English translation

SymBio Pharmaceuticals Limited

Summary of Financial Statements for the First Half of the Fiscal Year Ending December 31, 2019 [Japanese GAAP] (Non-consolidated)

August 7, 2019

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	Director, Head of Corporate Planning & Admin. Division and Chief Financial Officer	Kenji Murata	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	August 8, 2019	Date of Dividend Payment (plan)	—

Supplementary materials for the quarterly financial statements: Yes ・ [No]

Holding of quarterly earnings performance review: [Yes] ・ No

(Amounts of less than one million yen are rounded down.)

1. Business Results for the First Half of FY 2019 (January 1, 2019 to June 30, 2019)

(1) Operating Results (cumulative) (Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss)	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
1H FY 2019	2,004	4.0	(2,015)	—	(2,069)	—	(2,069)	—
1H FY 2018	1,928	8.0	(1,324)	—	(1,377)	—	(1,388)	—

	Earnings (Loss) per Share	Diluted Earnings per Share
	Yen	Yen
1H FY 2019	(95.58)	—
1H FY 2018	(95.15)	—

(Note 1) On July 1, 2019, the Company conducted a 1-for-4 consolidation of common stock. Earnings per share have been calculated based on the assumption that this consolidation was conducted at the beginning of FY 2018.

(Note 2) Diluted earnings per share is not stated above due to loss per share, despite the potential dilution of shares.

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	Millions of yen	Millions of yen	%
1H FY 2019 (as of June 30, 2019)	6,674	5,426	72.6
FY 2018 (as of December 31, 2018)	6,239	4,901	70.1

(Reference) Shareholders' equity: 1H FY 2019 (as of June 30, 2019) 4,845 million yen
FY 2018 (as of December 31, 2018) 4,371 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 2018	—	0.00	—	0.00	0.00
FY 2019	—	0.00			
FY 2019 (Forecast)			—	0.00	0.00

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

3. Earnings Forecasts for FY 2019 (January 1, 2019 to December 31, 2019)

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss)		Earnings (Loss) per Share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Full Year	3,092	(19.4)	(3,780)	—	(3,856)	—	(3,859)	—	(167.66)

(Note) Revision of earnings forecasts recently announced: Yes ・ No

On July 1, 2019, the Company conducted a 1-for-4 consolidation of common stock. The forecast for earnings per share in FY 2019 incorporates the impact of this consolidation. For details, please refer to “Explanation regarding the appropriate use of earnings forecasts and other matters.”

Regarding the earnings forecasts, please refer to the announcement “Revision to Earnings Forecasts for FY 2019 and Mid-Range Plan (FY 2019 to FY 2022)” released today (on August 7, 2019)

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 issued shares at the end of the period (including treasury shares)	1H FY 2019	24,362,681 shares	FY 2018	20,599,731 shares
(ii) Number of treasury shares at the end of the period	1H FY 2019	18 shares	FY 2018	18 shares
(iii) Average number of shares during the period (cumulative)	1H FY 2019	21,655,982 shares	1H FY 2018	14,593,392 shares

(Note) On July 1, 2019, the Company conducted a 1-for-4 consolidation of common stock. The number of issued shares at the end of the period, number of treasury shares at the end of the period, and average number of shares during the period have been calculated based on the assumption that this consolidation was conducted at the beginning of FY 2018.

* Summary of the quarterly financial statements is not subject to quarterly reviews by certified public accountants or accounting corporations.

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

1. 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 Company’s earnings forecasts are based and their usage, please refer to “1. Qualitative Information on Quarterly Financial Results, (3) Explanation of earnings forecasts and other forward-looking information,” on Page 7 of the attachment.
2. The Company approved a 1-for-4 consolidation of common stock at the 14th Ordinary General Meeting of Shareholders held on March 28, 2019. This consolidation of shares was carried out with an effective date of July 1, 2019. The earnings forecast for FY 2019, when calculated based on the number of shares outstanding prior to the reverse stock split is as follows:

   FY 2019 loss per share forecast (full year): 41.92 yen

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1. Qualitative Information on Quarterly Financial Results

(1) Explanation of business results

Progress in the Company's business for the first half of the fiscal year ending December 31, 2019 is as follows.

