English translation

SymBio Pharmaceuticals Limited

Summary of Financial Statements for the First Six Months of Fiscal Year Ending December 31, 2020 [Japanese GAAP] (Non-consolidated)

August 5, 2020

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 and Chief Financial Officer	Takaaki Fukushima	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	August 6, 2020	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 Six Months of FY 2020 (January 1, 2020 to June 30, 2020)

(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 2020	1,360	(32.1)	(1,839)	—	(1,883)	—	(1,884)	—
1H FY 2019	2,004	4.0	(2,015)	—	(2,069)	—	(2,069)	—

	Earnings (Loss) per Share	Diluted Earnings per Share
	Yen	Yen
1H FY 2020	(62.47)	—
1H FY 2019	(95.58)	—

(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 recording of a 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	%
1H FY 2020 (as of June 30, 2020)	6,585	5,792	78.9
FY 2019 (as of December 31, 2019)	5,273	4,400	71.7

(Reference) Shareholders' equity: 1H FY 2020 (as of June 30, 2020) 5,192 million yen

FY 2019 (as of December 31, 2019) 3,779 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 2019	—	0.00	—	0.00	0.00
FY 2020	—	0.00			
FY 2020 (Forecast)			—	0.00	0.00

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

3. Earnings Forecasts for FY 2020 (January 1, 2020 to December 31, 2020)

(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	3,404	20.0	(5,090)	—	(5,134)	—	(4,803)	—	(146.98)

(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 issued shares (common stock)

(i) Total number of issued shares at the end of the year (including treasury shares)	1H FY 2020	35,181,381 shares	FY 2019	26,437,681 shares
(ii) Total number of treasury shares at the end of the year	1H FY 2020	24,993 shares	FY 2019	22,593 shares
(iii) Average number of shares during the year (cumulative)	1H FY 2020	30,176,512 shares	1H FY 2019	21,655,982 shares

(Note) On July 1, 2019, the Company conducted a 1-for-4 consolidation of common stock. Total number of issued shares at the end of the year, total number of treasury shares at the end of the year, and average number of shares during the year 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

All forecasts presented in this document, including earnings forecasts, are based on the information currently available to the Company 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 8 of the attachment.

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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 six months of the fiscal year under review is as follows.

(i) Domestic business

[Establishment of the Company's own sales force]

The Company plans to transition the sale of TREAKISYM® in Japan to its own sales organization from January 2021 after its business partnership agreement with Eisai Co., Ltd. ("Eisai") expires in December 2020. In doing so, the Company aims to attain profitability in FY 2021 and achieve sustainable growth thereafter to solidify its future business development.

During the first six months of the fiscal year under review, the Company completed setting up a nationwide sales organization central to establishing its own sales structure as planned. It also hired additional employees to serve as TREAKISYM® sales representatives and regional sales managers, who are at the core of its nationwide sales organization, and trained them according to plan, making steady progress toward building a highly productive, high-performance sales force backed by an advanced level of expertise and extensive experience. Through these efforts, the Company was able to advance to the final stage of establishing a nationwide sales organization by mid-FY 2020. Further, continuing from the previous fiscal year, the Company made steady progress toward completing the development of its distribution and logistics functions centered on logistics bases strategically located in eastern and western Japan as well as its internal infrastructure, including enterprise resource planning (ERP) and other information systems.

[Issues concerning product defects]

The Company currently imports lyophilized injectable formulation of TREAKISYM® from Astellas Deutschland GmbH ("Astellas Deutschland"), a subsidiary of Astellas Pharma Inc. Contamination and appearance defects were found in some batches imported in 2019 for sale in Japan, and the extent of the contamination and defects significantly exceeded limits permitted by quality standards stipulated in the supply agreement entered between the Company and Astellas Deutschland. To prevent recurrence of similar quality issues, the Company has filed complaints with and urged Astellas Deutschland to fulfill its responsibilities as a supplier, including implementing a corrective and preventive action (CAPA). However, there was no sign of improvement in the first six months of FY 2020, as defect rates remained high in a number of batches imported from Astellas Deutschland and delivery dates continued to be unreliable. As a result, the Company continued to face issues with the supply of TREAKISYM®, which resulted in the product's inventory level remaining lower year on year; accordingly, sales of TREAKISYM® in the first six months of FY 2020 lagged behind the level recorded in the same period of the previous fiscal year. In the third quarter of FY 2020 (July–September 2020), to recover the inventory level of TREAKISYM® as soon as possible, the Company will continue discussions with Astellas Deutschland and manage its progress in addressing the quality and supply issues to lower the defect rates and stabilize supply.

