

# **Summary of Financial Results** For the Third Quarter of Fiscal Year Ending December 31, 2014 [Japanese GAAP] (Non-consolidated)

November 7, 2014

Company Name	Company Name SymBio Pharmaceuticals Limited		ies 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 10, 2014	Date of dividend payment (plan)	-			
Supplementary materials for th	e quarterly financial results: Yes	No				

Holding of quarterly earnings performance review:

English translation

**MRIO** 

SymBio Pharmaceuticals Limited

(millions of yen - rounded	ed down, unless	otherwise stated)
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1. Business Results for the Third Quarter of FY 2014 (January 1, 2014 to September 30, 2014) (1) Operating Results (cumulative) (D - ---

(1) Operating Results (cum	ulative)				(Percei	ntage indio	cates year-on-yea	ar change)
	Net Sale	es	Operating Inco	me (loss)	Ordinary Incor	ne (loss)	Quarterly Net (loss)	Income
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%
3Q FY 2014	1,348	1.9	(966)	—	(940)	—	(943)	—
3Q FY 2013	1,323	(12.8)	(1,192)	_	(1,187)	_	(1,190)	_

Yes

No

	Quarterly Net Income (loss) per share	Diluted Quarterly Net Income per share
	Yen	Yen
3Q FY 2014	(30.80)	-
3Q FY 2013	(52.93)	_

(Note) Diluted quarterly net income per share is not stated above due to quarterly net loss per share, although there are potential diluted shares.

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	millions of yen	millions of yen	%
3Q FY 2014 (as of September 30, 2014)	6,857	6,593	93.8
FY 2013 (as of December 31, 2013)	7,686	7,432	95.4

(Reference) Equity: 3Q FY 2014 (as of September 30, 2014) FY 2013 (as of December 31, 2013)

6,431 million yen 7,336 million yen

2. Dividends

		Annual Dividend per share						
	1st quarter	1st quarter 2nd quarter 3rd quarter Fiscal Year End						
	Yen	Yen	Yen	Yen	Yen			
FY 2013	-	0.00	_	0.00	0.00			
FY 2014	-	0.00	_					
FY 2014 (Forecast)				0.00	0.00			

(Note) Revisions to the dividends forecasts most recently announced: Yes · No

#### 3. Earnings Forecasts for FY 2014 (January 1, 2014 to December 31, 2014)

(recentage indicates year-on-year change)									
	Net Sa	ales Operating Ordinary Income (loss) Income (loss) Net Income (loss)		1 0		1 8 9		ne (loss)	Net Income (loss) per share
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%	Yen
Full Year	1,785	16.5	(1,654)	—	(1,650)	—	(1,654)	—	(52.63)

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

#### Notes:

- (1) Application of special accounting treatment in preparation of quarterly financial reports:
- (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:
  - (b) Changes in accounting polices due to other reason:
  - (c) Changes in accounting estimates:
  - (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)

	3Q FY 2014	30,724,257 shares	FY 2013	30,634,257 shares
	3Q FY 2014	75 shares	FY 2013	75 shares
1	3Q FY 2014	30,638,138 shares	3Q FY 2013	22,495,451 shares

#### \* The status of the quarterly review

The review of quarterly financial statements as required by the Financial Instruments and Exchange Act is proceeding as of the date of this disclosure document.

#### \* Explanation regarding the appropriate uses of earnings forecasts and other matters

All forecasts presented in this document including earnings forecasts are based on the information currently available to the management and the assumptions that we judge reasonable. Actual results may differ substantially from these forecasts due to various factors. Regarding the assumptions on which the earnings forecasts are based and its usage, please refer to "1. Qualitative Information Concerning Quarterly Financial Results, (3) Qualitative information concerning earnings forecasts" on Page 2 of the attachment.

Yes · No Yes · No Yes · No Yes · No

No

Yes

(Percentage indicates vear-on-vear change)

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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 2014 is as follows:

#### (i) Domestic

[Anticancer agent SyB L-0501 (the generic name: bendamustine hydrochloride, the trade name: TREAKISYM<sup>®</sup>)] The Company has marketed anticancer agent SyB L-0501 in Japan through its business partner Eisai Co., Ltd. (hereinafter "Eisai"), for the indications of refractory/relapsed indolent non-Hodgkin's lymphoma and mantle cell lymphoma.

The Company has also conducted three clinical trials on TREAKISYM® for additional indications.

With respect to the Phase II clinical trial for the indications of previously untreated indolent non-Hodgkin's lymphoma and mantle cell lymphoma, the Company completed the trial in February 2014 and is currently preparing for the application for approval. In the EU, Astellas Pharma Europe Ltd. ("Astellas EU") has already completed the application process for the regulatory approval. Considering this approval progress, the Company plans to file an application for manufacturing and marketing approval in Japan.

