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

November 9, 2018

Company Name	**SymBio Pharmaceuticals Limited**	Listing: Tokyo Stock Exchange	
Securities Code	4582	URL: https://www.symbiopharma.com/	
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida	
Contact Person	Corporate Officer, Head of Corporate Planning and Administration, Chief Financial Officer	Kenji Murata	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	November 12, 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 Nine Months of FY 2018 (cumulative) (January 1, 2018 to September 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	%
Q3 FY 2018	3,032	25.5	(1,907)	–	(1,937)	–	(1,940)	–
Q3 FY 2017	2,416	71.7	(3,508)	–	(3,546)	–	(3,546)	–

	Quarterly Net Income (Loss) per Share	Diluted Quarterly Net Income per Share
	Yen	Yen
Q3 FY 2018	(31.31)	–
Q3 FY 2017	(72.64)	–

(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	%
Q3 FY 2018 (as of September 30, 2018)	5,466	4,645	73.9
FY 2017 (as of December 31, 2017)	4,252	3,239	63.6

(Reference) Shareholders' equity: Q3 FY 2018 (as of September 30, 2018) 4,041 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)	—	(46.53)

(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)	Q3 FY 2018	76,662,224 shares	FY 2017	54,049,224 shares
(ii) Number of shares of treasury stock at the end of the period	Q3 FY 2018	75 shares	FY 2017	75 shares
(iii) Average number of shares during the period (cumulative)	Q3 FY 2018	61,994,152 shares	Q3 FY 2017	48,814,135 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

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 4 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 first nine months of FY2018 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 (low-grade NHL) and mantle cell lymphoma (MCL) in December 2016, and for chronic lymphocytic leukemia (CLL) in August 2016. These are in addition to the approval for the indication of recurrent/refractory low-grade NHL and MCL 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, at medical clinics and hospitals. Further, the combination treatment (BR therapy) of TREAKISYM® and rituximab was newly included in the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues 2018 edited and published by the Japanese Society of Hematology in July 2018, with TREAKISYM® effectively establishing its foothold as the standard treatment for malignant lymphoma. In-market sales for the first nine months of the fiscal year ending December 31, 2018 posted a robust 15.2% increase 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 (r/r 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 maximizing 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 upon obtaining approval 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) (launched in August 2018) for the treatment of CD20 positive follicular lymphoma (FL), a common histologic type of low-grade NHL, enabling the Company to provide patients with a new treatment therapy. In September 2018, the Company applied for approval of partial revision to the manufacturing and marketing authorization of TREAKISYM® regarding its use as a pre-treatment for regenerative medicine products.

In addition to the intravenous formulation currently under development and on sale, the Company is exploring the potential of TREAKISYM® as the treatment for solid tumors and autoimmune diseases through the development of an oral formulation, 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 aims 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. Thirty-seven patients were enrolled as of September 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 statistical criteria in an adaptive design previously agreed upon with the U.S. Food and Drug Administration (FDA). Based on the results of the trial, 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 HR-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 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 3,032,365 thousand yen for the first nine months of fiscal year ending December 31, 2018, primarily reflecting product sales of TREAKISYM®. Overall net sales rose 25.5% year-on-year.

Selling, general and administrative expenses totaled 2,831,731 thousand yen (a year-on-year decrease of 32.3%), including research and development ("R&D") expenses of 1,293,080 thousand yen (a year-on-year decrease of 52.3%) 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 1,538,651 thousand yen (a year-on-year increase of 4.6%).

As a result, an operating loss of 1,907,504 thousand yen was recognized for the first nine months of fiscal year ending December 31, 2018 (compared to an operating loss of 3,508,173 thousand yen for the first nine months of the previous fiscal year). In addition, including non-operating expenses totaling 33,634 thousand yen primarily comprised of share issuance costs, ordinary loss totaled 1,937,509 thousand yen (compared to an ordinary loss of 3,546,844 thousand yen for the first nine months of the previous fiscal year) and net loss totaled 1,940,842 thousand yen (compared to a net loss of 3,546,022 thousand yen for the first nine months 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, 2018 stood at 5,466,799 thousand yen, an increase of 1,214,514 thousand yen from the previous fiscal year end. The increase was primarily due to increases of 895,001 thousand yen in cash and deposits, 381,812 thousand yen in accounts receivable-trade, and 20,131 thousand yen in advances paid, offsetting a decrease of 40,013 in merchandise and finished goods, 34,416 thousand yen in consumption taxes receivable, 14,359 thousand yen in lease and guarantee deposits, and 13,667 thousand yen in software.

