English translation

SymBio Pharmaceuticals Limited

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

November 6, 2015

Company Name	**SymBio Pharmaceuticals Limited**	Listing: Tokyo Securities Exchange	
Securities Code	4582	URL: http://www.symbiopharma.com/	
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida	
Contact Person	Director, Finance & Accounting	Tetsuya Maruyama	TEL 03(5472)1125
Scheduled Date to File Quarterly Report	November 9, 2015	Date of dividend payment (plan)	―

Supplementary materials for the quarterly financial results: Yes [No]

Holding of quarterly earnings performance review: Yes [No]

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

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

(1) Operating Results (cumulative) (Percentage indicates year-on-year change)

	Net Sales		Operating Income (loss)		Ordinary Income (loss)		Quarterly Net Income (loss)	
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%
3Q FY 2015	1,332	(1.2)	(987)	―	(1,056)	―	(1,059)	―
3Q FY 2014	1,348	1.9	(966)	―	(940)	―	(943)	―

	Quarterly Net Income (loss) per share	Diluted Quarterly Net Income per share
	Yen	Yen
3Q FY 2015	(32.71)	―
3Q FY 2014	(30.80)	―

(Note) Although dilutive shares in issue, diluted net income per share is not stated as net loss was reported for the period.

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	millions of yen	millions of yen	%
3Q FY 2015 (as of September 30, 2015)	6,164	5,981	92.5
FY 2014 (as of December 31, 2014)	7,453	6,963	90.7

(Reference) Equity: 3Q FY 2015 (as of September 30, 2015) 5,704 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 dividends forecasts recently announced: Yes ・ [No]

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

(Percentage indicates year-on-year change)

	Net Sales		Operating Income (loss)		Ordinary Income (loss)		Net Income (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 earnings forecasts 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: Yes ・ No

(3) Number of shares outstanding (common stock)

(i) Number of shares outstanding at the end of the period (including treasury stock)	3Q FY 2015	32,390,923 shares	FY 2014	32,390,923 shares
(ii) Number of shares of treasury stock at the end of the period	3Q FY 2015	75 shares	FY 2014	75 shares
(iii) Average number of shares during the period (cumulative)	3Q FY 2015	32,390,848 shares	3Q FY 2014	30,638,138 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.

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1. Qualitative Information Concerning Quarterly Financial Results

(1) Qualitative information concerning business results

Progress in the Company's business for the third quarter of FY 2015:

(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 first-line 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 supplemental New Drug Application (sNDA) for submission in Japan by holding a preliminary consultation with the Pharmaceuticals and Medical Devices Agency ("PMDA"). Regulatory approval in the EU is also underway with an application submitted by Astellas Pharma Europe Ltd.

Secondly, regarding the indication of chronic lymphocytic leukemia, patient enrollment was completed for the domestic Phase II clinical trial in October, 2014, and necessary procedures were undertaken for the successful completion of the trial in October, 2015, after the third quarter of fiscal year ending December 31, 2015. TREAKISYM® was designated as an orphan drug (pharmaceutical for the treatment of rare diseases) for the indication of chronic lymphocytic leukemia in June, 2012. In addition, the "Evaluation Committee on Unapproved or Off-Labeled Drugs with High Medical Needs," a committee established by the Ministry of Health, Labour and Welfare ("MHLW") in Japan, requested the Company to further develop TREAKISYM®. Using data from the Phase III clinical trial which has been completed overseas, the Company plans to file an application for manufacturing and marketing approval during the first quarter of the fiscal year ending December 31, 2016.

Thirdly, regarding the indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma, the Company continues to discuss the path forward for approval with the PMDA.

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

After having completed patient enrollment in January, 2015, the Company continued 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 (HR-MDS), a hematological malignancy. The clinical trial was successfully completed in October, 2015, after the third quarter of the fiscal year ending December 31, 2015.

Onconova Therapeutics, Inc. ("Onconova"), the U.S. Licensor, is conducting a global Phase III trial, with clinical trial sites in more than ten countries worldwide, for HR-MDS patients who do not respond to treatment with hypomethylating agents (HMAs) or who relapse after treatment under the current standard of care ("primary HMA failure").