The Phase II clinical trial for the indication of chronic lymphocytic leukemia was initiated in May 2013, and progress has been made with enrollment of patients. In this connection, TREAKISYM<sup>®</sup> was designated an orphan drug (pharmaceutical for treatment of rare diseases) for the indication of chronic lymphocytic leukemia during June 2012.

Discussion about future approaches to development for refractory/relapsed aggressive non-Hodgkin's lymphoma is being continued with the Pharmaceuticals and Medical Devices Agency.

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

The Japanese Phase I clinical trial on anticancer agent SyB L-1101 (intravenous formulation) for the indication of refractory/relapsed myelodysplastic syndrome (MDS), which is a hematological malignancy, is in progress.

During February 2014, Onconova Therapeutics, Inc. ("Onconova"), the US company from which these agents were licensed in, released the results of the Phase III clinical trial (ONTIME trial, intravenous formulation), carried out in Europe and the US, in patients with refractory/relapsed (higher risk) MDS. In these results, although no statistically significant difference in the primary endpoint, overall survival time, was found in comparison with the best supportive care (BSC), the results of subpopulation analysis suggest that there was such a statistically significant difference in the group of patients consisting of those who showed progressive disease or no response during previous treatment with hypomethylating agents ("HMA").

Onconova continued its discussions with the US FDA and European regulatory agencies regarding the possibility of approval based on the top-line results of the Phase III ONTIME trial. These discussions have consequently led Onconova to focus its development efforts on the unmet medical need of patients who do not respond to initial treatment with the current standard of care hypomethylating agents ("Primary HMA Failure"). Onconova announced a development plan for Primary HMA Failure.

The Company will continue Phase I clinical trial in Japan and reassess the domestic development plan by contemplating Onconova's development plan which will be announced in due course.

In addition, the Japanese Phase I clinical trial on SyB C-1101 (oral formulation) as a frontline treatment for MDS is being continued.

#### (ii) Overseas

In June 2014, SyB L-0501 was approved in South Korea for the indication of refractory/relapsed indolent non-Hodgkin's lymphoma in addition to the earlier approval for the indications of chronic lymphocytic leukemia and multiple myeloma. Eisai Korea Inc., a Korean subsidiary of Eisai Co., Ltd., promotes the product for these three indications. The Company sells the product in Taiwan through InnoPharmax Inc. In Singapore, the Company sells the product through Eisai, as is the case in Japan or Korea. The Company's sales in each country have been growing steadily as planned.

#### (iii) Business results

As a result of the above, net sales totaled 1,348,206 thousand yen for the third quarter of the fiscal year ending December 31, 2014, primarily reflecting product sales of SyB L-0501 in Japan and overseas. The net domestic sales of TREAKISYM<sup>®</sup> showed a year-on-year increase of 0.4%. Besides, while the net overseas sales increased by 2.3 times compared to the third quarter of the previous year, the milestone revenue showed a year-on-year decrease of 85.0%. In total, the net sales increased by 1.9% compared to the third quarter of the previous year.

SymBio Pharmaceuticals Limited (4582) Summary of Financial Results [Japanese GAAP] (Non-consolidated) Results for the third quarter of fiscal year ending December 31, 2014

On the other hand, selling, general and administrative expenses totaled 1,320,137 thousand yen (a year-on-year decrease of 10.0%), including research and development ("R&D") expenses of 545,345 thousand yen (a year-on-year decrease of 33.2%) primarily due to expenses associated with the clinical trials for SyB L-0501, SyB L-1101 and SyB C-1101, as well as other selling, general and administrative expenses of 774,792 thousand yen (a year-on-year increase of 19.1%).

As a result, operating loss of 966,650 thousand yen was recognized for the third quarter of the fiscal year ending December 31, 2014 (operating loss of 1,192,955 thousand yen for the third quarter of the previous fiscal year). In addition, recording of non-operating income totaling 33,375 thousand yen, primarily comprising foreign exchange gains, led to ordinary loss of 940,772 thousand yen (ordinary loss of 1,187,907 thousand yen for the third quarter of the previous fiscal year) and net loss of 943,652 thousand yen (net loss of 1,190,757 thousand yen for the third quarter of the previous fiscal year).

Segment information is omitted since the Company operates a single segment of pharmaceutical business including research and development of pharmaceutical drugs as well as manufacturing, marketing and other related activities.

#### (2) Qualitative information concerning financial position

Total assets as of September 30, 2014 stood at 6,857,698 thousand yen, a decrease of 829,249 thousand yen from the previous fiscal year end, which consisted of increase in: marketable securities of 395,466 thousand yen, merchandise and finished goods of 110,596 thousand yen, property, plant and equipment of 14,972 thousand yen and intangible assets of 57,344 thousand yen and decrease in: cash and deposits of 1,308,454 thousand yen, prepaid expenses of 21,807 thousand yen, advances paid of 46,143 thousand yen and other current assets of 65,603 thousand yen.