(i) Domestic

[Preparation for the establishment of the Company's own salesforce]

In October 2018, the Company began preparations to establish its own salesforce for the sale of TREAKISYM® in Japan ahead of the expiration of a business partnership agreement with Eisai Co., Ltd. ("Eisai") in December 2020. The Company's top management objectives are to attain profitability in the fiscal year ending December 31, 2021 and to achieve sustainable growth thereafter. By transitioning to its own salesforce, the Company plans to solidify its future business development.

During the first half of the fiscal year under review, the Company made progress on the personnel expansion and training required to complete the structure of 20 TREAKISYM® managers that it views as the core of its salesforce's framework. It also proceeded with preparations to distribute personnel to their areas of responsibility according to plan. The Company is aiming to establish a high-performance and highly productive sales organization that is based on deep expertise and abundant experience. Concurrently, preparation for the construction of infrastructure for logistics, distribution, and information systems is currently underway and progressing according to plan.

[Anticancer agents: 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. The Company obtained manufacturing and marketing approval for first-line treatment of low-grade non-Hodgkin's lymphoma (Note 1) (low-grade NHL) and mantle cell lymphoma (MCL) in December 2016, for recurrent/refractory low-grade NHL and MCL in October 2010, and for chronic lymphocytic leukemia (CLL) in August 2016. 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, becoming recommended as a choice for standard treatment for all previously approved indications. With this development, TREAKISYM® has been effectively establishing its foothold as the standard treatment for malignant lymphoma, and surveys conducted by the Company indicate that its share of the fist-line treatment has risen to 55%.

In addition to the three already-approved indications, the Company is conducting a Phase III clinical trial for TREAKISYM® targeting recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). The trial is in response to serious need at clinics and hospitals as there is currently no reliable standard treatment. Patient groups and relevant academic societies 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, after enrolling its first patient in January 2018, steadily continued to accumulate cases, finally completing the enrollment process in April 2019. After the follow-up period for enrolled patients is complete, the Company will proceed in earnest with preparations to apply for the approval of the additional indication.

The Company is targeting a transition to TREAKISYM® liquid formulation (RTD and RI liquid formulations) (Note 2), for which it concluded an exclusive license agreement (in Japan), with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) ("Eagle") in September 2017. In accordance with this goal, the Company is already industriously preparing to apply for approval concerning RTD liquid formulation products through consultations with the Pharmaceutical and Medical Devices Agency. A clinical trial for RI liquid formulation began in November 2018, with the primary goal of confirming their safety. The Company has been steadily accumulating cases since the enrollment of the first patient began in April 2019. This drug will provide added value by greatly reducing the burdens placed on patients and healthcare providers, and liquid formula patent protection will enable the extension of its product life until 2031. With this drug, the Company is aiming to maximize business value while focusing on development strategies.

Further, the Company acquired approval for the partial revision to the manufacturing and marketing authorization in July 2018. As a result, TREAKISYM® can now be used in combination with not only rituximab but also other new anti-CD20 antibodies for the treatment of CD20 positive follicular lymphoma (FL), a common histologic type of low-grade NHL. As a new treatment option, it is being offered to patients in combination with obinutuzumab (Note 3), which was launched in August 2018. In March

2019, the Company received approval for changes to a portion of its application concerning the use of TREAKISYM® as a pretreatment agent for tumor-specific T-cell infusion therapy (Note 4). This will allow TREAKISYM® to be used as a pretreatment for Kymriah® intravenous infusion (Note 5), which was approved as the first chimeric antigen receptor T-cell (CAR-T) therapy (Note 6) in Japan and included in the NHI price listings in May 2019. The status of TREAKISYM® as a standard treatment for malignant lymphoma is becoming stronger as its use as a pretreatment used with regenerative medicine and other products continues to spread.

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 verify the therapeutic effect of this product in the treatment of systemic lupus erythematosus (SLE), an autoimmune disease that is giving rise to extremely high treatment demand. The Company later conducted a preclinical trial with Keio University. Currently, the results of this trial are being collected and, once they have been evaluated, the Company will consider its plans moving forward, including future clinical trials.

