



Summary of Financial Results For the Second Quarter of Fiscal Year Ending December 31, 2015 [Japanese GAAP] (Non-consolidated)

August 5, 2015

SymBio Pharmaceuticals Limited Company Name Listing: Tokyo Securities Exchange

4582 URL: http://www.symbiopharma.com/ Securities Code

Representative Director, Representative

Fuminori Yoshida President and Chief Executive Officer

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Scheduled Date to File

Date of dividend August 6, 2015 Quarterly Report payment (plan)

Supplementary materials for the quarterly financial results: Yes

Holding of quarterly earnings performance review: No (For securities analyst and institutional investors) Yes

(millions of yen - rounded down, unless otherwise stated)

1. Business Results for the Second Quarter of FY 2015 (January 1, 2015 to June 30, 2015)

(1) Operating Results (cumulative)

(Percentage indicates year-on-year change)

	Net Sale	S	Operating Inco	me (loss)	Ordinary Incom	ne (loss)	Quarterly Net Inco	ome (loss)
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%
2Q FY 2015	976	0.1	(647)	_	(673)	_	(676)	_
2Q FY 2014	975	20.3	(646)	_	(713)	_	(715)	_

	Quarterly Net Income (loss) per share	Diluted Quarterly Net Income per share
	Yen	Yen
2Q FY 2015	(20.88)	_
2Q FY 2014	(23.35)	_

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	millions of yen	millions of yen	%
2Q FY 2015 (as of June 30, 2015)	7,046	6,335	86.4
FY 2014 (as of December 31, 2014)	7,453	6,963	90.7

(Reference) Equity: 2Q FY 2015 (as of June 30, 2015) 6,087 million yen FY 2014 (as of December 31, 2014) 6,763 million yen

2. Dividends

		Annual Dividend per Share					
	1st quarter	2nd quarter	3rd quarter	Fiscal Year End	Full year		
	Yen	Yen	Yen	Yen	Yen		
FY 2014	-	0.00	_	0.00	0.00		
FY 2015	-	0.00					
FY 2015 (Forecast)			_	0.00	0.00		

(Note) Revisions to the dividends forecasts most recently announced:

3. Earnings Forecasts for FY 2015 (January 1, 2015 to December 31, 2015)

(Percentage indicates year-on-year change)

	Net Sa	ales	Opera Income	U	Ordin Income		Net Incom	ne (loss)	Net Income (loss) per share
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%	Yen
Full Year	1,870	(4.3)	(2,452)	_	(2,481)	_	(2,485)	_	(68.61)

(Note) Revisions to the earnings forecasts most recently announced: Yes • No

Notes:

- (1) Application of special accounting treatment in preparation of quarterly financial reports:
- Yes · No
- (2) Changes in accounting policies, changes in accounting estimates and restatements after error corrections
 - (a) Changes in accounting polices due to revision of accounting standards:

Yes · No

- (b) Changes in accounting polices due to other reason:
- Yes · No
- (c) Changes in accounting estimates:
- Yes No
- (d) Restatements after error corrections:
- (3) Number of shares outstanding (Common stock)
 - (i) Number of shares outstanding at the end of the period (including treasury stock)
 - (ii) Number of shares of treasury stock at the end of the period
 - (iii) Average number of shares during the period (cumulative)

2Q FY 2015	32,390,923 shares	FY 2014	32,390,923 shares
2Q FY 2015	75 shares	FY 2014	75 shares
2Q FY 2015	32,390,848 shares	2Q FY 2014	30,634,182 shares

* Status of the quarterly review

Review of quarterly financial statements as required by the Financial Instruments and Exchange Act in the final stage as of the date of this disclosure document.

* Explanation regarding the appropriate use of earnings forecasts and other matters

All forecasts presented in this document, including earnings forecasts, are based on the information currently available to management and on assumptions judged to be reasonable. Actual results may differ substantially from these forecasts due to various factors. Regarding such assumptions on which the Company's earnings forecasts are based and their usage, please refer to "1. Qualitative Information Concerning Quarterly Financial Results, and (3) Qualitative information concerning earnings forecasts", on Page 3 of the attachment.

