English translation

SymBio Pharmaceuticals Limited

Summary of Financial Results
for the Second Quarter of Fiscal Year Ending December 31, 2016
[Japanese GAAP] (Non-consolidated)

August 4, 2016

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	
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Scheduled Date to File Quarterly Report	August 5, 2016	Date of Dividend Payment (plan)	–

Supplementary materials for quarterly financial results: Yes [No]

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

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

1. Business Results for the Second Quarter of FY 2016 (January 1, 2016 to June 30, 2016)

(1) Operating Results (cumulative) (Percentages indicate year-on-year changes)

	Net Sales		Operating Income (loss)		Ordinary Income (loss)		Quarterly Net Income (loss)	
	millions of yen	%	millions of yen	%	millions of yen	%	millions of yen	%
2Q FY 2016	1,210	24.0	(819)	–	(1,177)	–	(1,175)	–
2Q FY 2015	976	0.1	(647)	–	(673)	–	(676)	–

	Quarterly Net Income (loss) per share	Diluted Quarterly Net Income per share
	Yen	Yen
2Q FY 2016	(33.93)	–
2Q FY 2015	(20.88)	–

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	millions of yen	millions of yen	%
2Q FY 2016 (as of June 30, 2016)	7,477	5,429	67.8
FY 2015 (as of December 31, 2015)	4,984	4,431	82.9

(Reference) Equity: 2Q FY 2016 (as of June 30, 2016) 5,066 million yen

FY 2015 (as of December 31, 2015) 4,131 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 2015	–	0.00	–	0.00	0.00
FY 2016	–	0.00			
FY 2016 (Forecast)			–	0.00	0.00

(Note) Revision of dividend forecasts recently announced: Yes ・ [No]

3. Earnings Forecasts for FY 2016 (January 1, 2016 to December 31, 2016)

(Percentages indicate year-on-year changes)

	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	2,339	21.0	(2,778)	—	(2,811)	—	(2,815)	—	(68.33)

(Note) Revision of 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 policies due to revision of accounting standards: Yes ・ No

(b) Changes in accounting policies due to other reasons: Yes ・ No

(c) Changes in accounting estimates: Yes ・ No

(d) Restatements after error correction: Yes ・ No

(3) Number of shares outstanding (common stock)

(i) Number of shares outstanding at the end of the period (including treasury stock)	2Q FY 2016	41,199,074 shares	FY 2015	32,390,923 shares
(ii) Number of shares of treasury stock at the end of the period	2Q FY 2016	75 shares	FY 2015	75 shares
(iii) Average number of shares during the period (cumulative)	2Q FY 2016	34,643,145 shares	2Q FY 2015	32,390,848 shares

* Status of quarterly review

The review of quarterly financial statements as required by the Financial Instruments and Exchange Act was underway 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 assumptions judged to be reasonable. Actual results may differ substantially from these forecasts due to various factors. Regarding the 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.

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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 second quarter of FY 2016 is as follows:

(i) Domestic

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

The Company markets 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.

For patients who need new therapies and to maximize the product value of TREAKISYM®, the Company continues to pursue three additional indications:

Regarding the indications of first-line low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, the Company filed a supplemental New Drug Application (sNDA) in Japan to the Pharmaceuticals and Medical Devices Agency ("PMDA") in December 2015. In the EU, the Company received a notice from Astellas Pharma GmbH (Head office: Germany) that they withdrew their application in January 2016. However, the Company has continued with procedures for approval in Japan in consultation with the PMDA.

Regarding the indication of chronic lymphocytic leukemia, the Company filed a sNDA in Japan in December 2015; this was followed by a specialist consultation by the PMDA in June 2016. Approval processes are underway towards early approval. 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 in Japan, requested the Company to further develop TREAKISYM®.

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.

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

For the global Phase III trial of the intravenous formulation of rigosertib conducted by Onconova Therapeutics, Inc. (Head office: Pennsylvania, U.S.; "Onconova"), the U.S. Licensor of the agent, the Company is in charge of the clinical development in Japan and has started the domestic trial in December 2015. The global Phase III trial is conducted with clinical trial sites in more than ten countries worldwide, for higher-risk myelodysplastic syndrome (HR-MDS) patients who do not respond to the current standard treatment with hypomethylating agents (HMAs) or who relapse after treatment under the current standard of care ("primary HMA failure"). The Company worked on procedures to enroll patients with the disease and accordingly completed the first patient enrollment in July 2016, after the end of the second quarter of fiscal year ending December 31, 2016.