(Note 1) Non-Hodgkin's lymphoma (NHL) is a generic term of all types of malignant lymphoma other than Hodgkin's lymphoma. Malignant lymphoma refers to malignant growths that form when the lymphatic corpuscles inside of white blood cells become cancerous. The majority of malignant lymphoma identified in Japanese patients is non-Hodgkin's lymphoma.

(Note 2) RTD and RI are predissolved 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, greatly reducing the burdens placed on patients and providing significant added value to healthcare providers.

(Note 3) 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, and attacks and destroys them along with the body's immune system.

(Note 4) Tumor-specific T-cell infusion therapy is a treatment method in which tumor-specific T-cells (T-cells that specifically recognize cancer cells) taken from cancer patients are artificially bestowed with cancer specificity extracorporeally, amplified and then administered to the patient.

(Note 5) Kymriah® intravenous infusion (generic name: tisagenlecleucel; marketed by Novartis Pharma K.K.): Kymriah® intravenous infusion is the first chimeric antigen receptor T-cell (CAR-T) therapy approved within Japan. The Company received manufacturing and marketing approval for Kymriah® for use in the treatment of CD19 positive recurrent/refractory B-cell acute lymphoblastic leukemia (B-ALL) and CD19 positive recurrent/refractory diffuse large B-cell lymphoma (DLBCL) in March 2019. Kymriah® intravenous infusion was included in NHI price listings in May 2019.

(Note 6) Chimeric antigen receptor T-cell (CAR-T) therapy is a type of tumor-specific T-cell infusion therapy that introduces genes that code chimeric antigen receptors (CARs) into T-cells, amplifies these cells and then infuses them. These chimeric antigen receptors are produced by combining the intracellular domains of T-cell receptors with the antigen-binding sites of antibodies capable of recognizing membrane antigens attached to tumor cells. In clinical trials using CARs to target CD19 that expresses on B-cells, CD19-targeting CARs were introduced into T-cells that were later administered to patients with B-cell tumors. These modified cells produced clear clinical effects.

[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. Forty-four patients were enrolled as of July 31, 2019. According to Onconova, out of the target of 360 total patients worldwide, 75% had been enrolled as of March 2019. 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 completed Phase I/II clinical trials in the U.S. for the target indication of first-line HR-MDS (in combination with azacitidine (Note 7)) and is conducting 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 Company continued to steadily accumulate cases since the first patient was enrolled in October 2017 and completed patient enrollment in June 2019. After completion of this trial, the Company plans to promptly conduct a Phase I clinical trial for combination therapy with azacitidine. Further, to apply for approval of the oral formulation of rigosertib in Japan no later than in the U.S. and Europe, it plans to take part in a global Phase III clinical trial for combination therapy with azacitidine for the first-line treatment of patients with higher-risk MDS, which Onconova currently plans to conduct. In order to accelerate this global clinical trial's examination process, Onconova applied for a Special Protocol Assessment (SPA) (Note 8) with the US Food and Drug Administration (FDA) in December 2018. A Phase III clinical trial is expected to begin once approval from the FDA is received. With respect to the development for the target indication of transfusion-dependent lower-risk MDS, the Company will continue to consider participating from Japan in view of the status of the development by Onconova.

(Note 7) Azacitidine (Vidaza®: marketed by Nippon Shinyaku Co., Ltd.): This hypomethylating agent (for injection) 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. It is currently used as a first-line 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.

(Note 8) Special Protocol Assessment (SPA): A system under which after completion of a phase II trial and prior to the launch of phase III trial, sponsors can reach an agreement with the FDA regarding the phase III trial protocol such as target illness, purpose, trial design, primary and secondary endpoints, and method of data analysis. The agreement indicates that the FDA concurs with the adequacy of the overall protocol design and the design can be used (without changing the terms) in the approval filing process when the phase III trial is completed. The SPA is intended to shorten FDA's review period of new drug application, as it boosts the possibility of drug approval provided the trial endpoints are achieved.

[Patient-controlled pain management drug: SyB P-1501]

In October 2015, the Company entered into an agreement with Incline Therapeutics, Inc., a wholly owned subsidiary of 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 was not able 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, aiming to expand both profitability and growth potential over the long term in a manner that is aligned with management objectives and strategies. Discussions with multiple potential licensors are ongoing.

