English translation

SymBio Pharmaceuticals Limited

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

November 11, 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	
Contact Person	Director, Finance & Accounting	Makio Yamaguchi	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	November 14, 2016	Date of Dividend Payment (plan)	―

Supplementary materials for quarterly financial results: Yes [No]

Holding of quarterly earnings performance review: Yes [No]

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

1. Business Results for the Third Quarter of FY 2016 (January 1, 2016 to September 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	%
3Q FY 2016	1,407	5.6	(1,532)	―	(1,916)	―	(1,915)	―
3Q FY 2015	1,332	(1.2)	(987)	―	(1,056)	―	(1,059)	―

	Quarterly Net Income (loss) per share	Diluted Quarterly Net Income per share
	Yen	Yen
3Q FY 2016	(51.61)	―
3Q FY 2015	(32.71)	―

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	millions of yen	millions of yen	%
3Q FY 2016 (as of September 30, 2016)	6,987	5,629	74.8
FY 2015 (as of December 31, 2015)	4,984	4,431	82.9

(Reference) Equity: 3Q FY 2016 (as of September 30, 2016) 5,226 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)	—	(71.77)

(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)	3Q FY 2016	45,464,474 shares	FY 2015	32,390,923 shares
(ii) Number of shares of treasury stock at the end of the period	3Q FY 2016	75 shares	FY 2015	75 shares
(iii) Average number of shares during the period (cumulative)	3Q FY 2016	37,123,292 shares	3Q 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 summary of financial results.

* 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 Companyôs earnings forecasts are based and their usage, please refer to ñ1. Qualitative Information Concerning Quarterly Financial Results, and (3) Qualitative information concerning earnings forecasts,ò 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 Companyôs business for the third 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. (ñEisaiò), for the indications of refractory/relapsed low-grade non-Hodgkinôs lymphoma and mantle cell lymphoma. Net sales through Eisai increased as expected.

By pursuing four indications, the Company has already obtained approvals for two indications, and continues to pursue approval for the remaining two additional indications, for patients who need new therapies and for maximizing the business value of TREAKISYM®.

The Company filed a supplemental New Drug Application (sNDA) in Japan in December 2015 for the indication of chronic lymphocytic leukemia, and obtained approval for the additional indication in August 2016. The Company has developed and applied for this indication upon request of the Ministry of Health, Labour and Welfare in Japan as one of the ñUnapproved or Off-Labeled Drugs with High Medical Needs.ò This is the second approval after the approval of an sNDA for the indication of refractory/relapsed low-grade non-Hodgkinôs lymphoma and mantle cell lymphoma which the Company has already received in October 2010.

Regarding the indications of first-line low-grade non-Hodgkinôs lymphoma and mantle cell lymphoma, the Company filed an sNDA in Japan to the Pharmaceuticals and Medical Devices Agency (ñPMDAò) 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 obtaining approval in Japan in consultation with the PMDA.

Lastly, regarding the indication of refractory/relapsed intermediate/high-grade non-Hodgkinôs 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 Sodium]

Regarding these agents, for which a license agreement was entered into in July 2011, the Company has changed their generic name from ñRigosertibò to ñRigosertib Sodiumò in accordance with the notice of decision on its Japanese Accepted Names for Pharmaceuticals (JAN) received in October 2016. For the global Phase III trial of the intravenous formulation of Rigosertib Sodium conducted by Onconova Therapeutics, Inc. (Head office: Pennsylvania, U.S.; ñOnconovaò), the U.S. Licensor of the agent, the Company is in charge of the clinical development in Japan and 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 (ñprimary HMA failureò). The Company worked on procedures to enroll patients with the disease and accordingly completed the first patient enrollment in Japan in July 2016. Enrollments are currently accumulating.