Regarding the oral formulation of rigosertib, the Company started its domestic Phase I clinical trial of the oral formulation of rigosertib in combination with azacitidine (Note) for the target indication of HR-MDS in December 2015, but the provision of the investigational drug of this clinical trial has been delayed, and at present, patient enrollment has not yet been started. As soon as this issue is resolved, the Company will commence patient enrollment, complete this clinical trial as planned, and consider its participation in the global Phase III clinical trial to be conducted by Onconova.

(Note) About azacitidine (Vidaza®: currently marketed by Nippon Shinyaku Co., Ltd.): This drug was confirmed to extend overall survival for the first time in the Phase III clinical trial for the indication of HR-MDS, and was approved in Japan in 2011. It is currently used as a first-line drug for MDS patients who have difficulties in hematopoietic stem cell transplantation.

[Patient-controlled iontophoretic transdermal system for the short-term management of acute postoperative pain: SyB P-1501]

In October 2015, the Company entered into an agreement with Incline Therapeutics, Inc., a wholly-owned subsidiary of U.S.-based The Medicines Company (Head office: New Jersey, U.S.), for an exclusive license to develop and commercialize in Japan SyB P-1501. The Company commenced a domestic Phase III clinical trial for SyB P-1501 in June, examining the applicability of the drug for inpatients to control short-term acute postoperative pain. The Company intends to complete the Phase III clinical trial at the earliest possible time, with the aim of obtaining approval by the end of 2019.

[New drug candidates]

The Company continued with search and evaluation activities to acquire license rights of new drug candidates in global terms, aiming to grow into a bio-pharmaceutical company with both profitability and growth potential, always from a medium-to-long-term perspective.

Meanwhile, in May 2016, the Company established a wholly-owned subsidiary, SymBio Pharma USA, Inc. (Head office: Menlo Park, California, U.S., "SymBio Pharma USA"), as the Company's strategic base for its overseas business development. The Company will accelerate its transformation into a global specialty bio-pharmaceutical company by actively acquiring the worldwide rights concerning new drug candidates, developing and commercializing new drugs in the U.S., Japan, Europe and other global major markets.

(ii) Overseas

SyB L-0501 is also marketed in South Korea, Taiwan and Singapore, and product sales of SyB L-0501 in these countries grew steadily as planned.

(iii) Business results

As a result of the above, net sales totaled 1,210,725 thousand yen for the second quarter of fiscal year ending December 31, 2016, primarily reflecting product sales of TREAKISYM® in Japan. Product sales showed a year-on-year increase of 20.9%, and the Company recorded non-recurring revenue resulting from achieving the sales milestone of SyB L-0501 in Taiwan. Accordingly, overall net sales rose 24.0% year-on-year.

Selling, general and administrative expenses totaled 1,224,729 thousand yen (a year-on-year increase of 31.6%), including research and development ("R&D") expenses of 518,349 thousand yen (a year-on-year increase of 28.4%) primarily due to expenses associated with the clinical trial for the intravenous and oral formulations of rigosertib and preparations for the clinical trial of SyB P-1501, and other selling, general and administrative expenses of 706,379 thousand yen (a year-on-year increase of 34.1%) primarily due to expenses associated with negotiating license agreements for new drug candidates or takeovers of firms that are in possession of new drug candidates.

As a result, operating loss of 819,937 thousand yen was recognized for the second quarter of fiscal year ending December 31, 2016 (operating loss of 647,968 thousand yen for the second quarter of the previous fiscal year). In addition, mainly because the Company recorded non-operating expenses totaling 360,324 thousand yen primarily comprising foreign exchange loss, ordinary loss totaled 1,177,202 thousand yen (ordinary loss of 673,992 thousand yen for the second quarter of the previous fiscal year) and net loss totaled 1,175,338 thousand yen (net loss of 676,424 thousand yen for the second 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 June 30, 2016 stood at 7,477,080 thousand yen, an increase of 2,492,790 thousand yen from the previous fiscal year end. This was primarily due to increases of 2,000,000 thousand yen in marketable securities, 570,483 thousand yen in cash and deposits, 43,601 thousand yen in accounts receivable-trade, 24,329 thousand yen in prepaid expenses and 13,310 thousand yen in tools, furniture and fixtures, offsetting decreases of 133,029 thousand yen in merchandise and finished goods and 25,569 thousand yen in advances paid.

