



# **Summary of Financial Statements** for the First Six Months of Fiscal Year Ending December 31, 2021 [Japanese GAAP] (Non-consolidated)

			August 4, 2021
Company Name	SymBio Pharmaceuticals Limited	Listing: Tokyo Stock E	xchange
Securities Code	4582	URL: https://www.sym	biopharma.com/
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida	
Contact Person	Corporate Officer, Chief Financial Officer, and Head of Administrative Division	Takaaki Kishida	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	August 5, 2021	Date of Dividend Payment (plan)	_

Supplementary materials for the quarterly financial statements: Yes • No No Holding of quarterly earnings performance review: Yes

(Amounts	of less	than	one	million	yen	are	rounded	down.	)
June 30 2	021)								

1. Business Results for the First Six Months of FY 2021 (January 1, 2021 to June 30, 2021) (1) Operating Results (cumulative) (Percentages indicate year-on-year changes.)

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	Net Sales		Operating Prof	it (Loss)	Ordinary Profit	(Loss)	Profit (Lo	ss)
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
1H FY 2021	3,146	131.3	(194)	_	(203)	_	(205)	_
1H FY 2020	1,360	(32.1)	(1,839)	—	(1,883)		(1,884)	
	Earnings (Loss) po	er Share	Diluted Earnings per Share					
		Yen	Yen					
1H FY 2021	(5.37)			_				

(Note) 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

1H FY 2020

	Total Assets	Net Assets	Equity Ratio
	Millions of yen	Millions of yen	%
1H FY 2021 (as of June 30, 2021)	5,493	4,451	72.4
FY 2020 (as of December 31, 2020)	6,274	4,657	64.3

(62.47)

(Reference) Shareholders' equity: 1H FY 2021 (as of June 30, 2021)

FY 2020 (as of December 31, 2020)

## 2. Dividends

	Annual Dividend per Share						
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year End	Full Year		
	Yen	Yen	Yen	Yen	Yen		
FY 2020	_	0.00	—	0.00	0.00		
FY 2021	—	0.00					
FY 2021 (Forecast)			_	0.00	0.00		
(Note) Revision of dividend forecasts recently announced: Yes • No							

## 3. Earnings Forecasts for FY 2021 (January 1, 2021 to December 31, 2021)

	Net Sale	Net Sales Operating Profit Ordinary Profit Profit			Dperating Profit Ordinary Profit F				Earnings per Share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Full Year	9,151	206.4	1,361	_	1,350	_	1,149	_	29.99
(Note) Revision of	(Note) Revision of earnings forecasts recently announced: Yes • No								

(Note) Revision of earnings forecasts recently announced:

## 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:
  - (b) Changes in accounting policies due to other reasons:
  - (c) Changes in accounting estimates:
  - (d) Restatements after error corrections:

- (i) Total number of issued shares at the end of the period (including treasury shares)
- (ii) Total number of treasury shares at the end of the period
- (iii) Average number of shares during the period (cumulative)
- 1H FY 2021 38,432,981 shares FY 2020 38,202,956 shares 1H FY 2021 76,868 shares FY 2020 30,143 shares 1H FY 2021 38,259,460 shares 1H FY 2020 30,176,512 shares
- \* 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 6 of the attachment.

Yes •	No
Yes •	No
Yes •	No
Yes •	No

(Percentages indicate vear-on-vear changes.)

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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

[Transition to the Company's own salesforce and business expansion]

With the expiration of the business partnership agreement with Eisai Co., Ltd. ("Eisai") in FY 2020, the Company transitioned the sale of TREAKISYM<sup>®</sup> to its own sales organization in December 2020. Attaining profitability in FY 2021 and achieving sustainable growth are priorities of the Company, and the transition of sales to our own sales organization provides a solid foundation for our future business development.

To prepare plans tailored to the needs of local communities, and build a more productive sales team, the Company has assigned medical representatives nationwide and hematology experts in each region of its operation. Given the business partnership agreement with Eisai has now expired, to achieve nationwide distribution, the Company have signed agreements with Suzuken Co., Ltd. and Toho Pharmaceutical Co., Ltd. for the distribution of pharmaceutical products, making them the Company's exclusive wholesalers. The Company has also begun working with S.D. Collabo Co., Ltd. on building nationwide logistics and has set up two logistics centers—one in Eastern Japan and the other in Western Japan.

During the first six months of the fiscal year under review, the Company commenced sales of the ready-to-dilute (RTD) intravenous formulation of TREAKISYM<sup>®</sup> on January 12, 2021 after obtaining marketing approval in September 2020.