[Anticancer agents: SyB L-0501 (lyophilized powder formulation), SyB L-1701 (ready-to-dilute ("RTD") formulation), SyB L-1702 (rapid infusion ("RI") formulation) (generic name: bendamustine hydrochloride; trade name: TREAKISYM®)]

The Company obtained manufacturing and marketing approval for first-line treatment of low-grade non-Hodgkin's lymphoma (low-grade NHL) (Note 1) 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. TREAKISYM® is thus widely used in the field of malignant lymphoma. Further, the combination treatment of TREAKISYM® and rituximab (BR therapy) was added to the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues 2018 updated and published by the Japanese Society of Hematology in July 2018, which recommends BR therapy as a choice for standard treatment for all previously approved indications. With this achievement, TREAKISYM® has established its foothold as the standard treatment for malignant lymphoma.

In July 2018, the Company obtained approval to partially revise the manufacturing and marketing authorization, allowing TREAKISYM® to be used in combination with not only rituximab but also other new anti-CD20 antibodies for the treatment of CD-20 positive follicular lymphoma (FL), a typical histologic type of low-grade NHL. As a new treatment option, TREAKISYM® is offered to patients in combination with obinutuzumab (Note 2), which was launched in August 2018. In March 2019, the Company obtained approval for a partial change to its application concerning the use of TREAKISYM® as a pretreatment agent for tumor-specific T-cell infusion therapy (Note 3). This allowed TREAKISYM® to be used as a pretreatment agent for Kymriah® intravenous infusion (Note 4), the first chimeric antigen receptor T-cell (CAR-T) therapy (Note 5) to be approved in Japan (included in the National Health Insurance price list in May 2019). The expansion of its use as a pretreatment agent for

regenerative medicine and other pharmaceutical products has strengthened the position of TREAKISYM® as the standard treatment for malignant lymphoma.

The Company conducted a Phase III clinical trial of BR therapy targeting recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), the fourth indication of TREAKISYM® following three approved indications. After obtaining favorable results from the trial, with the overall response rate—the primary endpoint of the trial—exceeding expected levels, the Company applied for approval of a partial change to the manufacturing and marketing authorization of TREAKISYM® in May 2020. In June 2020, Chugai Pharmaceutical Co., Ltd. ("Chugai") filed for manufacturing and marketing approval of polatuzumab vedotin (Note 6) used in combination with BR therapy targeting patients with r/r DLBCL. In response, the Company applied for approval in July 2020 to partially amend the manufacturing and marketing authorization of TREAKISYM® used in combination with polatuzumab vedotin and rituximab. Once polatuzumab vedotin is included in the NHI price list after applications submitted by the Company and Chugai are approved, TREAKISYM® can be used in combination with polatuzumab vedotin and BR therapy. Because currently there exists no effective treatment for r/r DLBCL, combination therapies comprising of multiple anticancer drugs are being used as rescue chemotherapy. However, because these therapies often cause serious adverse effects, the development of highly effective new drugs with little adverse effects is in dire need. BR therapy is already used to treat patients with r/r DLBCL in Europe and the U.S., and in Japan, patient organizations and relevant academic societies have submitted a request to the Ministry of Health, Labour and Welfare, asking the authorities to make BR therapy available as soon as possible. Once approval is granted, the Company expects TREAKISYM® to be widely available as a treatment option for many patients.

In September 2017, the Company concluded an exclusive license agreement with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S., "Eagle") and obtained exclusive rights to develop and market TREAKISYM® liquid formulation (RTD and RI liquid formulations) (Note 7) in Japan. For the RTD liquid formation, the Company filed an application for approval in September 2019 and plans to launch in the first three months of FY 2021. For the RI liquid formulation, the Company commenced a clinical trial in November 2018 with the primary goal of confirming its safety, and completed patient enrollment in March 2020. The Company expects to obtain approval in the second half of FY 2022 by promptly filing for an application after the trial ends. The RI liquid formulations of TREAKISYM® will significantly reduce the time required for administration to 10 minutes, down from the 60 minutes required by the currently available lyophilized powder and RTD formulations. This will likely greatly lessen the burdens placed on patients and healthcare providers, enabling the Company to provide substantial added value. Furthermore, the protection of multiple patents through liquid formula manufacturing licenses will make it possible to extend the life of these products until 2031, further strengthening the foundation of the Company's business growth.

