English translation

SymBio Pharmaceuticals Limited

Summary of Financial Results
for the Third Quarter of Fiscal Year Ending December 31, 2017
[Japanese GAAP] (Non-consolidated)

November 10, 2017

Company Name	**SymBio Pharmaceuticals Limited**	Listing: Tokyo Stock Exchange	
Securities Code	4582	URL: http://www.symbiopharma.com/	
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida	
Contact Person	Director, Finance & Accounting	Kenji Murata	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	November 13, 2017	Date of Dividend Payment (plan)	–

Supplementary materials for 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 2017 (cumulative) (January 1, 2017 to September 30, 2017)

(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 2017	2,416	71.7	(3,508)	–	(3,546)	–	(3,546)	–
3Q FY 2016	1,407	5.6	(1,532)	–	(1,916)	–	(1,915)	–

	Quarterly Net Income (Loss) per Share	Diluted Quarterly Net Income per Share
	Yen	Yen
3Q FY 2017	(72.64)	–
3Q FY 2016	(51.61)	–

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

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	Millions of yen	Millions of yen	%
3Q FY 2017 (as of September 30, 2017)	5,255	2,941	45.6
FY 2016 (as of December 31, 2016)	6,878	5,484	73.5

(Reference) Shareholders' equity: 3Q FY 2017 (as of September 30, 2017) 2,396 million yen

FY 2016 (as of December 31, 2016) 5,053 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 2016	–	0.00	–	0.00	0.00
FY 2017	–	0.00	–		
FY 2017 (Forecast)				0.00	0.00

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

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3. Earnings Forecasts for FY 2017 (January 1, 2017 to December 31, 2017)

(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	3,583	51.3	(3,932)	—	(4,009)	—	(4,009)	—	(82.16)

(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 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 2017	50,674,624 shares	FY 2016	46,530,824 shares
(ii) Number of shares of treasury stock at the end of the period	3Q FY 2017	75 shares	FY 2016	75 shares
(iii) Average number of shares during the period (cumulative)	3Q FY 2017	48,814,135 shares	3Q FY 2016	37,123,292 shares

* The quarterly financial statements are not subject to quarterly reviews.

* Explanation regarding the appropriate use of earnings forecasts and other matters

All forecasts presented in this document, including the outlook on earnings, 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, (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 2017 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"). The Company obtained marketing approval for first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma in December 2016, and for chronic lymphocytic leukemia in August 2016. These are in addition to the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma for which marketing approval was obtained in October 2010. The indication expansion resulted in a significant in-market sales increase of 53.4% year-on-year (NHI price basis). Net sales to Eisai also grew considerably, by 68.0% year-on-year.

In addition to the three already approved indications, the Company continues to pursue label expansion thereby benefitting patients in need of new therapies and maximizing product value. The Company completed the Phase II clinical trial for recurrent/refractory intermediate/high-grade non-Hodgkin's lymphoma (diffuse large B-cell lymphoma) and, through consultation with the Pharmaceuticals and Medical Devices Agency ("PMDA"), began the Phase III clinical trial in August 2017.

In addition to the ongoing label expansion initiatives, the Company concluded an exclusive license agreement with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) ("Eagle") in September 2017, under which Eagle licensed to the Company rights under Eagle's intellectual property to develop, market, and sell bendamustine hydrochloride ("bendamustine HCl") ready-to-dilute ("RTD") and rapid infusion ("RI") injection products in Japan. This will further enable the Company to extend the product life until 2031 through patent protection and maximize the value of TREAKISYM®, while bringing significant benefits to patients and medical professionals. (See press release dated September 21, 2017 titled "Eagle Pharmaceuticals Licenses Japanese Rights for Bendamustine Hydrochloride Ready-to-dilute and Rapid Infusion Injection Products to SymBio Pharmaceuticals Limited.")

In addition to the development and expansion of the intravenous formulation product, the Company has been exploring the development of an oral formulation of TREAKISYM® with a focus on the treatment of solid tumors and autoimmune diseases, potentially further expanding the business, with an aim to solidify its managerial foundations through TREAKISYM® as a business platform.

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

The U.S. Licensor Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.) ("Onconova") is conducting a global Phase III clinical trial (with trial sites in more than 10 countries) of the intravenous formulation of rigosertib sodium for higher-risk myelodysplastic syndromes (HR-MDS) which do not respond to the current standard treatment with hypomethylating agents ("primary HMA failure") or which relapse after treatment under the current standard of care. The Company is responsible for the clinical development in Japan and started the domestic trial in December 2015. The Company completed the first patient enrollment in Japan in July 2016 and patient enrollment is proceeding favorably.

