English translation

SymBio Pharmaceuticals Limited

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

May 11, 2017

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	Kenji Murata	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	May 11, 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 ï rounded down, unless otherwise stated)

1. Business Results for the First Quarter of FY 2017 (January 1, 2017 to March 31, 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	%
1Q FY 2017	869	350.1	(525)	―	(583)	―	(582)	―
1Q FY 2016	193	(52.7)	(518)	―	(655)	―	(652)	―

	Quarterly Net Income (loss) per share	Diluted Quarterly Net Income per share
	Yen	Yen
1Q FY 2017	(12.12)	―
1Q FY 2016	(20.15)	―

(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	%
1Q FY 2017 (as of March 31, 2017)	6,478	5,450	77.0
FY 2016 (as of December 31, 2016)	6,878	5,484	73.5

(Reference) Equity: 1Q FY 2017 (as of March 31, 2017) 4,985 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	―				
FY 2017 (Forecast)		0.00	―	0.00	0.00

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

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	2,903	22.6	(3,238)	—	(3,303)	—	(3,306)	—	(71.07)

(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)	1Q FY 2017	48,964,524 shares	FY 2016	46,530,824 shares
(ii) Number of shares of treasury stock at the end of the period	1Q FY 2017	75 shares	FY 2016	75 shares
(iii) Average number of shares during the period (cumulative)	1Q FY 2017	48,095,755 shares	1Q FY 2016	32,390,848 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 Companyôs earnings forecasts are based and their usage, please refer to ñ1. Qualitative Information Concerning Quarterly Financial Results, (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 first 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. (ñEisaiò), for the new indications of chronic lymphocytic leukemia for which the Company obtained marketing approval in August 2016 and the first-line treatment of low-grade non-Hodgkinôs lymphoma and mantle cell lymphoma, for which it obtained marketing approval in December 2016, in addition to the indication of recurrent/refractory low-grade non-Hodgkinôs lymphoma and mantle cell lymphoma (for which marketing approval was obtained in October 2010). By expanding the indications for this agent, net sales increased significantly by 28.0% year-on-year (NHI price basis) and net sales through Eisai also grew considerably by 312.4% year-on-year.

In addition to the above three indications of this agent for which approval has already been obtained, the Company continues to pursue approval for the fourth indication for patients who need new therapies and for maximizing the product value. Regarding the indication of recurrent/refractory intermediate/high-grade non-Hodgkinôs lymphoma (diffuse large B-cell lymphoma), for which the Phase II clinical trial has been completed, the Company, in response to strong medical needs, is currently in consultation with the Pharmaceuticals and Medical Devices Agency (ñPMDAò) and continues to discuss the path forward for approval.

Furthermore, in order to solidify its management foundations, the Company will utilize TREAKISYM® as a firm base for its business activities, and to this end it is exploring the development of the oral formulation of TREAKISYM®, in addition to the intravenous formulation which is currently being developed and marketed, with a focus on the treatment of solid tumors and autoimmune diseases, considering the possibility of further expanding its business.

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

For the global Phase III clinical trial of the intravenous formulation of rigosertib sodium conducted by Onconova Therapeutics, Inc. (Head office: Pennsylvania, U.S.; ñOnconovaò), the U.S. Licensor, the Company is in charge of the clinical development in Japan and started the domestic trial in December 2015. This trial is conducted with clinical trial sites in more than ten countries worldwide, for higher-risk myelodysplastic syndromes (HR-MDS) which do not respond to the current standard treatment with hypomethylating agents (ñprimary HMA failureò) or which relapse after treatment under the current standard of care. The Company completed the first patient enrollment in Japan in July 2016, and enrollments are currently accumulating.

Regarding the oral formulation of rigosertib sodium, the Company started its domestic Phase I clinical trial in combination with azacitidine (Note) for the target indication of HR-MDS in December 2015. However, the provision of the investigational drug 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, and upon completion of the Phase I clinical trial, consider its participation in the global clinical trial to be conducted by Onconova.

(Note) About azacitidine (Vidaza®: currently marketed by Nippon Shinyaku Co., Ltd.): This drug 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 difficulties in 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 U.S.-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 3 clinical trial for SyB P-1501 in June 2016 and completed the first patient enrollment in November 2016, with enrollments accumulating. However, the Company, acting in the best interest of patients, decided on April 21, 2017 to temporarily suspend new patient enrollment in the trial due to its recently arising concern as to the continuity of The Medicines Companyôs business regarding the product.

[New drug candidates]

The Company continues with search and evaluation activities to acquire license rights of new drug candidates in global terms, aiming to grow into a biopharmaceutical company with both profitability and growth potential, always from a medium-to-long-term perspective, and 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 Companyõs strategic base for its overseas business development. By actively acquiring the worldwide rights concerning new drug candidates through SymBio Pharma USA as the base of global business, the Company will continue its transformation into a global specialty biopharmaceutical 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 progressed essentially as planned.