Index of the attachment

1. Qualitative Information Concerning Quarterly Financial Results	2
(1) Qualitative information concerning business results	2
(2) Qualitative information concerning financial position	3
(3) Qualitative information concerning earnings forecasts	3
2. Quarterly Financial Statements	4
(1) Balance sheets	4
(2) Statements of operations (cumulative)	6
(3) Quarterly cash flow statements	7
(4) Notes on quarterly financial statements	9
(Notes regarding going concern assumption)	9
(Notes regarding significant changes in shareholders' equity)	9
(Significant subsequent events)	9

1. Qualitative Information Concerning Quarterly Financial Results

(1) Qualitative information concerning business results

Progress in the Company's business for the second quarter of FY 2015 is as follows:

(i) Domestic

[Anticancer agent SyB L-0501 (generic name: bendamustine hydrochloride, trade name: TREAKISYM®)]

The Company markets the anticancer agent TREAKISYM® in Japan through its business partner, Eisai Co., Ltd. ("Eisai"), for the indications of refractory/relapsed low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. Net sales through Eisai increased as expected.

Aiming to maximize the product value of TREAKISYM®, the Company continues to pursue three additional indications: Firstly, regarding the indications of frontline low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, the Company completed its domestic Phase II clinical trial in February, 2014, and is currently 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. is completed in the EU.

Secondly, regarding the indication of chronic lymphocytic leukemia, patient enrollment was completed in October, 2014, and necessary procedures were undertaken for the domestic Phase II clinical trial. TREAKISYM® was designated as an orphan drug (pharmaceutical for the treatment of rare diseases) for the indication of chronic lymphocytic leukemia in June, 2012. The Company plans to complete the Phase II clinical trial as soon as possible, followed by the submission of a supplemental NDA.

Thirdly, regarding the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma, the Company's approach to development is now under consideration.

In addition, the "Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs," an expert team assembled by the Ministry of Health, Labour and Welfare in Japan, is currently evaluating the indications of frontline low-grade non-Hodgkin's lymphoma, mantle cell lymphoma and refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma.

[SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation), generic name: rigosertib]

After having completed patient enrollment in January, 2015, the Company continues to conduct its domestic Phase I clinical trial for the anticancer agent SyB L-1101 (intravenous formulation, or "IV rigosertib") in refractory/relapsed higher risk myelodysplastic syndrome (MDS), a hematological malignancy.

Onconova Therapeutics, Inc. ("Onconova"), 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.

The Company is considering its participation in the global clinical trial which is planned to begin in the second half 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 transfusion-dependent MDS, and is considering its participation in the global clinical trial to be conducted by Onconova.

(ii) Overseas

Product sales of SyB L-0501 in South Korea, Taiwan and Singapore grew steadily as planned.

(iii) Business results

As a result of the above, net sales totaled 976,194 thousand yen for the second quarter of fiscal year ending December 31, 2015, primarily reflecting product sales of SyB L-0501 in Japan and overseas markets. Net domestic sales of TREAKISYM® increased by 11.6% compared to the second quarter of the previous year while overseas sales were partially affected by inventory adjustments in the previous year. Thus, overall net sales showed a year-on-year increase of 1.7%.

Selling, general and administrative expenses totaled 930,553 thousand yen (a year-on-year increase of 4.2 %), including research and development ("R&D") expenses of 403,731 thousand yen (a year-on-year increase of 9.0 %) primarily due to expenses associated with clinical trials for SyB L-0501, SyB L-1101 and SyB C-1101, and other selling, general and administrative expenses of 526,821 thousand yen (a year-on-year increase of 0.7 %).

As a result, an operating loss of 647,968 thousand yen was recognized for the second quarter of fiscal year ending December 31, 2015 (operating loss of 646,260 thousand yen for the second quarter of the previous fiscal year). In addition,

the Company recorded non-operating expenses totaling 34,669 thousand yen primarily comprising foreign exchange loss. This resulted in an ordinary loss of 673,992 thousand yen (ordinary loss of 713,197 thousand yen for the second quarter of the previous fiscal year) and net loss of 676,424 thousand yen (net loss of 715,355 thousand yen for the second quarter of the previous fiscal year).

Segment information has been omitted since the Company operates within a single segment of the pharmaceutical industry which includes the development and commercialization of drugs, manufacturing, marketing and other related activities.

(2) Qualitative information concerning financial position

Total assets as of June 30, 2015 stood at 7,046,256 thousand yen, a decrease of 407,543 thousand yen from the previous fiscal year end, which consisted of an increase in merchandise and finished goods of 191,482 thousand yen, and decrease in marketable securities of 399,616 thousand yen, in cash and deposits of 99,753 thousand yen, in accounts receivable-trade of 22,852 thousand yen, in prepaid expenses of 14,162 thousand yen, and in other current assets of 39,960 thousand yen.

