Summary of Financial Results
for the First Half of Fiscal Year Ending December 31, 2018
[Japanese GAAP] (Non-consolidated)

August 07, 2018

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	Corporate Officer, Director of Finance & Accounting and Chief Financial Officer	Kenji Murata	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	August 08, 2018	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 First Half of FY 2018 (cumulative) (January 1, 2018 to June 30, 2018)

(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	%
1H FY 2018	1,928	8.0	(1,324)	–	(1,377)	–	(1,388)	–
1H FY 2017	1,786	47.5	(1,235)	–	(1,268)	–	(1,266)	–

	Quarterly Net Income (Loss) per Share	Diluted Quarterly Net Income per Share
	Yen	Yen
1H FY 2018	(23.79)	–
1H FY 2017	(26.09)	–

(Note) Diluted earnings per share are not shown for the six months ended June 30, 2018 because the company booked a net loss per share although fully diluted shares existed.

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	Millions of yen	Millions of yen	%
1H FY 2018 (as of June 30, 2018)	4,845	3,479	59.5
FY 2017 (as of December 31, 2017)	4,252	3,239	63.6

(Reference) Shareholders' equity: 1H FY 2018 (as of June 30, 2018) 2,882 million yen

FY 2017 (as of December 31, 2017) 2,702 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 2017	–	0.00	–	0.00	0.00
FY 2018	–	0.00			
FY 2018 (Forecast)			–	0.00	0.00

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

3. Earnings Forecasts for FY 2018 (January 1, 2018 to December 31, 2018)

(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	4,201	22.0	(2,981)	—	(3,044)	—	(3,056)	—	(50.62)

(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)	1H FY 2018	62,353,224 shares	FY 2017	54,049,224 shares
(ii) Number of shares of treasury stock at the end of the period	1H FY 2018	75 shares	FY 2017	75 shares
(iii) Average number of shares during the period (cumulative)	1H FY 2018	58,373,567 shares	1H FY 2017	48,538,769 shares

* The quarterly financial results are not subject to quarterly reviews by certified public accountants or an accounting auditor.

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

The forecasts and future projections contained herein have been prepared on the basis of rational decisions given the information available as of the date of announcement of this document. Actual performance may differ from forecasts for a variety of reasons. Please refer to 1. Qualitative Information Concerning Quarterly Financial Results (3) Qualitative information concerning earnings forecasts on page 4 of the attachment to this document for cautionary statements concerning performance forecasts and the conditions that serve as the basis for the forecasts.

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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 half of FY 2018 is as follows:

(i) Domestic

[Anticancer agent: SyB L-0501 (lyophilized powder formulation), SyB L-1701 (ready-to-dilute ("RTD") formulation), SyB L-1702 (rapid infusion ("RI") formulation) and SyB C-0501 (oral formulation) (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 approvals 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 approval for the indication of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma which was obtained in October 2010. Following this indication expansion, TREAKISYM® is steadily increasing its market share in the area of first-line treatment by replacing R-CHOP, the conventional standard treatment, resulting in a significant in-market sales increase of 22.3% year-on-year (NHI price basis). Net sales to Eisai are progressing as planned.

In addition to the three already-approved indications, the Company has started a Phase III clinical trial for recurrent/refractory diffuse large B-cell lymphoma (DLBCL) and is currently working on patient enrollment towards obtaining approval. The trial is in response to serious need at clinics and hospitals as there is currently no reliable standard treatment. Patient groups have petitioned to the regulatory authorities for the approval of BR therapy. With a view to providing new therapeutic alternatives and to maximize product value, the Company began the Phase III clinical trial in August 2017 and is diligently working to accumulate cases after completing enrollment of the first patient in January 2018.

In addition to these initiatives toward the approval of additional indications, the Company entered into 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 Eagle's TREAKISYM® liquid formulation (RTD and RI liquid formulations) (Note 1) 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 healthcare providers. The Company has already consulted with the Pharmaceutical and Medical Devices Agency regarding details of the application for approval of the RTD formulation and clinical trial design for the RI formulation, and is preparing for the launch of TREAKISYM® liquid formulation in Japan in FY2021 or later.

Further, the Company acquired approval for the partial revision to the marketing authorization in July 2018. As a result, TREAKISYM® can now be used in combination with not only rituximab but also obinutuzumab (Note 2) after its launch for the treatment of low-grade non-Hodgkin's lymphoma, enabling the Company to provide patients with a new treatment therapy.