Liabilities stood at 2,047,676 thousand yen, an increase of 1,495,199 thousand yen from the previous fiscal year end. This was primarily due to a decrease of 110,837 thousand yen in accounts payable-trade which was offset by increases of 1,575,000 thousand yen in bonds payable and 12,315 thousand yen in income taxes payable.

Net assets increased by 997,591 thousand yen from the previous fiscal year end to 5,429,403 thousand yen, due to the issuance of new shares and stock acquisition rights, offsetting a decrease of 1,175,338 thousand yen in retained earnings following the recognition of net loss.

As a result, the equity ratio decreased by 15.1 percentage points from the previous fiscal year end to 67.8%.

(3) Qualitative information concerning earnings forecasts

No revision was made to the earnings forecasts for FY 2016 as of the date of this document.

2. Quarterly Financial Statements

(1) Balance sheets

(Unit: thousands of yen)

	FY 2015 (as of December 31, 2015)	2Q FY 2016 (as of June 30, 2016)
Assets		
Current assets		
Cash and deposits	4,261,438	4,831,922
Accounts receivable-trade	300,742	344,344
Marketable securities	—	2,000,000
Merchandise and finished goods	133,029	—
Prepaid expenses	38,591	62,920
Advances paid	79,639	54,069
Other	13,337	22,613
Total current assets	4,826,778	7,315,870
Non-current assets		
Property, plant and equipment		
Buildings, net	22,208	21,493
Tools, furniture and fixtures, net	30,747	44,058
Total property, plant and equipment	52,956	65,552
Intangible assets		
Software	50,506	42,084
Software in progress	900	1,250
Lease assets	594	270
Total intangible assets	52,001	43,604
Investments and other assets		
Shares of subsidiaries	—	0
Long-term prepaid expenses	1,227	903
Lease and guarantee deposits	51,326	51,148
Total investments and other assets	52,553	52,052
Total non-current assets	157,510	161,209
Total assets	4,984,289	7,477,080
Liabilities		
Current liabilities		
Accounts payable-trade	319,866	209,029
Accounts payable-other	183,690	192,623
Income taxes payable	14,183	26,498
Forward exchange contracts	14,999	24,559
Other	18,200	18,629
Total current liabilities	550,940	471,338
Non-current liabilities		
Bonds payable	—	1,575,000
Provision for retirement benefits	1,537	1,338
Total non-current liabilities	1,537	1,576,338
Total liabilities	552,477	2,047,676

(Unit: thousands of yen)

	FY 2015 (as of December 31, 2015)	2Q FY 2016 (as of June 30, 2016)
Net assets		
Shareholders' equity		
Common stock	8,330,775	9,385,798
Capital surplus	8,300,775	9,355,798
Retained earnings	(12,499,609)	(13,674,948)
Treasury stock	(17)	(17)
Total shareholders' equity	4,131,924	5,066,629
Stock acquisition rights	299,887	362,773
Total net assets	4,431,811	5,429,403
Total liabilities and net assets	4,984,289	7,477,080

(2) Statements of operations (cumulative)

(For the second quarter of the fiscal year ending December 31, 2016)

(Unit: thousands of yen)

	2Q FY 2015 (from January 1, 2015 to June 30, 2015)	2Q FY 2016 (from January 1, 2016 to June 30, 2016)
Net sales	976,194	1,210,725
Cost of goods sold	693,610	805,933
Gross profit	282,584	404,792
Selling, general and administrative expenses	930,553	1,224,729
Operating loss	(647,968)	(819,937)
Non-operating income		
Interest income	6,919	2,973
Interest on securities	1,700	81
Other	24	4
Total non-operating income	8,645	3,058
Non-operating expenses		
Interest expenses	7	3
Commission fees	4,450	4,487
Stock issuance costs	160	7,497
Foreign exchange losses	29,379	330,411
Other	671	17,925
Total non-operating expenses	34,669	360,324
Ordinary loss	(673,992)	(1,177,202)
Extraordinary gain		
Gain on reversal of stock acquisition rights	689	4,903
Total extraordinary gain	689	4,903
Extraordinary loss		
Loss on retirement of non-current assets	1,221	1,139
Total extraordinary losses	1,221	1,139
Loss before income taxes	(674,524)	(1,173,438)
Income taxes-current	1,900	1,900
Total income taxes	1,900	1,900
Net loss	(676,424)	(1,175,338)

(3) Quarterly cash flow statements

(Unit: thousands of yen)