Total liabilities stood at 710,333 thousand yen, an increase of 220,109 thousand yen from the previous fiscal year end, primarily due to an increase in accounts payable-trade of 268,298 thousand yen and decrease in accounts payable-other of 47,114 thousand yen.

Net assets decreased by 627,653 thousand yen from the previous fiscal year end to 6,335,922 thousand yen primarily due to a net loss of 676,424 thousand yen.

As a result, the equity ratio decreased by 4.3 points to 86.4% from the previous fiscal year end.

(3) Qualitative information concerning earnings forecasts

No revision was made to the earnings forecasts for FY 2015 as of the date of this document.

2. Quarterly Financial Statements

(1) Balance sheets

Assets Current assets Cash and deposits Accounts receivable-trade Marketable securities Merchandise and finished goods Prepaid expenses Advances paid Other Total current assets	FY 2014 (as of December 31, 2014) 5,692,075 272,656 899,256 244,588 36,690 59,840 84,981 7,290,088	2Q FY 2015 (as of June 30, 2015) 5,592,321 249,804 499,640 436,070 22,528 47,327 45,020 6,892,713
Current assets Cash and deposits Accounts receivable-trade Marketable securities Merchandise and finished goods Prepaid expenses Advances paid Other Total current assets	272,656 899,256 244,588 36,690 59,840 84,981 7,290,088	249,804 499,640 436,070 22,528 47,327 45,020 6,892,713
Cash and deposits Accounts receivable-trade Marketable securities Merchandise and finished goods Prepaid expenses Advances paid Other Total current assets	272,656 899,256 244,588 36,690 59,840 84,981 7,290,088	249,804 499,640 436,070 22,528 47,327 45,020 6,892,713
Accounts receivable-trade Marketable securities Merchandise and finished goods Prepaid expenses Advances paid Other Total current assets	272,656 899,256 244,588 36,690 59,840 84,981 7,290,088	249,804 499,640 436,070 22,528 47,327 45,020 6,892,713
Marketable securities Merchandise and finished goods Prepaid expenses Advances paid Other Total current assets	899,256 244,588 36,690 59,840 84,981 7,290,088	499,640 436,070 22,528 47,327 45,020 6,892,713
Merchandise and finished goods Prepaid expenses Advances paid Other Total current assets	244,588 36,690 59,840 84,981 7,290,088	436,070 22,528 47,327 45,020 6,892,713
Prepaid expenses Advances paid Other Total current assets	36,690 59,840 84,981 7,290,088	22,528 47,327 45,020 6,892,713
Advances paid Other Total current assets	59,840 84,981 7,290,088	47,327 45,020 6,892,713
Other Total current assets	84,981 7,290,088	45,020 6,892,713
Total current assets	7,290,088	6,892,713
	21,554	
Noncurrent assets	21,554	
Property, plant and equipment	21,554	
Buildings, net		21,701
Tools, furniture and fixtures, net	27,441	24,131
Total property, plant and equipment	48,996	45,832
Intangible assets		
Software	62,273	57,851
Software in progress	2,556	_
Lease assets	1,243	918
Total intangible assets	66,073	58,770
Investments and other assets		
Long-term prepaid expenses	1,351	200
Lease and guarantee deposits	47,289	48,739
Total investments and other assets	48,641	48,940
Total noncurrent assets	163,710	153,543
Total assets	7,453,799	7,046,256
 Liabilities		
Current liabilities		
Accounts payable-trade	305,996	574,294
Accounts payable-other	142,884	95,769
Income taxes payable	21,254	19,363
Other	17,811	19,185
Total current liabilities	487,946	708,613
Noncurrent liabilities	·	<u> </u>
Provision for retirement benefits	1,634	1,427
Other	642	292
Total noncurrent liabilities	2,276	1,719
Total liabilities	490,223	710,333

(Unit:	thousands	of	ven)	١

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	FY 2014 (as of December 31, 2014)	2Q FY 2015 (as of June 30, 2015)
Net assets		
Shareholders' equity		
Capital stock	8,330,775	8,330,775
Capital surplus	8,300,775	8,300,775
Retained earnings	(9,867,514)	(10,543,938)
Treasury stock	(17)	(17)
Total shareholders' equity	6,764,019	6,087,595
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(744)	(360)
Total valuation and translation adjustments	(744)	(360)
Stock acquisition rights	200,300	248,687
Total net assets	6,963,576	6,335,922
Total liabilities and net assets	7,453,799	7,046,256