In May 2016, the Company established a wholly owned subsidiary, SymBio Pharma USA, Inc. (head office: Menlo Park, California, U.S., "SymBio Pharma USA"), as the Company's planned strategic base for overseas business development. Acquiring licenses 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 pharmaceutical 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 in line with the Company's forecasts.

(iii) Business results

As a result of the above, net sales totaled 2,004,976 thousand yen for the first half of the fiscal year ending December 31, 2019, primarily reflecting product sales of TREAKISYM®. Overall net sales rose 4.0% year on year.

Selling, general and administrative expenses totaled 2,544,503 thousand yen (+34.1% year on year), including research and development ("R&D") expenses of 962,598 thousand yen (+14.8% year on year) 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 1,581,904 thousand yen (+49.3% year on year).

As a result, an operating loss of 2,015,102 thousand yen was recognized for the first half of the fiscal year ending December 31, 2019 (compared to an operating loss of 1,324,638 thousand yen for the first half of the previous fiscal year). In addition, including non-operating expenses totaling 57,178 thousand yen primarily comprised of foreign exchange losses, ordinary loss totaled 2,069,366 thousand yen (compared to an ordinary loss of 1,377,648 thousand yen for the first half of the previous fiscal year) and a bottom-line loss totaled 2,069,929 thousand yen (compared to a loss of 1,388,502 thousand yen for the first half of the previous fiscal year).

Segment information has been omitted as the Company operates within a single segment, which includes the research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities.

(2) Explanation of financial position

Total assets as of June 30, 2019 stood at 6,674,140 thousand yen, up 434,717 thousand yen from December 31, 2018. This primarily reflected increases of 1,244,810 thousand yen in cash and deposits, 103,788 thousand yen in software in progress, and 51,586 thousand yen in prepaid expenses, offsetting decreases of 533,824 thousand yen in merchandise and finished goods, 400,630 thousand yen in accounts receivable–trade, and 32,008 thousand yen in consumption taxes receivable.

Total liabilities came to 1,247,768 thousand yen, down 89,855 thousand yen from December 31, 2018. This was mainly due to a decrease of 717,627 thousand yen in accounts payable–trade, offsetting an increase of 605,485 thousand yen in accounts payable–other.

Net assets totaled 5,426,372 thousand yen, up 524,572 thousand yen from December 31, 2018. This was mainly attributable to increases of 1,271,770 thousand yen in share capital, 1,271,770 thousand yen in capital surplus, and 50,962 thousand yen in share acquisition rights, offsetting a decrease of 2,069,929 thousand yen in retained earnings that was due to the recording of a loss for the quarter.

As a result, the equity ratio rose by 2.5 percentage points from December 31, 2018 to 72.6%.

(3) Note of earnings forecasts and other forward-looking information

Regarding the earnings forecasts, please refer to the announcement "Revision to Earnings Forecasts for FY 2019 and Mid-Range Plan (FY 2019 to FY 2022)" released today (on August 7, 2019).

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly balance sheet

(Thousands of yen)

	FY 2018 (as of December 31, 2018)	1H FY 2019 (as of June 30, 2019)
Assets		
Current assets		
Cash and deposits	4,821,355	6,066,166
Accounts receivable–trade	411,720	11,090
Merchandise and finished goods	533,824	—
Prepaid expenses	83,372	134,959
Advances paid	31,147	27,835
Consumption taxes receivable	124,855	92,846
Other	32,214	41,910
Total current assets	6,038,490	6,374,808
Non-current assets		
Property, plant and equipment		
Buildings, net	36,771	35,141
Tools, furniture and fixtures, net	20,180	22,879
Construction in progress	—	1,288
Total property, plant and equipment	56,951	59,308
Intangible assets		
Software	50,946	44,866
Software in progress	20,430	124,218
Total intangible assets	71,376	169,085
Investments and other assets		
Shares of subsidiaries	0	0
Long-term prepaid expenses	1,225	—
Leasehold and guarantee deposits	71,378	70,937
Total investments and other assets	72,604	70,937
Total non-current assets	200,932	299,331
Total assets	6,239,423	6,674,140
Liabilities		
Current liabilities		
Accounts payable–trade	726,100	8,473
Accounts payable–other	503,637	1,109,122
Income taxes payable	71,249	69,133
Other	35,354	59,550
Total current liabilities	1,336,342	1,246,281
Non-current liabilities		
Provision for retirement benefits	1,281	1,487
Total non-current liabilities	1,281	1,487
Total liabilities	1,337,623	1,247,768

