

# **Summary of Financial Results** for the First Quarter of Fiscal Year Ending December 31, 2015 [Japanese GAAP] (Non-consolidated)

May 7, 2015

Company Name SymBio Pharmaceuticals Limited		Listing: Tokyo Securities Exchange			
Securities Code	4582	URL: http://www.sym	biopharma.com/		
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida			
Contact Person	Chief Financial Officer	Kazuyasu Hakata	TEL 03 (5472) 1125		
Scheduled Date to File Quarterly Report	May 8, 2015	Date of dividend payment (plan)	-		
Supplementary materials for qu	uarterly financial results: Yes	No			

Yes

No

Holding of quarterly earnings performance review:

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SymBio Pharmaceuticals Limited

1. Business Results for the First Quarter of FY 2015 (January 1, 2015 to March 31, 2015) (1) Operating Results (cumulative)

(1) Operating Results (cumulative) (Percentage)							ndicates year-on-y	ear change)
	Net Sales Operating Income (loss)			Ordinary Income (loss)		Quarterly Net Incom (loss)		
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%
1Q FY 2015	408	135.0	(332)	_	(418)	—	(420)	—
1Q FY 2014	173	(64.5)	(415)		(453)	-	(454)	—

	Quarterly Net Income (loss) per share	Diluted Quarterly Net Income per share
	Yen	Yen
1Q FY 2015	(12.98)	-
1Q FY 2014	(14.85)	_

(Note) Diluted quarterly net income per share not stated above due to quarterly net loss per share, despite the potential dilution of shares.

(2) Financial Position

English translation

	Total Assets	Net Assets	Equity Ratio
	millions of yen	millions of yen	%
1Q FY 2015 (as of March 31, 2015)	7,017	6,566	90.4
FY 2014 (as of December 31, 2014)	7,453	6,963	90.7

(Reference) Equity: 1Q FY 2015 (as of March 31, 2015)

FY 2014 (as of December 31, 2014)

6,342 million yen 6,763 million yen

2. Dividend

	Annual Dividend per Share						
	1st quarter	1st quarter 2nd quarter 3rd quarter Fiscal Year End Fu					
	Yen	Yen	Yen	Yen	Yen		
FY 2014	-	0.00	_	0.00	0.00		
FY 2015	-						
FY 2015 (Forecast)		0.00	-	0.00	0.00		
(Note) Revision of dividend forecasts recently announced: Yes No							

(Note) Revision of dividend forecasts recently announced:

Yes No

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

	Net Sales		OperatingOrdinaryIncome (loss)Income (loss)		ales Net Income (Joss)		1 0		e (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) Revision of earnings forecasts recently announced: Yes No										

Yes

#### 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 correction
  - (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 correction:
- (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)

1Q FY 2015	32,390,923 shares	FY 2014	32,390,923 shares
1Q FY 2015	75 shares	FY 2014	75 shares
1Q FY 2015	32,390,848 shares	1Q FY 2014	30,634,182 shares

#### \* Status of quarterly review

The 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 2 of the attachment.

Yes No Yes No Yes No Yes No

No

(Percentage indicates year-on-year 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 first quarter of FY 2015 is as follows:

(i) Domestic

[SyB L-0501 (generic name: bendamustine hydrochloride, trade name: TREAKISYM<sup>®</sup>)]

The Company markets the anticancer agent TREAKISYM<sup>®</sup> 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 the Phase II clinical trial in February, 2014, and is currently preparing the application to be submitted for marketing approval. In the EU, Astellas Pharma Europe Ltd. has already completed the application process for regulatory approval. Considering this review process toward securing marketing approval in Europe, the Company plans to file the supplemental NDA in Japan;

Secondly, regarding the indication of chronic lymphocytic leukemia, patient enrollment for the Phase II clinical trial was completed in October, 2014, and necessary procedures followed. The Company plans to complete the clinical trial as soon as possible followed by submission of the supplemental NDA. TREAKISYM® was designated as an orphan drug (pharmaceutical for treatment of rare diseases) for the indication of chronic lymphocytic leukemia in June, 2012. Thirdly, regarding the additional indication of refractory/relapsed intermediate/high-grade non-Hodgkin's lymphoma, the Company's approach to development is being considered.

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

The domestic Phase I clinical trial of anticancer agent SyB L-1101 (intravenous formulation, or "IV rigosertib") for the indication of refractory/relapsed higher risk myelodysplastic syndrome (MDS), a hematological malignancy, is underway. Patient enrollment was completed in January, 2015.

In February, 2014, Onconova Therapeutics, Inc. ("Onconova"), the U.S. Licensor, announced the results from its Phase III ONTIME trial of IV rigosertib conducted at clinical trial sites in Europe and the U.S. Although treatment with IV rigosertib plus best supportive care (BSC) did not demonstrate a statistically significant improvement in median overall survival when compared to BSC only, post-hoc analysis demonstrated a statistically significant increase in median overall survival in the subset of patients who had progressed on or failed previous treatment with hypomethylating agents (HMAs) (i.e., had not responded to HMAs), thus demonstrating potential activity of rigosertib in these MDS patients. Onconova continues to discuss with the U.S. and European regulatory agencies the possibility of marketing approval based on 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 treatment with HMAs, the current standard of care ("Primary HMA Failure"). Onconova has announced its future development plan for Primary HMA Failures.