Regarding the oral formulation of Rigosertib Sodium, the Company started its domestic Phase I clinical trial of the oral formulation of Rigosertib Sodium in combination with azacitidine (Note) for the target indication of HR-MDS in December 2015. However, the provision of the investigational drug of this clinical trial by Onconova has been delayed. At present, patient enrollment has not yet been started. As soon as this issue on the provision of the investigational drug is resolved, the Company will resume 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

2016, 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. Negotiations for multiple licensing agreements are currently underway.

Meanwhile, in May 2016, the Company established a wholly-owned subsidiary, SymBio Pharma USA, Inc. (Head office: Menlo Park, California, U.S., ñSymBio Pharma USAò), as the Companyôs strategic base for its overseas business development. By actively acquiring the worldwide rights concerning new drug candidates with SymBio Pharma USA as the base of global business, the Company will accelerate its transformation into a global specialty bio-pharmaceutical company with the aim of developing and commercializing new drugs in the U.S., Japan, Europe and other major global 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 1,407,613 thousand yen for the third 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 3.3%, and the Company recorded non-recurring revenue resulting from achieving the sales milestone of SyB L-0501 in Taiwan. Accordingly, overall net sales rose 5.6% year-on-year.

Selling, general and administrative expenses totaled 2,010,728 thousand yen (a year-on-year increase of 45.4%), including research and development (ñR&Dò) expenses of 981,168 thousand yen (a year-on-year increase of 64.1%) primarily due to expenses associated with obtaining the approval for the additional indications of TREAKISYM®, the clinical trial for the intravenous and oral formulations of Rigosertib Sodium and preparations for the clinical trial of SyB P-1501, and other selling, general and administrative expenses of 1,029,560 thousand yen (a year-on-year increase of 31.2%) primarily due to expenses associated with negotiating license agreements for new drug candidates or takeovers of companies that are in possession of new drug candidates.

As a result, operating loss of 1,532,310 thousand yen was recognized for the third quarter of fiscal year ending December 31, 2016 (operating loss of 987,692 thousand yen for the third quarter of the previous fiscal year). In addition, mainly because the Company recorded non-operating expenses totaling 390,891 thousand yen primarily comprising foreign exchange loss, ordinary loss totaled 1,916,710 thousand yen (ordinary loss of 1,056,043 thousand yen for the third quarter of the previous fiscal year) and net loss totaled 1,915,796 thousand yen (net loss of 1,059,425 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, 2016 stood at 6,987,250 thousand yen, an increase of 2,002,961 thousand yen from the previous fiscal year end. This was primarily due to increases of 1,816,629 thousand yen in cash and deposits, 193,352 thousand yen in merchandise and finished goods, 23,807 thousand yen in prepaid expenses, 15,330 thousand yen in lease and guarantee deposits and 14,023 thousand yen in tools, furniture and fixtures, offsetting decreases of 88,102 thousand yen in accounts receivable-trade and 11,685 thousand yen in software.

Liabilities stood at 1,358,083 thousand yen, an increase of 805,606 thousand yen from the previous fiscal year end. This was primarily due to increases of 675,000 thousand yen in bonds payable and 129,307 thousand yen in accounts payable-other, which were offset by a decrease of 4,581 thousand yen in accounts payable-trade.

Net assets increased by 1,197,354 thousand yen from the previous fiscal year end to 5,629,166 thousand yen, due to the issuance of new shares and stock acquisition rights, offsetting a decrease of 1,915,796 thousand yen in retained earnings following the recognition of net loss.

As a result, the equity ratio decreased by 8.1 percentage points from the previous fiscal year end to 74.8%.