(Note 1) Non-Hodgkin's lymphoma (NHL) refers to malignant lymphoma other than Hodgkin's lymphoma. Malignant lymphoma is a cancer of the lymphatic system in which lymphocytes develop malignant growths. The majority of Japanese malignant lymphoma patients are suffering from NHL.

(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.

(Note 3) 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 4) 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. Novartis Pharma 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 5) 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.

(Note 6) Developed by Roche using Seattle Genetics' antibody-drug conjugate (ADC) technology, polatuzumab vedotin is a first-in-class anti-CD79b ADC (targeting CD79b) built by conjugating humanized monoclonal antibody targeting CD79b to a tubulin polymerization inhibitor. CD79b protein is specifically expressed on the surface of many B-cells, and is expected to be a promising target in new drug development. Polatuzumab vedotin selectively binds to CD79b while minimally affecting normal cells, and destroys B-cells with the chemotherapeutic agent it contains.

(Note 7) RTD and RI are pre-dissolved liquid formulations that differ from currently available lyophilized (freeze-dried) powder injection. 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.

[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 (also known as INSPIRE 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, relapse after treatment under the current standard of care, or are intolerant to hypomethylating agents. The Company is responsible for clinical development in Japan. Onconova announced in March 2020 that global patient enrollment (final target of 360 patients) was completed and further announced in July 2020 that it reached the required number of survival events. Onconova in the July 2020 announcement also stated that it expected to obtain the top-line results (primary endpoints) of the trial in the third quarter of 2020 and that scheduled to present the results at an academic conference within the same year. Based on the results of the trial, the Company plans 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 completed Phase I/II clinical trials in the U.S. for the target indication of first-line HR-MDS (in combination with azacitidine (Note 8)), and results suggested that the oral formulation of rigosertib and azacitidine were safe and effective when combined. 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. We began patient enrollment since the first patient was enrolled in October 2017 and completed the enrollment process in June 2019. After completion of this trial, the Company plans to take part in a global trial for combination therapy with azacitidine as the first-line treatment of patients with HR-MDS, which Onconova is currently considering conducting. Data from this global trial was announced at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in December 2019. Based on this data, Onconova announced in the same month that it is discussing the design of a Phase II/III adaptive clinical trial testing this combination therapy as a first-line treatment for HR-MDS.

(Note 8) 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, and 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.

[Antiviral drug: SyB V-1901 (generic name: brincidofovir)]

On September 30, 2019, the Company concluded an exclusive global licensing agreement for intravenous and oral formulation of antiviral drug brincidofovir (Note 9) (SyB V-1901; "BCV IV" and "BCV Oral," respectively) with Chimerix Inc. (head office: North Carolina, U.S., "Chimerix"). Under this agreement, the Company acquired the exclusive rights for the worldwide development, marketing, and manufacture of BCV for all human indications, excluding smallpox.

Since the Company acquired exclusive rights to BCV, it has continuously exchanged ideas with experts in infectious diseases in and outside Japan in formulating a global development plan. Taking into consideration multiple perspectives and upon carefully reviewing scientific and medical validity as well as the business feasibility of BCV, the Company has decided to prioritize global development of BCV IV targeting adenovirus (AdV) infections occurring after hematopoietic stem cell

transplantation, an area with high unmet medical needs as there currently exists no effective treatment. The global development will focus on Japan, the U.S., and Europe. Leveraging its knowledge of the efficacy and safety of BCV obtained from conducting clinical trials of the drug, the Company intends to expand target indications of BCV to include multiple viral infections occurring after hematopoietic stem cell transplantation, and further investigate whether it can be indicated for viral infections after kidney or other organ transplantation. Through these efforts, the Company aims to expand the target market of BCV and maximize its business value and strives to transform itself into a global specialty pharmaceutical company equipped with a comprehensive system for supplying quality pharmaceutical products.

BCV Oral has demonstrated highly active antiviral effects in clinical trials conducted by Chimerix in Europe and the U.S.. These trials have also confirmed that BCV Oral has broad-spectrum antiviral effects. The extensive antiviral effects of BCV Oral against various dsDNA viruses (Note 10) have led the Company to expect BCV IV to demonstrate efficacy and safety in the treatment and prevention of various viral infections occurring after hematopoietic stem cell transplantation.