(Thousands of yen)

	FY 2018 (as of December 31, 2018)	1H FY 2019 (as of June 30, 2019)
Net assets		
Shareholders' equity		
Share capital	12,972,579	14,244,349
Capital surplus	12,942,579	14,214,349
Retained earnings	(21,543,238)	(23,613,168)
Treasury shares	(17)	(17)
Total shareholders' equity	4,371,902	4,845,513
Share acquisition rights	529,897	580,859
Total net assets	4,901,799	5,426,113
Total liabilities and net assets	6,239,423	6,674,140

(2) Quarterly statement of income

(Thousands of yen)

	1H FY 2018 (from January 1, 2018 to June 30, 2018)	1H FY 2019 (from January 1, 2019 to June 30, 2019)
Net sales	1,928,378	2,004,976
Cost of sales	1,355,079	1,475,575
Gross profit	573,299	529,400
Selling, general and administrative expenses	1,897,937	2,544,503
Operating profit (loss)	(1,324,638)	(2,015,102)
Non-operating income		
Interest income	439	101
Interest on tax refund	116	76
Insurance claim income	—	2,736
Other	54	—
Total non-operating income	609	2,914
Non-operating expenses		
Commission expenses	5,504	5,257
Share issuance cost	19,114	9,282
Foreign exchange losses	29,002	42,411
Other	—	227
Total non-operating expenses	53,620	57,178
Ordinary profit (loss)	(1,377,648)	(2,069,366)
Extraordinary income		
Gain on reversal of share acquisition rights	876	1,336
Total extraordinary income	876	1,336
Extraordinary losses		
Loss on retirement of non-current assets	9,829	—
Total extraordinary losses	9,829	—
Profit (loss) before income taxes	(1,386,602)	(2,068,029)
Income taxes–current	1,900	1,900
Total income taxes	1,900	1,900
Profit (loss)	(1,388,502)	(2,069,929)

(3) Quarterly statement of cash flows

(Thousands of yen)

	1H FY 2018 (from January 1, 2018 to June 30, 2018)	1H FY 2019 (from January 1, 2019 to June 30, 2019)
Cash flows from operating activities		
Profit (loss) before income taxes	(1,386,602)	(2,068,029)
Depreciation	16,915	17,911
Share-based remuneration expenses	64,636	73,787
Increase (decrease) in provision for retirement benefits	128	206
Interest income	(439)	(101)
Foreign exchange losses (gains)	29,870	55,734
Commission expenses	5,504	5,257
Share issuance cost	19,114	9,282
Gain on reversal of share acquisition rights	(876)	(1,336)
Loss on retirement of non-current assets	9,829	—
Decrease (increase) in trade receivables	(321,062)	400,630
Decrease (increase) in inventories	(199,242)	533,824
Decrease (increase) in prepaid expenses	(22,238)	(56,844)
Decrease (increase) in advances paid	(20,533)	3,311
Decrease (increase) in consumption taxes refund receivable	31,994	32,008
Decrease (increase) in other current assets	31,614	360
Decrease (increase) in long-term prepaid expenses	5,123	1,225
Increase (decrease) in trade payables	278,270	(717,627)
Increase (decrease) in accounts payable–other	61,233	603,144
Increase (decrease) in other current liabilities	241	12,023
Other, net	745	440
Subtotal	(1,395,772)	(1,094,789)
Interest and dividends received	439	101
Income taxes paid	(1,900)	(1,900)
Net cash provided by (used in) operating activities	(1,397,232)	(1,096,587)
Cash flows from investing activities		
Purchase of property, plant and equipment	(27,834)	(6,596)
Purchase of intangible assets	(3,530)	(109,039)
Proceeds from refund of leasehold and guarantee deposits	13,747	—
Net cash provided by (used in) investing activities	(17,617)	(115,636)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	1,541,756	2,522,051
Proceeds from issuance of share acquisition rights	23,100	—
Payments for issuance of shares	(17,582)	(9,282)
Net cash provided by (used in) financing activities	1,547,274	2,512,769
Effect of exchange rate change on cash and cash equivalents	(29,870)	(55,734)
Net increase (decrease) in cash and cash equivalents	102,554	1,244,810
Cash and cash equivalents at beginning of period	2,947,059	4,821,355
Cash and cash equivalents at end of period	3,049,613	6,066,166

(4) Notes to quarterly financial statements

(Notes to going concern assumptions)

None to be reported.