Given the Company reached an agreement with the PMDA regarding its participation in the global Phase III trial in October, 2015, after the third quarter of fiscal year ending December 31, 2015, the Company has announced its decision to participate in the global Phase III trial. The Company will proceed with preparations for the trial, which is planned to begin in the fourth quarter of the fiscal year ending December 2015.

Regarding SyB C-1101 (oral formulation, or "Oral rigosertib"), the Company's domestic Phase I clinical trial for the target indication of HR-MDS was completed in June, 2015. The Company plans to continue with the development of Oral rigosertib in combination with azacitidine for HR-MDS, as well as for lower-risk transfusion-dependent MDS, and its participation in the global Phase III clinical trial to be conducted by Onconova is under consideration.

[New drug candidate]

In addition to TREAKISYM® and rigosertib, the Company has continued with search and evaluation activities to identify new drug candidates. In October, 2015, after the third quarter of the fiscal year ending December 31, 2015, the Company entered into an agreement with Incline Therapeutics, Inc. (the "Incline"), a wholly-owned subsidiary of U.S.-based The Medicines Company ("MEDCO"), for an exclusive license to develop and commercialize IONSYS® in Japan, a patient-controlled iontophoretic transdermal system for the short-term management of acute postoperative pain. The Company will begin preparations for a domestic Phase III trial to test IONSYS® in 2016.

(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 1,332,388 thousand yen for the third quarter of the fiscal year ending December 31, 2015, primarily reflecting product sales of SyB L-0501 in Japan and overseas markets. Although net domestic sales of TREAKISYM® increased by 6.1% compared to the third quarter of the previous year, overall net sales showed a year-on-year decrease of 1.2% since overseas sales were partially affected by inventory adjustments in the previous year.

Selling, general and administrative expenses totaled 1,382,780 thousand yen (a year-on-year increase of 4.7 %), including research and development ("R&D") expenses of 597,989 thousand yen (a year-on-year increase of 9.7 %) primarily due to expenses associated with (i) clinical trials for various indications and preparations regarding applications for SyB L-0501, and (ii) clinical trials and preparations regarding the next phase of clinical trials for SyB L-1101 and SyB C-1101, as well as other selling, general and administrative expenses of 784,791 thousand yen (a year-on-year increase of 1.3 %).

As a result, an operating loss of 987,692 thousand yen was recognized for the third quarter of fiscal year ending December 31, 2015 (operating loss of 966,650 thousand yen for the third quarter of the previous fiscal year). In addition, the Company recorded non-operating expenses totaling 81,697 thousand yen, primarily comprising foreign exchange loss. This resulted in an ordinary loss of 1,056,043 thousand yen (ordinary loss of 940,772 thousand yen for the third quarter of the previous fiscal year) and net loss of 1,059,425 thousand yen (net loss of 943,652 thousand yen for the third quarter of the previous fiscal year).

Segment information has been omitted as 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 September 30, 2015 stood at 6,164,412 thousand yen, a decrease of 1,289,386 thousand yen from the previous fiscal year end, which consisted of an increase in advances paid of 12,018 thousand yen, and decreases in cash and deposits of 526,891 thousand yen, in marketable securities of 399,426 thousand yen, in accounts receivable-trade of 272,656 thousand yen, in merchandise and finished goods of 24,755 thousand yen, and in other current assets of 69,164 thousand yen.

Total liabilities stood at 182,580 thousand yen, a decrease of 307,643 thousand yen from the previous fiscal year end, primarily due to decreases in accounts payable-trade of 282,484 thousand yen and in income taxes payable of 16,753 thousand yen.

Net assets decreased by 981,743 thousand yen from the previous fiscal year end to 5,981,832 thousand yen, primarily due to a net loss of 1,059,425 thousand yen.

