will have two distribution centers, one in Eastern Japan and the other in Western Japan, under management by S.D. Collabo Co., Ltd.

#### Stable product supply

SymBio imports lyophilized Treakisym® for injection from Astellas Deutschland (consolidated subsidiary of Astellas Pharma), which is marketed in Japan by sales agent Eisai. Treakisym® inventories were substantially depleted in 1H relative to year-ago levels, but inventory levels were recovering as of Q3 as secondary packaging and quality tests were applied to some batches of Treakisym® 100mg vials imported from Astellas Deutschland while shipments to Eisai were on track with plan.

#### 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 NHL and MCL(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. 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.

In the phase III clinical study of Treakisym® administered in combination with rituximab (BR therapy) targeting relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL), an additional indication following the above approved ones, results showed that the response rate (primary endpoint) was better than expected. Based on this, the company filed for approval for partial revision to manufacturing and marketing approval in May 2020. It is currently conducting a follow-up study with overall survival as the primary endpoint, because evaluating the survival data (e.g., overall survival and progression-free survival) for Treakisym® administered in combination with rituximab is crucial for establishing Treakisym® as a treatment for DLBCL. Also, after Chugai Pharmaceutical Co., Ltd. applied for manufacture and marketing approval for polatuzumab vedotin in combination with BR therapy to treat r/r DLBCL in June 2020, the company made a partial change to its application for approval for Treakisym® in combination with polatuzumab vedotin and rituximab. If the new drug applications by Chugai and SymBio are approved and polatuzumab vedotin is added to the NHI drug price list, Treakisym® can be used with polatuzumab vedotin 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, so development of a highly effective but safe new drug would be ideal. 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®. Manufacturing and marketing approval of the RTD formulation was obtained in September 2020, and the company plans to launch it in Q1 FY12/21. SymBio commenced a clinical trial for the RI formulation in November 2018 primarily to confirm safety, and the follow-up period for all patients enrolled in the trial was completed in September 2020 (LPLV: Last Patient Last Visit). The company will apply for approval without delay after the end of the clinical trial 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, conducted a global phase III trial (INSPIRE study) across more than 20 countries addressing higher-risk myelodysplastic syndromes (higher-risk MDS) with overall survival as the primary endpoint. The target is patients who do not respond to the current standard treatment with hypomethylating agents, relapse after treatment under the current standard of care, or are intolerant to hypomethylating agents. In August 2020, Onconova announced a comparator trial to physicians' choice of treatment failed to achieve the primary endpoint. The company leads clinical trials conducted in Japan and is looking to apply the knowledge gleaned from genomic analysis of the INSPIRE study to rigosertib development going forward.

Regarding the oral formulation of rigosertib, Onconova completed a phase I/II clinical trial 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 high-dose oral formulation of rigosertib as an initial treatment for higher-risk MDS among Japanese patients, SymBio began a phase I clinical trial in Japan in June 2017 and completed patient enrollment in June 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 a review at the global advisory board held in February 2020, 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 review the drug's efficacy against dsDNA viral infections in patients receiving hematopoietic stem cell transplantation and extend its target indications to include multiviral infections. By exploring the potential for expanding target disease areas to viral infections related to organ transplants (including kidney transplants), the company aims to grow the market for and maximize the business value of BCV. The company is presently in preparation to initiate a dose-finding study of the liquid formulation of BCV in pediatric patients slated to begin in December 2021.

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 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 the license agreement in light of its decision to withdraw from business activities relating to SyB P-1501 in the European and US markets was a material breach of the license agreement. In September 2020, SymBio announced it had received the arbitration judgment and although the Court of Arbitration did not award damages sought by the company, it did order MDCO to pay 50% of legal costs (about USD5mn) sought by the 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.

**In-licensing of drug candidates**

The company is currently focusing on unrolling global 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.

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

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