(Quarterly statement of income)

* 1 Inventories at quarter-end are stated after writing down based on the decrease in profitability.
The following amount is included within cost of sales as loss on valuation of inventories.

(Unit: thousands of yen)

	1H FY 2018 (from January 1, 2018 to June 30, 2018)	1H FY 2019 (from January 1, 2019 to June 30, 2019)
	—	187,840

A certain batch of TREAKISYM® 100mg was determined to be unsalable due to quality issues, which resulted in an inventory valuation loss. Inventory at quarter-end reflects their book value, taking this inventory valuation loss into account.

(Notes to significant changes in shareholders' equity)

During the first half of the fiscal year ending December 31, 2019, new shares were issued upon the exercise of parts of the 36th, 37th, 38th, and 46th warrants. As a result, during the first half of the fiscal year under review, share capital and legal capital surplus increased by 1,271,770 thousand yen and 1,271,770 thousand yen, respectively, amounting to 14,244,349 thousand yen and 14,214,349 thousand yen as of June 30, 2019.

(Significant subsequent events)

During a meeting held on February 28, 2019, the Board of Directors passed a resolution to submit a proposal concerning reverse stock split and a partial amendment to the Company's Articles of Incorporation at the 14th Ordinary General Meeting of Shareholders that was scheduled to take place on March 28, 2019. This proposal was approved at the same Ordinary General Meeting of Shareholders and took effect on July 1, 2019.

(1) Purpose of reverse stock split

Since its establishment, the Company has aimed to increase its capital in order to procure funds for the in-licensing of new drug candidates for development and to support its activities, including R&D necessary for advancing its pipeline development and increasing its number of drug candidates, staffing for the establishment of its own salesforce, system configuration, and development of a logistics and distribution infrastructure. As a result, the Company's total number of outstanding shares as of June 30, 2019 was 97,450,724. The Company believes that this share total is very large when considering its business scale. Our share price level also fell greatly beneath the desired investment unit level range of between 50,000 yen and 500,000 yen specified in Rule 445 of the Tokyo Stock Exchange's Securities Listing Regulations. In addition, the Company's share price volatility per yen was relatively high, amounting to a situation in which large fluctuations in the price of its shares, targets for speculative investment, were likely to occur. We were aware of the significant impact this had on all general investors.

Based on these circumstances, we conducted a 1-for-4 stock consolidation of common stock with the goals of bringing our number of outstanding shares in line with our business scale and adjusting our share price level to desirable investment unit levels.

(2) Percentage and timing of reverse stock split

On July 1, 2019, the Company conducted a 1-for-4 consolidation of common shares recorded in the final shareholders registry on June 30 ,2019.

(3) Share reduction due to reverse stock split

Number of shares outstanding prior to stock consolidation (as of June 30, 2019)	97,450,724 shares
Number of shares eliminated by stock consolidation	73,088,043 shares
Number of shares outstanding following stock consolidation	24,362,681 shares

(4) Handling of fractions of shares resulting from reverse stock split

Fractions of shares resulting from the stock consolidation will be sold collectively, and the proceeds distributed to their former shareholders based on the percentages of the share fractions that they had previously held, in accordance with Article 235 of the Companies Act.

(5) Partial amendment to the Articles of Incorporation associated with the reverse stock split

1) Reason for amendment

In accordance with the recent stock consolidation, the Company revised the total number of authorized shares under Article 6 of the Articles of Incorporation on July 1, 2019.

2) Amendments made to the Articles of Incorporation

(Underlined text indicates amendments.)

Articles of Incorporation prior to change	Articles of Incorporation following change
(Total number of authorized shares) Article 6 The total number of authorized shares for the Company shall be <u>167,000,000</u>.	(Total number of authorized shares) Article 6 The total number of authorized shares for the Company shall be <u>41,750,000</u>.

(6) Impact on per-share information

The impacts of the reverse stock split on per-share information have been included where they are pertinent.