Regarding the oral formulation, delays with the investigational drug by Onconova had prevented patient enrollment in the domestic Phase I clinical trial for combination therapy with azacitidine (Note) for the target indication of HR-MDS, which began in December 2015. Onconova has recently resumed provision of the investigational drug, and the Company commenced a new domestic Phase I clinical trial in June 2017 to confirm the safety of high-dose oral rigosertib, which was added to the Phase II clinical trial being conducted by Onconova in the U.S. for first-line treatment and recurrent/refractory treatment of patients with HR-MDS. The Company completed the first patient enrollment in October 2017. After safety is confirmed through this trial, the Company plans to resume the domestic clinical trial for combination therapy with azacitidine, and to take part in the global Phase III clinical trial for combination therapy with azacitidine for the first-line treatment of patients with HR-MDS, which is planned by Onconova.

(Note) Azacitidine (Vidaza®: currently marketed by Nippon Shinyaku Co., Ltd.) was approved in 2011 upon successful confirmation of extended overall survival for the first time in the Phase III clinical trial for the indication of MDS, and is currently used as a first-line drug for MDS patients who have complications with hematopoietic stem cell transplantation.

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

In October 2015, the Company entered into an agreement with Incline Therapeutics, Inc., a wholly-owned subsidiary of US-based The Medicines Company (Head Office: New Jersey, U.S.) for an exclusive license to develop and commercialize SyB P-1501 in Japan. The Company commenced a domestic Phase III clinical trial for SyB P-1501 in June 2016 and completed the first patient enrollment in November 2016, with enrollments accumulating. The Company, acting in the best interest of patients, determined on April 21, 2017 to temporarily suspend new patient enrollment due to its recently arising concern as to the continuity of The Medicines Company's business regarding the product. At present, the Company continues discussions with The Medicines Company about the impact on the conduct of this domestic trial and commercialization of the product. (See press releases "Temporary Suspension of New Patient Enrollment in the Domestic Phase III Clinical Trial of the Patient-controlled Pain Management Drug SyB P-1501," dated May 11, 2017, "SEC Filing by The Medicines Company as the Licensor of the Patient-controlled Pain Management Drug SyB P-1501," dated June 5, 2017, and "Current Status of the Domestic Phase III Clinical Trial of the Patient-controlled Pain Management Drug SyB P-1501," dated August 9, 2017.)

[New drug candidates]

The Company continues to actively seek new drug candidates and in-licensing opportunities globally, aiming to expand both profitability and growth potential over the medium-to-long-term, and discussions with multiple potential licensors are currently in progress.

In May 2016, the Company established a wholly-owned subsidiary, SymBio Pharma USA, Inc. (Menlo Park, California, U.S., "SymBio Pharma USA"), as the Company's planned strategic base for overseas business development. Acquiring rights to new drug candidates through SymBio Pharma USA as the base of global business will be part of the Company's continued transformation into a global specialty biopharmaceutical company with capability to develop and commercialize new drugs in the U.S., Japan, Europe, and other major global markets.

(ii) Markets outside Japan

SyB L-0501 is also marketed in South Korea, Taiwan and Singapore, and product sales of SyB L-0501 in these countries progressed favorably at a pace exceeding the Company's forecasts.

(iii) Business results (cumulative)

Net sales totaled 2,416,625 thousand yen for the third quarter of fiscal year ending December 31, 2017, primarily reflecting product sales of TREAKISYM®. Overall net sales rose 71.7% year-on-year.

Selling, general and administrative expenses totaled 4,182,845 thousand yen (a year-on-year increase of 108.0%), including research and development ("R&D") expenses of 2,711,167 thousand yen (a year-on-year increase of 176.3%) primarily due to expenses associated with the clinical trial for the intravenous and oral formulations of rigosertib sodium as well as SyB P-1501, the expenses associated with the licensing of bendamustine HCl RTD and RI injection products, and other selling, general and administrative expenses of 1,471,678 thousand yen (a year-on-year increase of 42.9%).

As a result, an operating loss of 3,508,173 thousand yen was recognized for the third quarter of fiscal year ending December 31, 2017 (compared to an operating loss of 1,532,310 thousand yen for the third quarter of the previous fiscal year). In addition, including non-operating expenses totaling 43,144 thousand yen primarily comprised of foreign exchange losses, ordinary loss totaled 3,546,844 thousand yen (compared to an ordinary loss of 1,916,710 thousand yen for the third quarter of the previous fiscal year) and net loss totaled 3,546,022 thousand yen (compared to a net loss of 1,915,796 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, 2017 stood at 5,255,095 thousand yen, a decrease of 1,623,289 thousand yen from the previous fiscal year end. The decrease was primarily due to decreases of 1,128,037 thousand yen in cash and deposits, 487,471 thousand yen in accounts receivable-trade, 22,207 thousand yen in merchandise and finished goods, 20,639 thousand yen in prepaid expenses, and 16,488 thousand yen in advances paid, offsetting increases of 40,356 thousand yen in other current assets and 26,476 thousand yen in software in development.

Liabilities stood at 2,314,088 thousand yen, an increase of 920,574 thousand yen from the previous fiscal year end, primarily reflecting decreases of 450,000 thousand yen in bonds payable and 58,924 thousand yen in accounts payable-trade, offsetting an increase of 1,433,998 thousand yen in accounts payable-other.