Liabilities stood at 821,282 thousand yen, a decrease of 191,599 thousand yen from the previous fiscal year end, primarily reflecting a decrease of 247,300 thousand yen in accounts payable-trade and 15,323 thousand yen in income taxes payable, offsetting increases of 67,109 thousand yen in accounts payable-other .

Net assets increased by 1,406,114 thousand yen from the previous fiscal year end to 4,645,517 thousand yen, due to increases of 1,639,634 thousand yen in common stock, 1,639,634 thousand yen in capital surplus, and 67,687 thousand yen in stock acquisition rights, offsetting a decrease of 1,940,842 thousand yen in retained earnings following the recognition of net loss.

As a result, the equity ratio rose by 10.4 percentage points to 73.9% 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)	Q3 FY 2018 (as of September 30, 2018)
Assets		
Current assets		
Cash and deposits	2,947,059	3,842,060
Accounts receivable-trade	489,874	871,687
Merchandise and finished goods	362,514	322,501
Prepaid expenses	73,720	81,582
Advances paid	18,760	38,892
Consumption taxes receivable	98,440	64,024
Other	46,152	56,267
Total current assets	4,036,522	5,277,016
Non-current assets		
Property, plant and equipment		
Buildings, net	28,486	37,586
Tools, furniture and fixtures, net	18,322	21,780
Construction in progress	64	—
Total property, plant and equipment	46,873	59,366
Intangible assets		
Software	65,583	51,916
Software in progress	3,295	—
Total intangible assets	68,878	51,916
Investments and other assets		
Shares of subsidiaries	0	0
Long-term prepaid expenses	14,209	7,059
Lease and guarantee deposits	85,799	71,439
Total investments and other assets	100,008	78,499
Total non-current assets	215,761	189,782
Total assets	4,252,284	5,466,799
Liabilities		
Current liabilities		
Accounts payable-trade	604,382	357,081
Accounts payable-other	330,867	397,976
Income taxes payable	54,813	39,489
Other	21,427	25,525
Total current liabilities	1,011,490	820,074
Non-current liabilities		
Provision for retirement benefits	1,392	1,208
Total non-current liabilities	1,392	1,208
Total liabilities	1,012,882	821,282
Net assets		
Shareholders' equity		
Common stock	10,761,676	12,401,311
Capital surplus	10,731,676	12,371,311
Retained earnings (accumulated deficits)	(18,790,705)	(20,731,548)

Treasury stock	(17)	(17)
Total shareholders' equity	2,702,629	4,041,057
Stock acquisition rights	536,772	604,459
Total net assets	3,239,402	4,645,517
Total liabilities and net assets	4,252,284	5,466,799

(2) Quarterly statements of income (cumulative)

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

(Unit: thousands of yen)

	Q3 FY 2017 (from January 1, 2017 to September 30, 2017)	Q3 FY 2018 (from January 1, 2018 to September 30, 2018)
Net sales	2,416,625	3,032,365
Cost of goods sold	1,741,953	2,108,138
Gross profit	674,672	924,227
Selling, general and administrative expenses	4,182,845	2,831,731
Operating loss	(3,508,173)	(1,907,504)
Non-operating income		
Interest income	3,058	491
Interest on refund	—	116
Dividend income of insurance	1,339	1,501
Foreign exchange gains	—	1,466
Other	75	54
Total non-operating income	4,473	3,629
Non-operating expenses		
Commission fees	6,747	8,302
Stock issuance costs	11,673	25,332
Foreign exchange losses	24,481	—
Other	240	—
Total non-operating expenses	43,144	33,634
Ordinary loss	(3,546,844)	(1,937,509)
Extraordinary gain		
Gain on reversal of stock acquisition rights	3,671	9,346
Total extraordinary gain	3,671	9,346
Extraordinary loss		
Loss on retirement of non-current assets	—	9,829
Total extraordinary loss	—	9,829
Loss before income taxes	(3,543,172)	(1,937,992)
Income taxes-current	2,850	2,850
Total income taxes	2,850	2,850
Net loss	(3,546,022)	(1,940,842)

(3) Notes on quarterly financial statements

(Notes regarding going concern assumption)

None to be reported.

(Notes regarding significant changes in shareholders' equity)

During the first nine months 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 nine months of fiscal year ending December 31, 2018, common stock and capital surplus increased by 1,639,634 thousand yen and 1,639,634 thousand yen respectively, amounting to 12,401,311 thousand yen and 12,371,311 thousand yen respectively as of September 30, 2018.

(Significant subsequent events)

None to be reported.