	First six months of Fiscal 2015 (from January 1, 2015 to June 30, 2015)	First six months of Fiscal 2016 (from January 1, 2016 to June 30, 2016)
Net cash provided by (used in) operating activities		
Quarterly (loss) before income taxes	(674,524)	(1,173,438)
Depreciation	11,715	12,704
Share-based compensation expenses	49,076	65,039
Increase (decrease) in provision for retirement benefits	(207)	(199)
Interest income	(8,620)	(3,054)
Interest expenses	7	3
Foreign exchange losses (gains)	4,190	359,903
Commission fees	4,450	4,487
Stock issuance cost	160	7,497
Gain on reversal of stock acquisition rights	(689)	(4,903)
Loss on retirement of non-current assets	1,221	1,139
Decrease (increase) in accounts receivable	22,852	(43,601)
Decrease (increase) in inventories	(191,482)	133,029
Decrease (increase) in prepaid expenses	9,711	(28,817)
Decrease (increase) in advances paid	12,513	25,569
Decrease (increase) in consumption taxes receivable	3,655	―
Decrease (increase) in current assets-other	20,540	469
Decrease (increase) in long-term prepaid expenses	1,151	323
Increase (decrease) in accounts payable-trade	268,298	(110,837)
Increase (decrease) in accounts payable-other	(34,930)	9,193
Increase (decrease) in other current liabilities	(522)	13,535
Other	(1,488)	17,925
Subtotal	(502,918)	(714,030)
Interest and dividends income received	8,434	2,868
Interest expenses paid	(7)	(3)
Income taxes paid	(1,900)	(1,900)
Net cash provided by (used in) operating activities	(496,391)	(713,064)
Net cash provided by (used in) investing activities		
Proceeds from redemption of securities	400,000	―
Purchase of shares of subsidiaries	―	(0)
Purchase of property, plant and equipment	(11,974)	(18,939)
Purchase of intangible assets	(900)	(1,250)
Payments for lease and guarantee deposits	(432)	(218)
Proceeds from collection of lease and guarantee deposits	16,420	―
Net cash provided by (used in) investing activities	403,113	(20,407)

(Unit: thousands of yen)

	First six months of Fiscal 2015 (from January 1, 2015 to June 30, 2015)	First six months of Fiscal 2016 (from January 1, 2016 to June 30, 2016)
Net cash provided by (used in) financing activities		
Proceeds from issuance of shares resulting from exercise of stock acquisition rights	—	678,018
Proceeds from issuance of bonds with stock acquisition rights	—	3,000,000
Proceeds from issuance of stock acquisition rights	—	9,776
Payments for issuance of common stock	(1,850)	(5,659)
Repayments for lease obligations	(344)	(349)
Other payments	(90)	(17,925)
Net cash provided by (used in) financing activities	(2,284)	3,663,859
Effect of foreign exchange rate change on cash and cash equivalents	(4,190)	(359,903)
Net increase (decrease) in cash and cash equivalents	(99,753)	2,570,483
Cash and cash equivalents at the beginning of the period	5,092,075	4,261,438
Cash and cash equivalents at the end of the period	4,992,321	6,831,922

(4) Notes on quarterly financial statements

(Notes regarding going concern assumption)

None to be reported.

(Notes regarding significant changes in shareholders' equity)

During the second quarter of fiscal year ending December 31, 2016, common stock and legal capital surplus increased by 712,500 thousand yen and 712,500 thousand yen respectively. This was due to the conversion into new shares in response to the exercise of part of stock acquisition rights granted to the 3rd unsecured convertible bonds. In addition, following the issuance of new shares upon the exercise of part of the 34th stock acquisition rights, common stock and legal capital surplus increased by 342,522 thousand yen and 342,522 thousand yen respectively.

As a result, common stock and legal capital surplus increased by 1,055,022 thousand yen and 1,055,022 thousand yen respectively, amounting to 9,385,798 thousand yen and 9,355,798 thousand yen respectively as of June 30, 2016.

(Significant subsequent events)

Issuance of new shares on the exercise of stock acquisition rights for bonds with stock acquisition rights

During the period from July 1, 2016 to August 4, 2016, a portion of the 3rd unsecured convertible bonds with stock acquisition rights was converted into new shares based on the exercise of rights. The summary of such exercise of the stock acquisition rights is as follows.

Number and type of shares issued:	710,900 shares of common stock
Total amount issued:	150,000 thousand yen
Decrease in convertible bonds with stock acquisition rights	150,000 thousand yen
Amount transferred to capital from the total amount issued:	75,000 thousand yen