Net assets decreased by 2,543,863 thousand yen from the previous fiscal year end to 2,941,006 thousand yen, due to a decrease of 3,546,022 thousand yen in retained earnings following the recognition of net loss, offsetting the exercise of stock acquisition rights, etc. (including exercise of stock acquisition rights for bonds with convertible bond type stock acquisition rights).

As a result, the equity ratio decreased by 27.9 percentage points from the previous fiscal year end to 45.6%.

(3) Qualitative information concerning earnings forecasts

The earnings forecast for FY 2017 announced on February 9, 2017 has been revised. For details, please refer to “Notice of Revision to the Earnings Forecast for FY2017” announced on September 21, 2017.

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2. Quarterly Financial Statements and Primary Notes

(1) Quarterly balance sheets

(Unit: thousands of yen)

	FY 2016 (as of December 31, 2016)	3Q FY 2017 (as of September 30, 2017)
Assets		
Current assets		
Cash and deposits	5,719,325	4,591,288
Accounts receivable-trade	487,471	—
Merchandise and finished goods	272,725	250,518
Prepaid expenses	79,104	58,464
Advances paid	66,465	49,977
Other	59,919	100,276
Total current assets	6,685,011	5,050,524
Non-current assets		
Property, plant and equipment		
Buildings, net	31,395	29,041
Tools, furniture and fixtures, net	43,129	35,282
Total property, plant and equipment	74,524	64,324
Intangible assets		
Software	41,985	44,603
Software in progress	—	26,476
Total intangible assets	41,985	71,079
Investments and other assets		
Shares of subsidiaries	0	0
Long-term prepaid expenses	11,649	6,438
Lease and guarantee deposits	65,214	62,727
Total investments and other assets	76,863	69,166
Total non-current assets	193,373	204,570
Total assets	6,878,384	5,255,095
Liabilities		
Current liabilities		
Accounts payable-trade	321,860	262,935
Accounts payable-other	552,510	1,986,508
Income taxes payable	36,586	32,081
Other	31,161	31,134
Total current liabilities	942,118	2,312,660
Non-current liabilities		
Bonds payable	450,000	—
Provision for retirement benefits	1,396	1,428
Total non-current liabilities	451,396	1,428
Total liabilities	1,393,514	2,314,088
Net assets		
Shareholders' equity		
Common stock	9,948,298	10,392,608
Capital surplus	9,918,298	10,362,608
Retained earnings (accumulated deficits)	(14,812,843)	(18,358,865)
Treasury stock	(17)	(17)
Total shareholders' equity	5,053,735	2,396,333
Stock acquisition rights	431,135	544,672
Total net assets	5,484,870	2,941,006
Total liabilities and net assets	6,878,384	5,255,095

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(2) Quarterly statements of operations (cumulative)

(For the third quarter of the fiscal year ending December 31, 2017)

(Unit: thousands of yen)

	3Q FY 2016 (from January 1, 2016 to September 30, 2016)	3Q FY 2017 (from January 1, 2017 to September 30, 2017)
Net sales	1,407,613	2,416,625
Cost of goods sold	929,195	1,741,953
Gross profit	478,418	674,672
Selling, general and administrative expenses	2,010,728	4,182,845
Operating loss	(1,532,310)	(3,508,173)
Non-operating income		
Interest income	5,017	3,058
Interest on securities	249	—
Dividend income	1,221	1,339
Other	4	75
Total non-operating income	6,491	4,473
Non-operating expenses		
Interest expenses	4	—
Commission fees	6,756	6,747
Stock issuance costs	10,759	11,673
Foreign exchange losses	356,057	24,481
Other	17,315	240
Total non-operating expenses	390,891	43,144
Ordinary loss	(1,916,710)	(3,546,844)
Extraordinary gain		
Gain on reversal of stock acquisition rights	4,903	3,671
Total extraordinary gain	4,903	3,671
Extraordinary loss		
Loss on retirement of non-current assets	1,139	—
Total extraordinary loss	1,139	—
Loss before income taxes	(1,912,946)	(3,543,172)
Income taxes-current	2,850	2,850
Total income taxes	2,850	2,850
Net loss	(1,915,796)	(3,546,022)

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(3) Notes on quarterly financial statements

(Notes regarding going concern assumption)

None to be reported.

(Notes regarding significant changes in shareholders' equity)

During the third quarter of fiscal year ending December 31, 2017, a portion of the third unsecured bonds with convertible bond type stock acquisition rights was converted into new shares through the exercise of the rights. In addition, new shares were issued upon the exercise of part of the 33rd stock acquisition rights, part of the 39th stock acquisition rights and part of the 42nd stock acquisition rights. As a result, during the third quarter of fiscal year ending December 31, 2017, common stock and capital surplus increased by 444,310 thousand yen and 444,310 thousand yen respectively, amounting to 10,392,608 thousand yen and 10,362,608 thousand yen respectively as of September 30, 2017.

(Significant subsequent events)

None to be reported.