(Note 9) Brincidofovir (BCV) has a structure in which cidofovir (an antiviral drug already approved and marketed in the U.S. and Europe, but unapproved in Japan; "CDV") is bound to a lipid chain (hexadecyloxypropyl; "HDP"). It is quickly absorbed into the lipid bilayer membrane and efficiently transfers into cells, and then the bound lipid chain is metabolized and separated from the structure by intracellular phospholipases. This process generates an activator (CDV-PP; CDV diphosphate) that is retained in the cells for a long period of time, dramatically raising the compound's antiviral activity. Furthermore, BCV avoids nephrotoxicity, a fundamental issue plaguing CDV, since HDP conjugation prevents the accumulation of the compound in renal tubular epithelial cells through organic anion transporter 1 (OAT1) and CDV is released at low levels in the bloodstream.

(Note 10) Double-stranded DNA (dsDNA) viruses includes herpesviridae, adenoviridae, polyomaviridae, papillomaviridae, poxviridae families of viruses, such as CMV, AdV, HHV-6, BK virus, HSV1/2, VZV, HPV, JCV, and small pox virus.

[Patient-controlled analgesia SyB P-1501]

The Company initiated an arbitration against The Medicines Company (head office: New Jersey, U.S., "MDCO") on October 11, 2017 under the rules of the International Chamber of Commerce, seeking damages of 82 million US dollars arising from MDCO's repudiation of the license agreement entered between the Company and MDCO for exclusive rights to SyB P-1501 (IONSYS in the U.S.). The Company announced on August 5, 2020 that the arbitral tribunal, while denying the Company's claim for damages, has awarded 50% of the legal fees and expenses that the Company sought to recover in the arbitration. In addition, the arbitral tribunal denied MDCO's counterclaim in full and awarded no recovery to MDCO. Any material impact of the award on the Company's earnings forecast for the fiscal year ending December 31, 2020 will be evaluated and disclosed by the Company in a timely manner.

(ii) Business outside Japan

SyB L-0501 is also marketed in South Korea, Taiwan, and Singapore, and product sales of SyB L-0501 in these countries were in line with the Company's forecasts.

(iii) Licensing of new drug candidates

The Company plans to focus on formulating and executing plans for the global development of the antiviral drug brincidofovir in-licensed in September 2019 for the time being. However, we will continue working on and reviewing multiple existing licensing projects while searching for and evaluating new drug candidates for potential in-licensing. Through these efforts, we aim to create long-term business value as a profitable biopharmaceutical company with growth potential.

(iv) Business results

As a result of the above, net sales totaled 1,360,648 thousand yen for the first six months of the FY 2020, primarily reflecting product sales of TREAKISYM®, and overall net sales fell 32.1% year on year.

Selling, general and administrative expenses totaled 2,169,841 thousand yen (-14.7% year on year), including research and development ("R&D") expenses of 833,697 thousand yen (-13.4% year on year) primarily due to expenses associated with clinical trials for the intravenous formulation of TREAKISYM® and the intravenous and oral formulations of rigosertib, as well as other selling, general and administrative expenses of 1,336,143 thousand yen (-15.5% year on year), including upfront spending to establish an internal sales structure.

As a result, an operating loss of 1,839,942 thousand yen was recognized in the first six months of FY 2020 (versus an operating loss of 2,015,102 thousand yen in the same period of FY 2019). Due to non-operating expenses of 43,377 thousand yen, primarily comprising of foreign exchange losses of 18,985 thousand yen and share issuance cost of 22,896 thousand yen, ordinary loss totaled 1,883,076 thousand yen (versus an ordinary loss of 2,069,366 thousand yen in the same period of FY 2019) and bottom-line loss in the first three months of the FY 2020 totaled 1,884,976 thousand yen (versus a loss of 2,069,929 thousand yen in the same period of FY 2019).