Total liabilities stood at 263,959 thousand yen, an increase of 10,008 thousand yen from the previous fiscal year end, primarily due to an increase in accounts payable of 107,841 thousand yen and a decrease in accounts payable-other of 85,246 thousand yen.

Net assets decreased by 839,257 thousand yen from the previous fiscal year end to 6,593,738 thousand yen primarily due to a net loss of 943,652 thousand yen for the third quarter.

As a result, the equity ratio decreased by 1.6 percentage points to 93.8% from the previous fiscal year end.

#### (3) Qualitative information concerning earnings forecasts

No revision is made to the earnings forecasts for FY 2014 as of the date of this document.

## 2. Quarterly Financial Statements

(1) Balance sheets

		(Unit: thousands of yen)
	FY 2013 (as of December 31, 2013)	3Q FY 2014 (as of September 30, 2014)
Assets		
Current assets		
Cash and deposits	6,163,231	4,854,776
Marketable securities	1,100,270	1,495,736
Merchandise and finished goods	125,056	235,652
Prepaid expenses	64,306	42,499
Advances paid	87,862	41,718
Other	93,235	27,631
Total current assets	7,633,962	6,698,014
Noncurrent assets		
Property, plant and equipment		
Buildings, net	2,444	1,978
Tools, furniture and fixtures, net	6,187	21,626
Total property, plant and equipment	8,632	23,604
Intangible assets		
Software	5,898	4,368
Software in progress	-	59,361
Lease assets	1,891	1,405
Total intangible assets	7,789	65,134
Investments and other assets		
Long-term prepaid expenses	9,427	2,160
Lease and guarantee deposits	27,135	68,783
Total investments and other assets	36,562	70,944
Total noncurrent assets	52,985	159,683
Total assets	7,686,947	6,857,698
Liabilities		
Current liabilities		
Accounts payable-trade	_	107,841
Accounts payable-other	207,134	121,888
Income taxes payable	22,554	9,465
Other	21,252	22,340
Total current liabilities	250,941	261,535
Noncurrent liabilities		
Provision for retirement benefits	1,675	1,608
Other	1,334	816
Total noncurrent liabilities	3,009	2,424
Total liabilities	253,950	263,959
	,	,

SymBio Pharmaceuticals Limited (4582) Summary of Financial Results [Japanese GAAP] (Non-consolidated) Results for the third quarter of fiscal year ending December 31, 2014

		(Unit: thousands of yen)
	FY 2013 (as of December 31, 2013)	3Q FY 2014 (as of September 30, 2014)
Net assets		
Shareholders' equity		
Capital stock	8,058,860	8,080,775
Capital surplus	8,028,860	8,050,775
Retained earnings	(8,751,636)	(9,695,288)
Treasury stock	(17)	(17)
Total shareholders' equity	7,336,067	6,436,245
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	167	(4,264)
Total valuation and translation adjustments	167	(4,264)
Stock acquisition rights	96,761	161,757
Total net assets	7,432,996	6,593,738
Total liabilities and net assets	7,686,947	6,857,698

(2) Statements of operations (cumulative)

(For the third quarter of the fiscal year ending December 31, 2014)

		(Unit: thousands of yen)
	3Q FY 2013 (from January 1, 2013 to September 30, 2013)	3Q FY 2014 (from January 1, 2014 to September 30, 2014)
Net sales	1,323,544	1,348,206
Cost of sales	1,050,394	994,719
Gross profit	273,150	353,487
Selling, general and administrative expenses	1,466,105	1,320,137
Operating loss	(1,192,955)	(966,650)
Non-operating income		
Interest income	4,853	11,797
Interest on securities	2,176	6,612
Gain on sales of securities	5,354	-
Interest on tax refunded	104	44
Dividend income of insurance	1,104	1,116
Foreign exchange gain	4,275	13,635
Other	172	169
Total non-operating income	18,041	33,375
Non-operating expenses		
Interest expenses	24	63
Commission fee	8,077	7,180
Stock issuance cost	4,791	254
Other	100	-
Total non-operating expenses	12,994	7,498
Ordinary loss	(1,187,907)	(940,772)
Extraordinary income		
Gain on reversal of stock acquisition rights		317
Total extraordinary income		317
Extraordinary loss		
Loss on retirement of non-current assets	—	347
Total extraordinary loss		347
Loss before income taxes	(1,187,907)	(940,802)
Income taxes-current	2,850	2,850
Total income taxes	2,850	2,850
Net loss	(1,190,757)	(943,652)

#### (3) Notes on quarterly financial statements

(Notes concerning going concern assumption) None to report

(Notes concerning significant changes in shareholders' equity)

No significant changes in the amount of shareholders' equity compared to previous fiscal year end.

(Significant subsequent events)

None to report