As a result, the equity ratio increased by 1.8 points to 92.5% 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

(Unit: thousands of yen)

	FY 2014 (as of December 31, 2014)	3Q FY 2015 (as of September 30, 2015)
Assets		
Current assets		
Cash and deposits	5,692,075	5,165,183
Accounts receivable-trade	272,656	—
Marketable securities	899,256	499,830
Merchandise and finished goods	244,588	219,833
Prepaid expenses	36,690	34,306
Advances paid	59,840	71,859
Other	84,981	15,816
Total current assets	7,290,088	6,006,829
Noncurrent assets		
Property, plant and equipment		
Buildings, net	21,554	21,205
Tools, furniture and fixtures, net	27,441	32,599
Total property, plant and equipment	48,996	53,804
Intangible assets		
Software	62,273	54,346
Software in progress	2,556	—
Lease assets	1,243	756
Total intangible assets	66,073	55,103
Investments and other assets		
Long-term prepaid expenses	1,351	133
Lease and guarantee deposits	47,289	48,542
Total investments and other assets	48,641	48,675
Total noncurrent assets	163,710	157,583
Total assets	7,453,799	6,164,412
Liabilities		
Current liabilities		
Accounts payable-trade	305,996	23,511
Accounts payable-other	142,884	138,441
Income taxes payable	21,254	4,501
Other	17,811	14,529
Total current liabilities	487,946	180,984
Noncurrent liabilities		
Provision for retirement benefits	1,634	1,478
Other	642	117
Total noncurrent liabilities	2,276	1,595
Total liabilities	490,223	182,580

(Unit: thousands of yen)

	FY 2014 (as of December 31, 2014)	3Q FY 2015 (as of September 30, 2015)
Net assets		
Shareholders' equity		
Common stock	8,330,775	8,330,775
Capital surplus	8,300,775	8,300,775
Retained earnings	(9,867,514)	(10,926,939)
Treasury stock	(17)	(17)
Total shareholders' equity	6,764,019	5,704,594
Valuation and translation adjustments		
Unrealized holding gain (loss) on securities	(744)	(170)
Total valuation and translation adjustments	(744)	(170)
Stock acquisition rights	200,300	277,408
Total net assets	6,963,576	5,981,832
Total liabilities and net assets	7,453,799	6,164,412

(2) Statements of operations (cumulative)

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

(Unit: thousands of yen)

	3Q FY 2014 (from January 1, 2014 to September 30, 2014)	3Q FY 2015 (from January 1, 2015 to September 30, 2015)
Net sales	1,348,206	1,332,388
Cost of sales	994,719	937,300
Gross profit	353,487	395,087
Selling, general and administrative expenses	1,320,137	1,382,780
Operating loss	(966,650)	(987,692)
Non-operating income		
Interest income	11,797	9,730
Interest on securities	6,612	2,519
Dividend income	1,116	1,072
Foreign exchange gains	13,635	―
Other	214	24
Total non-operating income	33,375	13,347
Non-operating expenses		
Interest expenses	63	11
Commission fees	7,180	6,713
Stock issuance cost	254	160
Foreign exchange losses	―	74,142
Other	―	671
Total non-operating expenses	7,498	81,697
Ordinary loss	(940,772)	(1,056,043)
Extraordinary income		
Gain on reversal of stock acquisition rights	317	689
Total extraordinary income	317	689
Extraordinary loss		
Loss on retirement of non-current assets	347	1,221
Total extraordinary loss	347	1,221
Loss before income taxes	(940,802)	(1,056,575)
Income taxes-current	2,850	2,850
Total income taxes	2,850	2,850
Net loss	(943,652)	(1,059,425)

(3) Notes on quarterly financial statements

(Notes regarding going concern assumption)

None to report

(Notes regarding significant changes in shareholders' equity)

No significant changes in shareholders' equity since December 31, 2014.

(Significant subsequent events)

Conclusion of a license agreement

On October 2, 2015, the Company entered into an agreement with Incline Therapeutics, Inc. (the "Incline"), a wholly-owned subsidiary of U.S.-based The Medicines Company ("MEDCO"), for an exclusive license to develop and commercialize IONSYS® in Japan, a patient-controlled iontophoretic transdermal system for the short-term management of acute postoperative pain. Based on the agreement, the Company will make the following payments to the Incline: (i) an upfront payment, (ii) milestone payments in accordance with development progress and (iii) after launch, the Company will also pay royalties, as well as commercial milestone payments on achievement of annual sales.

The Company will begin preparations for a domestic Phase III trial to test IONSYS® in 2016.