Segment information has been omitted since 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, 2020 stood at 6,585,397 thousand yen, an increase of 1,311,441 thousand yen from the previous fiscal year end. This was primarily due to increases of 1,498,876 thousand yen in cash and deposits, 151,893 thousand yen in merchandise and finished goods, 43,753 thousand yen in prepaid expenses, 31,522 thousand yen in software in progress, 23,555 thousand yen in software, 19,902 thousand yen in tools, furniture and fixture, and 10,936 thousand yen in lease and guarantee deposits, offsetting decrease of 314,728 thousand yen in accounts receivable–trade, 139,809 thousand yen in consumption taxes receivable, 27,066 thousand yen in advances paid, and 17,713 thousand yen in construction in progress .

Total liabilities stood at 792,949 thousand yen, a decrease of 80,888 thousand yen from the previous fiscal year end, owing mainly to a decrease of 155,592 thousand yen in accounts payable–other, which offset an increase of 72,990 in accounts payable–trade.

Under net assets, decreases of 21,251 thousand yen in share acquisition rights and 1,884,976 thousand yen in retained earnings due to the recording of a bottom-line loss were offset by increases of 1,650,573 thousand yen in capital surplus and 1,648,467 thousand yen in share capital. As a result, total net assets increased by 1,392,330 thousand yen from the previous fiscal year end to 5,792,447 thousand yen.

The equity ratio consequently rose 7.2 percentage points from the previous fiscal year end to 78.9%.

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

No revision was made to the earnings forecasts for FY 2020 as of the date of this document.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly balance sheet

(Unit: thousands of yen)

	FY 2019 (as of December 31, 2019)	1H FY 2020 (as of June 30, 2020)
Assets		
Current assets		
Cash and deposits	3,910,830	5,409,697
Accounts receivable–trade	549,275	234,546
Merchandise and finished goods	—	151,893
Prepaid expenses	94,002	137,755
Advances paid	41,791	14,725
Consumption taxes receivable	275,324	135,515
Other	16,267	48,289
Total current assets	4,887,491	6,132,424
Non-current assets		
Property, plant and equipment		
Buildings, net	34,734	33,040
Tools, furniture and fixtures, net	19,242	39,144
Construction in progress	21,513	3,800
Total property, plant and equipment	75,491	75,985
Intangible assets		
Software	94,974	118,529
Software in progress	145,551	177,073
Total intangible assets	240,525	295,603
Investments and other assets		
Shares of subsidiaries	0	0
Leasehold and guarantee deposits	70,446	81,383
Total investments and other assets	70,446	81,383
Total non-current assets	386,463	452,972
Total assets	5,273,955	6,585,397
Liabilities		
Current liabilities		
Accounts payable–trade	120,913	193,903
Accounts payable–other	639,482	483,890
Income taxes payable	87,756	88,499
Other	24,066	24,860
Total current liabilities	872,219	791,153
Non-current liabilities		
Provision for retirement benefits	1,619	1,796
Total non-current liabilities	1,619	1,796
Total liabilities	873,838	792,949

(Unit: thousands of yen)

	FY 2019 (as of December 31, 2019)	1H FY 2020 (as of June 30, 2020)
Net assets		
Shareholders' equity		
Share capital	14,870,639	16,519,107
Capital surplus	14,843,137	16,493,711
Retained earnings	(25,919,496)	(27,804,473)
Treasury shares	(15,077)	(15,559)
Total shareholders' equity	3,779,202	5,192,785
Share acquisition rights	620,913	599,661
Total net assets	4,400,116	5,792,447
Total liabilities and net assets	5,273,955	6,585,397

(2) Quarterly statement of income
(For the first six months of FY 2020)

(Unit: thousands of yen)

	1H FY 2019 (from January 1, 2019 to June 30, 2019)	1H FY 2020 (from January 1, 2020 to June 30, 2020)
Net sales	2,004,976	1,360,648
Cost of sales	*1,475,575	*1,030,749
Gross profit	529,400	329,898
Selling, general and administrative expenses	2,544,503	2,169,841
Operating profit (loss)	(2,015,102)	(1,839,942)
Non-operating income		
Interest income	101	120
Interest on tax refund	76	120
Insurance claim income	2,736	—
Other	—	2
Total non-operating income	2,914	244
Non-operating expenses		
Commission expenses	5,257	1,495
Share issuance costs	9,282	22,896
Foreign exchange losses	42,411	18,985
Other	227	—
Total non-operating expenses	57,178	43,377
Ordinary profit (loss)	(2,069,366)	(1,883,076)
Gain on reversal of share acquisition rights	1,336	—
Total extraordinary income	1,336	—
Profit (loss) before income taxes	(2,068,029)	(1,883,076)
Income taxes–current	1,900	1,900
Total income taxes	1,900	1,900
Profit (loss)	(2,069,929)	(1,884,976)