In addition to the development and expansion of the intravenous formulation product, the Company is exploring the development of an oral formulation of TREAKISYM® with a focus on the treatment of solid tumors and autoimmune diseases and intends to further expand the business, with an aim to solidify its business through a platform of TREAKISYM® products. Amid such initiatives, the Company commenced a Phase I clinical trial for progressive solid tumors in January 2018, with the aim of examining the recommended dosage and administration schedule as well as tolerability and safety of the oral formulation of TREAKISYM®, and identifying potential target tumor types. After completing enrollment of the first patient in May 2018, the Company is currently working to accumulate cases. Meanwhile, with a view to evaluating the effect of oral administration of TREAKISYM® on the immune system, the Company

concluded a joint research agreement with Keio University in May 2018 to conduct a pre-clinical trial to verify the therapeutic value of this product in the treatment of systemic lupus erythematosus (SLE), a form of autoimmune disease. The pre-clinical trial is currently underway.

(Note 1) RTD and RI are pre-dissolved liquid formulations that differ from the currently available freeze-dried ("FD") powder formulation. RTD (ready-to-dilute) will significantly reduce the preparation time and labor cost for healthcare providers, and RI (rapid infusion) will reduce infusion duration to 10 minutes from the current 60 minutes, providing significant benefit and value to both patients and healthcare providers.

(Note 2) Obinutuzumab (Gazyva®, marketed by Chugai Pharmaceutical Co., Ltd.): Like rituximab recommended by treatment guidelines for non-Hodgkin's lymphoma in Japan and overseas, obinutuzumab is a glycoengineered type II anti-20 monoclonal antibody that directly binds to CD20 (a protein expressed on B-cells other than stem cells or plasma cells) on target B-cells to attack and destroy them along with the body's immune system.

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

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 20 countries) of the intravenous formulation of rigosertib for higher-risk myelodysplastic syndromes (HR-MDS) which do not respond to the current standard treatment with hypomethylating agents, which relapse after treatment under the current standard of care, or which are intolerant to hypomethylating agents. The Company is responsible for clinical development in Japan and in December 2015 began the trial. 36 patients were enrolled as of June 30, 2018, and patient enrollment is proceeding favorably. Based on the results of the interim analysis completed in January 2018, the Company will continue the trial with a one-time increase in patient enrollment in accordance with pre-determined statistical criteria. On the basis of these results, the Company is planning to apply for approval in Japan at the same time as in the U.S. and Europe.

As for the oral formulation of rigosertib, Onconova has been conducting Phase I/II clinical trials in the U.S. for the target indication of first-line higher-risk myelodysplastic syndromes (MDS) (in combination with azacitidine (Note 3)), along with a Phase II clinical trial for the target indication of transfusion-dependent lower-risk MDS. The Company started a domestic Phase I clinical trial in June 2017 to confirm the tolerability and safety of the oral formulation of rigosertib for Japanese patients. The first patient was enrolled in October 2017 and patient enrollment is proceeding favorably. After completion of this trial, the Company plans to conduct a clinical trial for combination therapy with azacitidine, to take part in Onconova's planned global Phase III clinical trial for combination therapy with azacitidine for the first-line treatment of patients with higher-risk MDS, and to apply for approval of the oral formulation of rigosertib in Japan in timing alignment with the U.S. and Europe. With respect to the development for the target indication of transfusion-dependent lower-risk MDS, the Company will continue to monitor Onconova's development activities with a view to participating from Japan.

(Note 3) Azacitidine (Vidaza®: currently marketed by Nippon Shinyaku Co., Ltd.): This drug (for injection) was approved in 2011 based on results showing extended overall survival for the first time in the Phase III clinical trial for the indication of MDS. It is currently used as a first-choice drug for MDS patients who have difficulties in hematopoietic stem cell transplantation. MDS is a preleukemic state, and decrease in tumor suppressor gene due to excessive methylation of DNA is thought to be related to the disease. Hypomethylating agents such as azacitidine are thought to

suppress progress to leukemia by restoring tumor suppressor gene with a deterrent effect against methylation of DNA.

[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, acting in the best interest of patients, determined to temporarily suspend new patient enrollment for SyB P-1501 from April 21, 2017 due to its recently arising concern as to the continuity of The Medicines Company's business regarding the product.

The Company later initiated arbitration against The Medicines Company on October 11, 2017 under the rules of the International Chamber of Commerce, seeking damages of 82 million U.S. dollar (approximately 9.0 billion yen) arising from The Medicines Company's repudiation of the license agreement. The Company claims that The Medicines Company failed to provide the Company with adequate assurance of performance of its contractual obligations under the license agreement in light of its decision to discontinue commercialization activities regarding the product and withdraw from markets in the U.S. and Europe, and that such failure by The Medicines Company is a material breach of the license agreement. Furthermore, the Company terminated the license agreement on November 30, 2017, based on the fact that breach of the license agreement by The Medicines Company was not remedied within the stipulated time, and terminated the development of SyB P-1501 on February 9, 2018.