(iii) Business results

As a result of the above, net sales totaled 869,614 thousand yen for the first quarter of fiscal year ending December 31, 2017, primarily reflecting product sales of TREAKISYM®. Accordingly, overall net sales rose 350.1% year-on-year.

Selling, general and administrative expenses totaled 764,216 thousand yen (a year-on-year increase of 32.9%), including research and development (ñR&Dò) expenses of 395,148 thousand yen (a year-on-year increase of 76.8%) primarily due to expenses associated with the clinical trial for the intravenous and oral formulations of rigosertib sodium as well as SyB P-1501, and other selling, general and administrative expenses of 369,067 thousand yen (a year-on-year increase of 5.0%).

As a result, operating loss of 525,204 thousand yen was recognized for the first quarter of fiscal year ending December 31, 2017 (operating loss of 518,404 thousand yen for the first quarter of the previous fiscal year). In addition, mainly because the Company recorded non-operating expenses totaling 59,426 thousand yen primarily comprising foreign exchange losses, ordinary loss totaled 583,008 thousand yen (ordinary loss of 655,445 thousand yen for the first quarter of the previous fiscal year) and net loss totaled 582,768 thousand yen (net loss of 652,631 thousand yen for the first 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 March 31, 2017 stood at 6,478,104 thousand yen, a decrease of 400,279 thousand yen from the previous fiscal year end. This was primarily due to decreases of 674,991 thousand yen in cash and deposits, 55,740 thousand yen in accounts receivable-trade and 26,003 thousand yen in advances paid, offsetting increases of 340,931 thousand yen in merchandise and finished goods, 13,179 thousand yen in prepaid expenses and 11,250 thousand yen in software in progress.

Liabilities stood at 1,027,702 thousand yen, a decrease of 365,812 thousand yen from the previous fiscal year end, primarily reflecting decreases of 450,000 thousand yen in bonds payable, 16,911 thousand yen in income taxes payable, and 14,922 thousand yen in accounts payable-other, offsetting an increase of 124,609 thousand yen in accounts payable-trade.

Net assets decreased by 34,467 thousand yen from the previous fiscal year end to 5,450,402 thousand yen, due to a decrease of 582,768 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 increased by 3.5 percentage points from the previous fiscal year end to 77.0%.

(3) Qualitative information concerning earnings forecasts

No revision was made to the earnings forecasts for FY 2017 as of the date of this document.

2. Quarterly Financial Statements

(1) Balance sheets

(Unit: thousands of yen)

	FY 2016 (as of December 31, 2016)	1Q FY 2017 (as of March 31, 2017)
Assets		
Current assets		
Cash and deposits	5,719,325	5,044,333
Accounts receivable-trade	487,471	431,730
Merchandise and finished goods	272,725	613,656
Prepaid expenses	79,104	92,284
Advances paid	66,465	40,462
Other	59,919	62,213
Total current assets	6,685,011	6,284,680
Non-current assets		
Property, plant and equipment		
Buildings, net	31,395	30,710
Tools, furniture and fixtures, net	43,129	40,493
Total property, plant and equipment	74,524	71,203
Intangible assets		
Software	41,985	38,388
Software in progress	―	11,250
Total intangible assets	41,985	49,638
Investments and other assets		
Shares of subsidiaries	0	0
Long-term prepaid expenses	11,649	9,495
Lease and guarantee deposits	65,214	63,086
Total investments and other assets	76,863	72,582
Total non-current assets	193,373	193,424
Total assets	6,878,384	6,478,104
Liabilities		
Current liabilities		
Accounts payable-trade	321,860	446,470
Accounts payable-other	552,510	537,587
Income taxes payable	36,586	19,674
Forward exchange contracts	―	5,853
Other	31,161	16,726
Total current liabilities	942,118	1,026,312
Non-current liabilities		
Bonds payable	450,000	―
Provision for retirement benefits	1,396	1,390
Total non-current liabilities	451,396	1,390
Total liabilities	1,393,514	1,027,702
Net assets		
Shareholdersô equity		
Common stock	9,948,298	10,205,382
Capital surplus	9,918,298	10,175,382
Retained earnings (accumulated deficits)	(14,812,843)	(15,395,611)
Treasury stock	(17)	(17)
Total shareholdersô equity	5,053,735	4,985,135
Stock acquisition rights	431,135	465,267
Total net assets	5,484,870	5,450,402
Total liabilities and net assets	6,878,384	6,478,104

(2) Statements of operations (cumulative)

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

(Unit: thousands of yen)

	1Q FY 2016 (from January 1, 2016 to March 31, 2016)	1Q FY 2017 (from January 1, 2017 to March 31, 2017)
Net sales	193,183	869,614
Cost of goods sold	136,676	630,602
Gross profit	56,506	239,012
Selling, general and administrative expenses	574,911	764,216
Operating loss	(518,404)	(525,204)
Non-operating income		
Interest income	1,849	1,552
Other	—	69
Total non-operating income	1,849	1,621
Non-operating expenses		
Interest expenses	1	—
Commission fees	2,243	2,260
Stock issuance costs	—	1,969
Foreign exchange losses	136,644	55,197
Total non-operating expenses	138,890	59,426
Ordinary loss	(655,445)	(583,008)
Extraordinary gain		
Gain on reversal of stock acquisition rights	4,903	1,190
Total extraordinary gain	4,903	1,190
Extraordinary loss		
Loss on retirement of non-current assets	1,139	—
Total extraordinary loss	1,139	—
Loss before income taxes	(651,681)	(581,818)
Income taxes-current	950	950
Total income taxes	950	950
Net loss	(652,631)	(582,768)

(3) Notes on quarterly financial statements

(Notes regarding going concern assumption)

None to be reported.