(3) Quarterly statement of cash flows

(Unit: thousands of yen)

	1H FY 2019 (from January 1, 2019 to June 30, 2019)	1H FY 2020 (from January 1, 2020 to June 30, 2020)
Cash flows from operating activities		
Loss before income taxes	(2,068,029)	(1,883,076)
Depreciation	17,911	20,405
Share-based remuneration expenses	73,787	55,106
Increase (decrease) in provision for retirement benefits	206	177
Interest income	(101)	(120)
Foreign exchange losses (gains)	55,734	20,272
Commission expenses	5,257	1,495
Share issuance costs	9,282	22,896
Gain on reversal of share acquisition rights	(1,336)	—
Decrease (increase) in trade receivables	400,630	314,728
Decrease (increase) in inventories	533,824	(151,893)
Decrease (increase) in prepaid expenses	(56,844)	(45,249)
Decrease (increase) in advances paid	3,311	27,066
Decrease (increase) in consumption taxes refund receivable	32,008	139,809
Decrease (increase) in other current assets	360	(32,022)
Decrease (increase) in long-term prepaid expenses	1,225	—
Increase (decrease) in trade payables	(717,627)	72,990
Increase (decrease) in accounts payable–other	603,144	(155,565)
Increase (decrease) in other current liabilities	12,023	1,536
Other, net	440	440
Subtotal	(1,094,789)	(1,591,002)
Interest and dividends received	101	121
Income taxes paid	(1,900)	(1,900)
Net cash provided by (used in) operating activities	(1,096,587)	(1,592,780)
Cash flows from investing activities		
Purchase of property, plant and equipment	(6,596)	(9,955)
Purchase of intangible assets	(109,039)	(68,451)
Payments of leasehold and guarantee deposits	—	(11,377)
Net cash provided by (used in) investing activities	(115,636)	(89,785)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	2,522,051	3,215,468
Proceeds from issuance of share acquisition rights	—	10,540
Payments for issuance of shares	(9,282)	(20,494)
Purchase of treasury shares	—	(4,129)
Proceeds from disposal of treasury shares	—	321
Net cash provided by (used in) financing activities	2,512,769	3,201,706
Effect of exchange rate change on cash and cash equivalents	(55,734)	(20,272)
Net increase (decrease) in cash and cash equivalents	1,244,810	1,498,867
Cash and cash equivalents at beginning of period	4,821,355	3,910,830
Cash and cash equivalents at end of period	6,066,166	5,409,697

(4) Notes to quarterly financial statements

(Notes to going concern assumptions)

None to be reported.

(Relating to the quarterly statement of income)

*The value of ending inventory is the amount after inventory write-downs in connection with a decline in profitability, and the following loss on valuation of inventories is included in the cost of sales.

(Unit: thousands of yen)

	1H FY 2019 (from January 1, 2019 to June 30, 2019)	1H FY 2020 (from January 1, 2020 to June 30, 2020)
	187,840	68,838

The above figures reflect the booking of a loss on valuation of inventories, as the Company determined that some batches of TREAKISYM® 100mg vials were unfit for sales due to quality defects.

(In case of significant changes to shareholders' equity)

In the first six months of FY 2020, the Company issued new shares due to the exercise of some of share acquisition rights pertaining to the 33rd, 36th, 37th, 38th, 40th, 41st, 47th, and 50th warrants. As a result, share capital and capital surplus each increased by 1,648,467 thousand yen. The total value of treasury shares increased 4,129 thousand yen as a result of a share repurchase.

Further, the Company disposed of treasury shares due to the exercise of some of share acquisition rights issued in the 33rd, 36th, and 38th warrants. As a result, the total value of treasury shares fell 3,259 thousand yen and other capital surplus increased 2,176 thousand yen.

The disposal of treasury shares in response to the request to sell shares by shareholders of less-than-one unit of shares led to declines of 387 thousand yen in the total value of treasury shares and 71 thousand yen in other capital surplus.

As a result, as of June 30, 2020 share capital was 16,519,107 thousand yen, capital surplus 16,493,711 thousand yen, and the total value of treasury shares 15,559 thousand yen.

(Significant subsequent events)

None to be reported.