Arbitration proceedings against The Medicines Company are still ongoing.

[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 ongoing.

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 the product sales of SyB L-0501 in these countries progressed mainly in line with the Company's forecasts.

(iii) Business results (cumulative)

As a result of the above, net sales totaled 1,928,378 thousand yen for the first half of fiscal year ending December 31, 2018, primarily reflecting product sales of TREAKISYM®. Overall net sales rose 8.0% year-on-year.

Selling, general and administrative expenses totaled 1,897,937 thousand yen (a year-on-year increase of 8.7%), including research and development ("R&D") expenses of 838,631 thousand yen (a year-on-year decrease of 0.1%) primarily due to expenses associated with the clinical trial for the intravenous and oral formulations of TREAKISYM® as well as the intravenous and oral formulations of rigosertib, and other selling, general and administrative expenses of 1,059,306 thousand yen (a year-on-year increase of 16.9%).

As a result, an operating loss of 1,324,638 thousand yen was recognized for the first half of fiscal year ending December 31, 2018 (compared to an operating loss of 1,235,880 thousand yen for the first half of

the previous fiscal year). In addition, including non-operating expenses totaling 53,620 thousand yen primarily comprised of foreign exchange losses, ordinary loss totaled 1,377,648 thousand yen (compared to an ordinary loss of 1,268,118 thousand yen for the first half of the previous fiscal year) and net loss totaled 1,388,502 thousand yen (compared to a net loss of 1,266,346 thousand yen for the first half 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, 2018 stood at 4,845,810 thousand yen, an increase of 593,525 thousand yen from the previous fiscal year end. The increase was primarily due to increases of 321,062 thousand yen in accounts receivable-trade, 199,242 thousand yen in merchandise and finished goods, 102,554 thousand yen in cash and deposits, 20,533 thousand yen in advances paid, and 16,733 thousand yen in prepaid expenses, offsetting a decrease of 14,139 thousand yen in lease and guarantee deposits.

Liabilities stood at 1,366,293 thousand yen, an increase of 353,411 thousand yen from the previous fiscal year end, primarily reflecting increases of 278,270 thousand yen in accounts payable-trade and 62,696 thousand yen in accounts payable-other despite a decrease of 4,483 thousand yen in income taxes payable.

Net assets increased by 240,114 thousand yen from the previous fiscal year end to 3,479,517 thousand yen, due to increases of 784,194 thousand yen in common stock, 784,194 thousand yen in capital surplus, and 60,227 thousand yen in stock acquisition rights, offsetting a decrease of 1,388,502 thousand yen in retained earnings following the recognition of net loss.

As a result, the equity ratio fell to 59.5% by 4.1 percentage points from the previous fiscal year end.

(3) Qualitative information concerning earnings forecasts

No revision was made to the earnings forecasts for FY 2018 as of the date of this document.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly balance sheets

(Unit: thousands of yen)

	FY 2017 (as of December 31, 2017)	1H FY 2018 (as of June 30, 2018)
Assets		
Current assets		
Cash and deposits	2,947,059	3,049,613
Accounts receivable-trade	489,874	810,936
Merchandise and finished goods	362,514	561,757
Prepaid expenses	73,720	90,454
Advances paid	18,760	39,294
Consumption taxes receivable	98,440	66,446
Other	46,152	26,612
Total current assets	4,036,522	4,645,115
Non-current assets		
Property, plant and equipment		
Buildings, net	28,486	38,401
Tools, furniture and fixtures, net	18,322	23,894
Construction in progress	64	—
Total property, plant and equipment	46,873	62,295
Intangible assets		
Software	65,583	57,653
Software in progress	3,295	—
Total intangible assets	68,878	57,653
Investments and other assets		
Shares of subsidiaries	0	0
Long-term prepaid expenses	14,209	9,085
Lease and guarantee deposits	85,799	71,660
Total investments and other assets	100,008	80,746
Total non-current assets	215,761	200,695
Total assets	4,252,284	4,845,810
Liabilities		
Current liabilities		
Accounts payable-trade	604,382	882,652
Accounts payable-other	330,867	393,563
Income taxes payable	54,813	50,329
Other	21,427	38,227
Total current liabilities	1,011,490	1,364,773
Non-current liabilities		
Provision for retirement benefits	1,392	1,520
Total non-current liabilities	1,392	1,520
Total liabilities	1,012,882	1,366,293
Net assets		
Shareholders' equity		
Common stock	10,761,676	11,545,871
Capital surplus	10,731,676	11,515,871
Retained earnings (accumulated deficits)	(18,790,705)	(20,179,207)