The Company will complete phase 1 of its development program for IV rigosertib in higher risk MDS in Japan. Based on Onconova's development plan in the US and Europe, the Company will consider the future development of rigosertib in Japan.

As for SyB C-1101 (oral formulation, or "Oral rigosertib"), the Phase I clinical trial for the target indication of higher risk MDS is also underway. With the completion of patient enrollment in August, 2014, the Company continues to meet regulatory requirements toward completion of its development program for Oral rigosertib in Japan. The Company plans to complete clinical trials as soon as possible, and develop Oral rigosertib in combination with azacitidine for higher risk MDS as well as for transfusion-dependent lower risk MDS.

#### (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 408,221 thousand yen for the first 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 2.1 times compared to the first quarter of the previous year due to adjustments in inventory levels in the previous year. Thus, net sales showed a year-on-year increase of 135.0%.

Selling, general and administrative expenses totaled 452,711 thousand yen (a year-on-year increase of 1.1%), including

SymBio Pharmaceuticals Limited (4582) Summary of Financial Results [Japanese GAAP] (Non-consolidated) Results for the first quarter of fiscal year ending December 31, 2015

research and development ("R&D") expenses of 206,178 thousand yen (a year-on-year increase of 15.2%) 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 246,532 thousand yen (a year-on-year decrease of 8.3%).

As a result, an operating loss of 332,295 thousand yen was recognized for the first quarter of fiscal year ending December 31, 2015 (operating loss of 415,544 thousand yen for the first quarter of the previous fiscal year). In addition, the Company recorded non-operating expenses totaling 91,460 thousand yen primarily comprising foreign exchange loss. This resulted in an ordinary loss of 418,875 thousand yen (ordinary loss of 453,905 thousand yen for the first quarter of the previous fiscal year) and net loss of 420,496 thousand yen (net loss of 454,855 thousand yen for the first 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 March 31, 2015 stood at 7,017,314 thousand yen, a decrease of 436,484 thousand yen from the previous fiscal year end, which consisted of an increase in cash and deposits of 288,840 thousand yen, and decrease in marketable securities of 399,826 thousand yen, in accounts receivable-trade of 231,986 thousand yen, in merchandise and finished goods of 15,194 thousand yen, and in other current assets of 65,152 thousand yen.

Total liabilities stood at 450,941 thousand yen, a decrease of 39,281 thousand yen from the previous fiscal year end, primarily due to an increase in other current liabilities of 39,249 thousand yen, and decrease in accounts payable-trade of 43,647 thousand yen and accounts payable-other of 23,216 thousand yen.

Net assets decreased by 397,202 thousand yen from the previous fiscal year end to 6,566,373 thousand yen primarily due to a net loss of 420,496 thousand yen for the first quarter.

As a result, the equity ratio decreased by 0.3 percentage points to 90.4% 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

		(Unit: thousands of yen)
	FY 2014 (as of December 31, 2014)	1Q FY 2015 (as of March 31, 2015)
Assets		
Current assets		
Cash and deposits	5,692,075	5,980,916
Accounts receivable-trade	272,656	40,669
Marketable securities	899,256	499,430
Merchandise and finished goods	244,588	229,394
Prepaid expenses	36,690	36,915
Advances paid	59,840	50,666
Other	84,981	19,828
Total current assets	7,290,088	6,857,819
Noncurrent assets		
Property, plant and equipment		
Buildings, net	21,554	22,198
Tools, furniture and fixtures, net	27,441	25,044
Total property, plant and equipment	48,996	47,242
Intangible assets		
Software	62,273	61,857
Software in progress	2,556	_
Lease assets	1,243	1,081
Total intangible assets	66,073	62,938
Investments and other assets		
Long-term prepaid expenses	1,351	267
Lease and guarantee deposits	47,289	49,047
Total investments and other assets	48,641	49,314
Total noncurrent assets	163,710	159,495
Total assets	7,453,799	7,017,314
Liabilities		
Current liabilities		
Accounts payable-trade	305,996	262,348
Accounts payable-other	142,884	119,667
Income taxes payable	21,254	9,699
Other	17,811	57,060
Total current liabilities	487,946	448,776
Noncurrent liabilities		
Provision for retirement benefits	1,634	1,697
Other	642	468
Total noncurrent liabilities	2,276	2,165
Total liabilities	490,223	450,941
		150,941

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		(Unit: thousands of yen)
	FY 2014 (as of December 31, 2014)	1Q FY 2015 (as of March 31, 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)	(10,288,010)
Treasury stock	(17)	(17)
Total shareholders' equity	6,764,019	6,343,523
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(744)	(570)
Total valuation and translation adjustments	(744)	(570)
Stock acquisition rights	200,300	223,420
Total net assets	6,963,576	6,566,373
Total liabilities and net assets	7,453,799	7,017,314

(2) Statement of operations (cumulative)