(Notes regarding significant changes in shareholdersô equity)

During the first 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 39th stock acquisition rights. As a result, during the first quarter of fiscal year ending December 31, 2017, common stock and capital surplus increased by 257,084 thousand yen and 257,084 thousand yen respectively, amounting to 10,205,382 thousand yen and 10,175,382 thousand yen respectively as of March 31, 2017.

(Significant subsequent events)

1. Issuance of 40th stock acquisition rights (stock option)

At the Board of Directorsô meeting held on March 29, 2017, a resolution was passed regarding the issuance of stock acquisition rights as stock option to the six (6) Directors of the Company as follows. The stock option was allotted to relevant Directors on the allotment date of April 24, 2017.

Number of stock option	2,800 units
Class and number of shares underlying the stock option	Common stock 280,000 shares
Issue price/ Total issue price of the stock option	Issue price 20,300 yen Total issue price 56,840,000 yen
Amount to be paid in for the stock option	Amount to be paid in: 203 yen per share The Person Granted* 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 one (1) yen
Period during which the stock option can be exercised	From March 30, 2020 to March 29, 2027
Terms and conditions for exercise of the stock option	(1) The Person Granted must have the status as a director or employee of the Company or its affiliates at the time of exercise. However, this is not necessarily the case if: (a) the Person Granted is a director of the Company or its affiliates and retires due to the expiry of her/his term, (b) the Person Granted is an employee of the Company or its affiliates and retires due to compulsory retirement or (c) the Person Granted is a director or employee of the Company or its affiliates and the Board of Directors resolves that he/she has resigned or retired with honorable recognition. (2) For other terms and conditions, the Company and directors shall comply with the Stock Option Allotment Agreement concluded between the parties.
Increase in paid-in capital 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 one-half of the maximum amount of paid-in capital increase and others, which is calculated in accordance with Article 17 of the Corporation Accounting Rules, 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 Directorsô meeting.

* Refers to those who receive the allotment of stock acquisition rights

2. Issuance of 41st stock acquisition rights (stock option)

At the Board of Directorsô meeting held on March 29, 2017, a resolution was passed regarding the issuance of stock acquisition rights as stock option to the 71 Company employees as follows. The stock option was allotted to relevant employees on the allotment date of April 24, 2017.

Number of stock option	4,512 units
Class and number of shares underlying the stock option	Common stock 451,200 shares
Issue price/ Total issue price of the stock option	Issue price 20,300 yen Total issue price 91,593,600 yen
Amount to be paid in for the stock option	Amount to be paid in: 203 yen per share The Person Granted 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 one (1) yen
Period during which the stock option can be exercised	From March 30, 2020 to March 29, 2027
Terms and conditions for exercise of the stock option	(1) The Person Granted must have the status as a director or employee of the Company or its affiliates at the time of exercise. However, this is not necessarily the case if: (a) the Person Granted is a director of the Company or its affiliates and retires due to the expiry of her/his term, (b) the Person Granted is an employee of the Company or its

	affiliates and retires due to compulsory retirement or (c) the Person Granted is a director or employee of the Company or its affiliates and the Board of Directors resolves that he/she has resigned or retired with honorable recognition. (2) For other terms and conditions, the Company and the employees shall comply with the Stock Option Allotment Agreement concluded between the parties.
Increase in paid-in capital 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 one-half of the maximum amount of paid-in capital increase and others, which is calculated in accordance with Article 17 of the Corporation Accounting Rules, 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 Directorsô meeting.

3. Temporary suspension of new patient enrollment in the SyB P-1501 domestic Phase 3 clinical trial

While having entered into an agreement in October 2015 with The Medicines Company (through its subsidiary, Incline Therapeutics, Inc.) for an exclusive license in Japan for SyB P-1501 and commencing a domestic Phase 3 clinical trial in June 2016 with a target indication for patient-controlled, short-term management of acute postoperative pain during hospitalization, the Company, acting in the best interest of patients, decided on April 21, 2017 to temporarily suspend new patient enrollment in the trial due to its recently arising concern as to the continuity of The Medicines Companyôs business regarding the product. Details are stated in the separately released announcement, ñTemporary Suspension of New Patient Enrollment in the Domestic Phase 3 Clinical Trial of the Patient-controlled Pain Management Drug ñSyB P-1501ò dated May 11, 2017..