(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)	3Q FY 2016 (as of September 30, 2016)
Assets		
Current assets		
Cash and deposits	4,261,438	6,078,068
Accounts receivable-trade	300,742	212,639
Merchandise and finished goods	133,029	326,381
Prepaid expenses	38,591	62,398
Advances paid	79,639	72,333
Other	13,337	59,107
Total current assets	4,826,778	6,810,929
Non-current assets		
Property, plant and equipment		
Buildings, net	22,208	20,971
Tools, furniture and fixtures, net	30,747	44,771
Total property, plant and equipment	52,956	65,743
Intangible assets		
Software	50,506	38,821
Software in progress	900	4,250
Lease assets	594	108
Total intangible assets	52,001	43,179
Investments and other assets		
Shares of subsidiaries	—	0
Long-term prepaid expenses	1,227	741
Lease and guarantee deposits	51,326	66,656
Total investments and other assets	52,553	67,398
Total non-current assets	157,510	176,321
Total assets	4,984,289	6,987,250
Liabilities		
Current liabilities		
Accounts payable-trade	319,866	315,285
Accounts payable-other	183,690	312,998
Income taxes payable	14,183	22,156
Forward exchange contracts	14,999	15,921
Other	18,200	15,263
Total current liabilities	550,940	681,624
Non-current liabilities		
Bonds payable	—	675,000
Provision for retirement benefits	1,537	1,342
Other	—	117
Total non-current liabilities	1,537	676,459
Total liabilities	552,477	1,358,083

(Unit: thousands of yen)

	FY 2015 (as of December 31, 2015)	3Q FY 2016 (as of September 30, 2016)
Net assets		
Shareholdersôequity		
Common stock	8,330,775	9,835,798
Capital surplus	8,300,775	9,805,798
Retained earnings	(12,499,609)	(14,415,406)
Treasury stock	(17)	(17)
Total shareholdersôequity	4,131,924	5,226,171
Stock acquisition rights	299,887	402,994
Total net assets	4,431,811	5,629,166
Total liabilities and net assets	4,984,289	6,987,250

(2) Statements of operations (cumulative)

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

(Unit: thousands of yen)

	3Q FY 2015 (from January 1, 2015 to September 30, 2015)	3Q FY 2016 (from January 1, 2016 to September 30, 2016)
Net sales	1,332,388	1,407,613
Cost of goods sold	937,300	929,195
Gross profit	395,087	478,418
Selling, general and administrative expenses	1,382,780	2,010,728
Operating loss	(987,692)	(1,532,310)
Non-operating income		
Interest income	9,730	5,017
Interest on securities	2,519	249
Dividend income	1,072	1,221
Other	24	4
Total non-operating income	13,347	6,491
Non-operating expenses		
Interest expenses	11	4
Commission fees	6,713	6,756
Stock issuance costs	160	10,759
Foreign exchange losses	74,142	356,057
Other	671	17,315
Total non-operating expenses	81,697	390,891
Ordinary loss	(1,056,043)	(1,916,710)
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	(1,056,575)	(1,912,946)
Income taxes-current	2,850	2,850
Total income taxes	2,850	2,850
Net loss	(1,059,425)	(1,915,796)

(3) Notes on quarterly financial statements

(Notes regarding going concern assumption)

None to be reported.

(Notes regarding significant changes in shareholdersô equity)

During the third quarter of fiscal year ending December 31, 2016, common stock and capital surplus increased by 1,162,500 thousand yen and 1,162,500 thousand yen respectively. This was due to the conversion into new shares in response to the exercise of a portion of the 3rd unsecured convertible bonds with stock acquisition rights. In addition, new shares were issued upon the exercise of part of the 34th stock acquisition rights, and common stock and capital surplus increased by 342,522 thousand yen and 342,522 thousand yen respectively.

As a result, common stock and capital surplus increased by 1,505,022 thousand yen and 1,505,022 thousand yen respectively, amounting to 9,835,798 thousand yen and 9,805,798 thousand yen respectively as of September 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 October 1, 2016 to November 11, 2016, a portion of the 3rd unsecured convertible bonds with stock acquisition rights was converted into new shares upon exercise of the rights. The summary of such exercise of the stock acquisition rights is as follows.

Number and type of shares issued:	355,450 shares of common stock
Total amount issued:	75,000 thousand yen
Amount of decrease in convertible bonds with stock acquisition rights:	75,000 thousand yen
Amount transferred to common stock:	37,500 thousand yen