(2) Statements of operations (cumulative)

(For the second quarter of the fiscal year ending December 31, 2015)

		(Unit: thousands of yen)
	2Q FY 2014 (from January 1, 2014 to June 30, 2014)	2Q FY 2015 (from January 1, 2015 to June 30, 2015)
Net sales	975,345	976,194
Cost of sales	728,216	693,610
Gross profit	247,128	282,584
Selling, general and administrative expenses	893,389	930,553
Operating loss	(646,260)	(647,968)
Non-operating income		
Interest income	7,299	6,919
Interest on securities	4,470	1,700
Other	214	24
Total non-operating income	11,983	8,645
Non-operating expenses		
Interest expenses	57	7
Commission fees	4,760	4,450
Stock issuance cost	101	160
Foreign exchange losses	74,000	29,379
Other		671
Total non-operating expenses	78,919	34,669
Ordinary loss	(713,197)	(673,992)
Extraordinary income		
Gain on reversal of stock acquisition rights	89	689
Total extraordinary income	89	689
Extraordinary loss		
Loss on retirement of non-current assets	347	1,221
Total extraordinary loss	347	1,221
Loss before income taxes	(713,455)	(674,524)
Income taxes-current	1,900	1,900
Total income taxes	1,900	1,900
Net loss	(715,355)	(676,424)

(3) Quarterly cash flow statements

	First six months of Fiscal 2014 (from January 1, 2014 to June 30, 2014)	(Unit: thousands of yen First six months of Fiscal 201 (from January 1, 2015 to June 30, 2015)
Net cash provided by (used in) operating activities		
Quarterly (loss) before income taxes	(713,455)	(674,524
Depreciation	4,061	11,71
Share-based compensation expenses	41,855	49,07
Increase (decrease) in provision for retirement benefits	(112)	(207
Interest income	(11,769)	(8,620
Interest expenses	57	
Foreign exchange losses (gains)	63,803	4,19
Commission fees	4,760	4,45
Stock issuance cost	101	16
Gain on reversal of stock acquisition rights	(89)	(689
Loss on retirement of non-current assets	347	1,22
Decrease (increase) in accounts receivable	(227,359)	22,85
Decrease (increase) in inventories	(153,489)	(191,482
Decrease (increase) in prepaid expenses	11,296	9,71
Decrease (increase) in advances paid	49,350	12,51
Decrease (increase) in consumption taxes receivable	19,095	3,65
Decrease (increase) in current assets-other	54,444	20,54
Decrease (increase) in long-term prepaid expenses	5,571	1,15
Increase (decrease) in accounts payable-trade	150,848	268,29
Increase (decrease) in accounts payable-other	(119,951)	(34,930
Increase (decrease) in other current liabilities	711	(52)
Other	(953)	(1,488
Subtotal	(820,873)	(502,918
Interest and dividends income received	11,721	8,43
Interest expenses paid	(57)	(*)
Income taxes paid	(1,900)	(1,900
Net cash provided by (used in) operating activities	(811,100)	(496,39)
Net cash provided by (used in) investing activities		
Transfer from time-deposits	338,419	-
Purchase of marketable securities	(1,000,000)	-
Proceeds from redemption of securities	600,000	400,00
Purchase of property, plant and equipment	(18,980)	(11,974
Purchase of intangible assets	(29,600)	(900
Payments for lease and guarantee deposits	(41,486)	(432
Proceeds from collection of lease and guarantee deposits	216	16,42
Net cash provided by (used in) investing activities	(151,431)	403,11

		(Unit: thousands of yen)
	First six months of Fiscal 2014 (from January 1, 2014 to June 30, 2014)	First six months of Fiscal 2015 (from January 1, 2015 to June 30, 2015)
Net cash provided by (used in) financing activities		
Payments for issuance of common stock	(101)	(1,850)
Repayments for lease obligations	(340)	(344)
Other payments	_	(90)
Net cash provided by (used in) financing activities	(441)	(2,284)
Effect of foreign exchange rate change on cash and cash equivalents	(33,129)	(4,190)
Net increase (decrease) in cash and cash equivalents	(996,112)	(99,753)
Cash and cash equivalents at the beginning of the period	5,294,137	5,092,075
Cash and cash equivalents at the end of the period	4,298,024	4,992,321

(4) Notes on quarterly financial statements

(Notes regarding going concern assumption)

None to report

(Notes regarding significant changes in shareholders' equity)

None to report

(Significant subsequent events)

None to report