Treasury stock	(17)	(17)
Total shareholders' equity	2,702,629	2,882,516
Stock acquisition rights	536,772	597,000
Total net assets	3,239,402	3,479,517
Total liabilities and net assets	4,252,284	4,845,810

(2) Quarterly statements of income (cumulative)

(For the first half of the fiscal year ending December 31, 2018)

(Unit: thousands of yen)

	1H FY 2017 (from January 1, 2017 to June 30, 2017)	1H FY 2018 (from January 1, 2018 to June 30, 2018)
Net sales	1,786,005	1,928,378
Cost of goods sold	1,276,110	1,355,079
Gross profit	509,894	573,299
Selling, general and administrative expenses	1,745,774	1,897,937
Operating loss	(1,235,880)	(1,324,638)
Non-operating income		
Interest income	1,585	439
Interest on refund	—	116
Other	70	54
Total non-operating income	1,656	609
Non-operating expenses		
Commission fees	4,504	5,504
Stock issuance costs	2,079	19,114
Foreign exchange losses	27,266	29,002
Other	45	—
Total non-operating expenses	33,894	53,620
Ordinary loss	(1,268,118)	(1,377,648)
Extraordinary gain		
Gain on reversal of stock acquisition rights	3,671	876
Total extraordinary gain	3,671	876
Extraordinary loss		
Loss on retirement of non-current assets	—	9,829
Total extraordinary loss	—	9,829
Loss before income taxes	(1,264,446)	(1,386,602)
Income taxes-current	1,900	1,900
Total income taxes	1,900	1,900
Net loss	(1,266,346)	(1,388,502)

(3) Quarterly statement of cash flow

(Unit: thousands of yen)

	1H FY 2017 (from January 1, 2017 to June 30, 2017)	1H FY 2018 (from January 1, 2018 to June 30, 2018)
Net cash provided by (used in) operating activities		
Loss before income taxes	(1,264,446)	(1,386,602)
Depreciation	14,365	16,915
Share-based compensation expenses	67,120	64,636
Increase (decrease) in provision for retirement benefits	(28)	128
Interest income	(1,585)	(439)
Foreign exchange losses (gains)	29,126	29,870
Commission fees	4,504	5,504
Stock issuance costs	2,079	19,114
Gain on reversal of stock acquisition rights	(3,671)	(876)
Loss on retirement of non-current assets	—	9,829
Decrease (increase) in accounts receivable-trade	182,505	(321,062)
Decrease (increase) in inventories	(159,842)	(199,242)
Decrease (increase) in prepaid expenses	(5,953)	(22,238)
Decrease (increase) in advances paid	28,979	(20,533)
Decrease (increase) in consumption taxes receivable	(5,052)	31,994
Decrease (increase) in other current assets	(47,868)	31,614
Decrease (increase) in long-term prepaid expenses	2,365	5,123
Increase (decrease) in accounts payable-trade	237,785	278,270
Increase (decrease) in accounts payable-other	71,610	61,233
Increase (decrease) in other current liabilities	2,118	241
Other	309	745
Subtotal	(845,577)	(1,395,772)
Interest and dividends income received	1,625	439
Income taxes paid	(1,900)	(1,900)
Net cash provided by (used in) operating activities	(845,852)	(1,397,232)
Net cash provided by (used in) investing activities		
Purchase of property, plant and equipment	(10,662)	(27,834)
Purchase of intangible assets	(13,149)	(3,530)
Proceeds from collection of lease and guarantee deposits	3,065	13,747
Net cash provided by (used in) investing activities	(20,747)	(17,617)
Net cash provided by (used in) financing activities		
Proceeds from issuance of stock resulting from exercise of stock acquisition rights	63,529	1,541,756
Proceeds from issuance of stock acquisition rights	—	23,100
Payments for issuance of common stock	(2,079)	(17,582)
Net cash provided by (used in) financing activities	61,450	1,547,274
Effect of foreign exchange rate change on cash and cash equivalents	(29,126)	(29,870)
Net increase (decrease) in cash and cash equivalents	(834,275)	102,554
Cash and cash equivalents at the beginning of the year	5,719,325	2,947,059
Cash and cash equivalents at the end of the year	4,885,050	3,049,613

(4) Notes on quarterly financial statements

(Notes regarding going concern assumption)

None to be reported.

(Notes regarding significant changes in shareholders' equity)

During the first half of fiscal year ending December 31, 2018, new shares were issued upon the exercise of part of the 33rd, 36th, 42nd, and 45th stock acquisition rights. As a result, during the first half of fiscal year ending December 31, 2018, common stock and capital surplus increased by 784,194 thousand yen and 784,194 thousand yen respectively, amounting to 11,545,871 thousand yen and 11,515,871 thousand yen respectively as of June 30, 2018.

(Significant subsequent events)

None to be reported.