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

		(Unit: thousands of yen)
	1Q FY 2014 (From January 1, 2014 To March 31, 2014)	1Q FY 2015 (From January 1, 2015 To March 31, 2015)
Net sales	173,681	408,221
Cost of sales	141,322	287,805
Gross profit	32,359	120,416
Selling, general and administrative expenses	447,904	452,711
Operating loss	(415,544)	(332,295)
Non-operating income		
Interest income	3,692	3,967
Interest on securities	2,345	895
Other	197	18
Total non-operating income	6,235	4,880
Non-operating expenses		
Interest expenses	51	4
Commission fees	2,367	2,213
Stock issuance costs	101	160
Foreign exchange loss	42,076	88,501
Other		581
Total non-operating expenses	44,596	91,460
Ordinary loss	(453,905)	(418,875)
Extraordinary income		
Gain on reversal of stock acquisition rights	_	366
Total extraordinary income	_	366
Extraordinary loss		
Loss on retirement of non-current assets	-	1,037
Total extraordinary loss		1,037
Loss before income tax	(453,905)	(419,546)
Income taxes-current	950	950
Total income taxes	950	950
Net loss	(454,855)	(420,496)

(3) 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)

(a) Issuance of stock acquisition rights (stock option) to the Company's Directors

At the Board of Directors' meeting held on March 26, 2015, a resolution was passed regarding the issuance of stock acquisition rights as a stock option to six (6) Directors of the Company as follows. The stock option was allotted to relevant Directors on the allotment date of April 10, 2015.

Number of stock option	2,042 units
Class and number of shares underlying the stock option	Common stock 204,200 shares
Issue price/ Total issue price	Issue price 30,600 yen
of the stock option	Total issue price 62,485,200 yen
Amount to be paid in for the stock option	Amount to be paid in: 306 yen per share The person who receives the allotment of stock acquisition rights shall set off his/her claims for compensation against the Company in lieu of payment of monies for the stock acquisition rights allotted.
Exercise price of the stock option	Exercise price per share of 1 yen
Period during which the stock option can be exercised	From March 27, 2018 to March 26, 2025
Terms and conditions for exercise of the stock option	<ol> <li>The person allotted shall be a director or an employee of the Company or its affiliate at the time of exercise. However, the terms and conditions for the exercise of stock option described herein shall not apply when: (a) the person resigns from the Company or its affiliate due to the expiry of her/his term, (b) the person retires from the Company or its affiliate due to compulsory retirement age or (c) the Board of Directors resolves that he/she has resigned or retired on an amicable basis.</li> <li>For other terms and conditions, the Company and Directors shall comply with the "Stock Option Allotment Agreement" concluded between the parties.</li> </ol>
Paid-in capital amount increased due to the issuance of shares upon exercise of the stock option	Increase in the amount of paid-in capital due to the issuance of shares upon the exercise of stock option shall be half of the maximum amount of paid-in capital increase and others, which is calculated in accordance with Article 17 of the Corporation Accounting Regulations, and any fraction less than one (1) yen arising therefrom shall be rounded up to the nearest one (1) yen.
Matters concerning transfer of the stock option	Requires approval at the Board of Directors' meeting.

(b) Issuance of stock acquisition rights (stock option) to the Company's employees

At the Board of Directors' meeting held on March 26, 2015, a resolution was passed regarding the issuance of stock acquisition rights as a stock option to 61 Company employees as follows. The stock option was allotted to relevant employees on the allotment date of April 10, 2015.

Number of stock option	3,120 units
Class and number of shares underlying the stock option	Common stock 312,000 shares
Issue price/ Total issue price	Issue price 30,600 yen
of the stock option	Total issue price 95,472,000 yen
Amount to be pain in for the stock option	Amount to be paid in: 306 yen per share The person who receives the allotment of stock acquisition rights shall set off his/her claims for compensation against the Company in lieu of payment of monies for the stock acquisition rights allotted.
Exercise price of the stock option	Exercise price per share of 1 yen
Period during which the stock option can be exercised	From March 27, 2018 to March 26, 2025
Terms and conditions for exercise of the stock option	<ol> <li>The person allotted shall be a director or employee of the Company or its affiliate at the time of exercise. However, the terms and conditions for the exercise of stock option described herein shall not apply when: (a) the person resigns from the Company or its affiliate due to the expiry of her/his term, (b) the person has retires from the Company or its affiliate due to compulsory retirement age or (c) the Board of Directors resolves that he/she has resigned or retired on an amicable basis.</li> <li>(2) For other terms and conditions, the Company and Company employees shall comply with the "Stock Option Allotment Agreement" concluded between the parties.</li> </ol>
Paid-in capital amount increased due to the issuance of shares upon exercise of the stock option	Increase in the amount of paid-in capital due to the issuance of shares upon the exercise of stock option shall be half of the maximum amount of paid-in capital increase and others, which is calculated in accordance with Article 17 of the Corporation Accounting Regulations, and any fraction less than one (1) yen arising therefrom shall be rounded up to the nearest one (1) yen.
Matters concerning transfer of the stock option	Requires approval at the Board of Directors' meeting.