# SymBio Pharmaceuticals | 4582 |



On **August 5, 2015**, SymBio Pharmaceuticals announced earnings results for Q2 FY12/15.

| Quarterly Performance (cumulative) | FY12/14 | | | | FY12/15 | | | | FY12/15 | |
|---|---|---|---|---|---|---|---|---|---|---|
| (JPYmn) | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | % of FY | FY Est. |
| Sales | 174 | 975 | 1,348 | 1,955 | 408 | 976 | | | 52.2% | 1,870 |
| YoY | -64.5% | 20.3% | 1.9% | 27.6% | 135.0% | 0.1% | | | | 122.1% |
| Gross profit | 32 | 247 | 353 | 527 | 120 | 283 | | | | |
| YoY | -78.6% | 34.1% | 29.4% | 65.6% | 272.1% | 14.3% | | | | |
| GPM | 18.6% | 25.3% | 26.2% | 26.9% | 29.5% | 28.9% | | | | |
| SG&A expenses | 448 | 893 | 1,320 | 1,830 | 453 | 931 | | | | |
| YoY | -9.0% | -9.9% | -10.0% | -8.4% | 1.1% | 4.2% | | | | |
| SG&A / sales | 257.9% | 91.6% | 97.9% | 93.6% | 110.9% | 95.3% | | | | |
| Operating profit | -416 | -646 | -967 | -1,303 | -332 | -648 | | | | -2,452 |
| YoY | - | - | - | - | - | - | | | | - |
| OPM | - | - | - | - | - | - | | | | - |
| Recurring profit | -454 | -713 | -941 | -1,110 | -419 | -674 | | | | -2,481 |
| YoY | - | - | - | - | - | - | | | | - |
| RPM | - | - | - | - | - | - | | | | - |
| Net income | -455 | -715 | -944 | -1,116 | -420 | -676 | | | | -2,485 |
| YoY | - | - | - | - | - | - | | | | - |
| NPM | - | - | - | - | - | - | | | | - |

| Quarterly Performance | FY12/14 | | | | FY12/15 | | | |
|---|---|---|---|---|---|---|---|---|
| (JPYmn) | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Sales | 174 | 802 | 373 | 607 | 408 | 568 | | |
| YoY | -64.5% | 149.1% | -27.3% | 191.0% | 135.0% | -29.2% | | |
| Gross profit | 32 | 215 | 106 | 173 | 120 | 162 | | |
| YoY | -78.6% | 543.6% | 19.8% | 286.1% | 272.1% | -24.5% | | |
| GPM | 18.6% | 26.8% | 28.5% | 28.5% | 29.5% | 28.6% | | |
| SG&A expenses | 448 | 445 | 427 | 510 | 453 | 478 | | |
| YoY | -9.0% | -10.8% | -10.1% | -4.3% | 1.1% | 7.3% | | |
| SG&A / sales | 257.9% | 55.6% | 114.5% | 84.0% | 110.9% | 84.1% | | |
| Operating profit | -416 | -231 | -320 | -337 | -332 | -316 | | |
| YoY | - | - | - | - | - | - | | |
| OPM | - | - | - | - | - | - | | |
| Recurring profit | -454 | -259 | -228 | -170 | -419 | -255 | | |
| YoY | - | - | - | - | - | - | | |
| RPM | - | - | - | - | - | - | | |
| Net income | -455 | -261 | -228 | -172 | -420 | -256 | | |
| YoY | - | - | - | - | - | - | | |
| NPM | - | - | - | - | - | - | | |

Source: Company data

Figures may differ from company materials due to differences in rounding methods.

Sales for Q2 FY12/15 totaled JPY976mn (+0.1% YoY) due to domestic and overseas sales of SyB L-0501 (Treakisym).

Though domestic sales of Treakisym increased 11.6% YoY, total sales of the product were up only 1.7% as overseas shipments were partially implemented in advance in the previous year.

SG&A expenses came to JPY931mn (+4.2% YoY), including research and development expenses worth JPY404mn (+9.0%), mainly for clinical trials for SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation), and other SG&A expenses worth JPY527mn (+0.7%).

As a result, operating loss totaled JPY648mn (Q2 FY12/14: loss of JPY646mn). The company also reported a recurring loss of JPY674mn (Q2 FY12/14: loss of JPY713mn), owing to non-operating expenses of JPY35mn, mainly from forex losses of JPY29mn. Net loss totaled JPY676mn (Q2 FY12/14: loss of JPY715mn)

**Domestic**

Treakisym (SyB L-0501; 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). Sales through Eisai increased as expected.

SymBio completed the phase II clinical trial of Treakisym for the first-line treatment of low-grade NHL and MCL in February 2014. The company is preparing the New Drug Application (NDA) for submission in Japan. The company will apply for approval as soon as the regulatory approval process for the application submitted by Astellas Pharma Europe Ltd. (a European subsidiary of Astellas Pharma Inc.; TSE1: 4503) is completed in the European Union.

The company completed patient enrollment for a phase II clinical trial for chronic lymphocytic leukemia (CLL) in October 2014. It plans to complete the trial and file an sNDA for marketing approval as soon as possible. Treakisym was designated as an orphan drug (drug for the treatment of rare diseases) for CLL in June 2012.

The company is still considering applying for approval for use of the drug for relapsed or refractory aggressive NHL.

Rigosertib (SyB L-1101 [IV]/SyB C-1101 [oral]; anticancer agent)
The company is conducting a domestic phase I clinical trial for the intravenous (IV) form of rigosertib in relapsed or refractory higher-risk myelodysplastic syndromes (MDS), a hematological malignancy. Patient enrollment was completed in January 2015.

Onconova Therapeutics, Inc., the U.S. licensor, plans to conduct a global Phase III trial for higher risk MDS patients who do not respond to treatment with hypomethylating agents (HMAs), the current standard of care ("Primary HMA Failure"), with clinical trial sites in more than ten countries worldwide. SymBio is considering its participation in the global clinical trial which is planned to begin in 2H of 2015 after completion of the domestic Phase I clinical trial.

As for SyB C-1101 (oral formulation, or Oral rigosertib), the company's domestic Phase I clinical trial for the target indication of higher risk MDS was completed in June, 2015. The company plans to continue clinical trials for the development of Oral rigosertib in combination with azacitidine for higher risk MDS, as well as for lower risk transfusiondependent MDS, and is considering its participation in the global clinical trial to be conducted by Onconova.

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

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