On March 23, 2021, the Company obtained approval for a partial change to the marketing authorization of the freeze-dried (FD) formulation of TREAKISYM<sup>®</sup>, allowing the product to be used in the bendamustine-rituximab (BR) therapy as well as in the polatuzumab vedotin plus bendamustine-rituximab (P+BR) therapy to treat recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). Upon receiving the approval, the FD formulation of TREAKISYM<sup>®</sup> became available for use in BR therapy. On April 28, 2021, the Company obtained approval for a partial change to the marketing approval of the RTD formulation of TREAKISYM<sup>®</sup> for its use in BR therapy and P+BR therapy for the treatment of r/r DLBCL. On May 19, 2021, polatuzumab vedotin was listed in the NHI drug price list, allowing TREAKISYM<sup>®</sup> to be used in the P+BR therapy.

## [Stable product supply]

The Company commenced sales of the RTD formulation of TREAKISYM<sup>®</sup> in January 2021, and now sells both RTD liquid formulation and FD formulation of TREAKISYM<sup>®</sup>.

The FD formulation of TREAKISYM<sup>®</sup> is imported from Astellas Deutschland GmbH, a subsidiary of Astellas Pharma Inc. The Company imports the RTD formulation of TREAKISYM<sup>®</sup> from Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.). In the first six months of the fiscal year, the Company conducted secondary packaging and quality screening on imported batches as planned, and currently maintains sufficient inventory to support stable supply of product.

The Company is promoting conversion in the market from FD formulation to RTD formulation, and aims to achieve 91% conversion by 2021 year-end.

[Anticancer agents: SyB L-0501 (FD formulation), SyB L-1701 (ready-to-dilute ("RTD") formulation), SyB L-1702 (rapid infusion ("RI") injection) (generic name: bendamustine hydrochloride or bendamustine hydrochloride hydrate, trade name: TREAKISYM<sup>®</sup>)]

SymBio obtained marketing approval for TREAKISYM<sup>®</sup> for the indication of low-grade non-Hodgkin's lymphoma (lowgrade NHL) as first-line treatment <sup>(Note 1)</sup> and mantle cell lymphoma (MCL) in December 2016, and for the indications of recurrent/refractory low-grade NHL and MCL in October 2010 and chronic lymphocytic leukemia (CLL) in August 2016. TREAKISYM<sup>®</sup> is thus being used to treat a wide array of malignant lymphoma. Further, BR therapy was newly included in the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues published by the Japanese Society of Hematology in July 2018, becoming recommended as an option for standard treatment for all previously approved indications. With this development, TREAKISYM<sup>®</sup> has established its foothold as a standard treatment for malignant lymphoma.

In July 2018, the Company obtained approval for a partial change to the marketing authorization of TREAKISYM<sup>®</sup>, allowing the product 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. Having obtained approval for the partial change, TREAKISYM<sup>®</sup> is being offered to patients as a new treatment option in combination with obinutuzumab <sup>(Note 2)</sup>. In March 2019, the Company obtained approval for a partial change to the marketing authorization, allowing the use of TREAKISYM<sup>®</sup> as a pretreatment agent for tumor-specific T-cell infusion therapy <sup>(Note 3)</sup>. This allowed TREAKISYM<sup>®</sup> to be used

as a pretreatment agent for Kymriah<sup>®</sup> intravenous infusion <sup>(Note 4)</sup>, the first chimeric antigen receptor T-cell (CAR-T) therapy <sup>(Note 5)</sup> to be approved in Japan. Increased use as a pretreatment agent for regenerative medicine and other pharmaceutical products has further solidified the status of TREAKISYM<sup>®</sup> as the standard treatment for malignant lymphoma.

Following the already-approved indications, SymBio conducted a Phase III clinical trial of BR therapy targeting r/r DLBCL, and in May 2020 it applied for a partial change to the marketing authorization to include this additional indication. The approval was granted in March 2021. In April 2021, the Company obtained approval for a partial change to the marketing approval of the RTD formulation of TREAKISYM® for its use in BR and P+BR therapies for the treatment of r/r DLBCL. Further, the Company conducted a follow-up study with overall survival as the primary endpoint, since survival data (e.g., overall survival and progression-free survival) for the bendamustine<sup>®</sup>-rituximab combined therapy is crucial in establishing TREAKISYM<sup>®</sup> as a DLBCL treatment. The Company is currently preparing to publish the follow-up study results. In June 2020, Chugai Pharmaceutical Co., Ltd. ("Chugai Pharmaceutical") filed for marketing approval of polatuzumab vedotin (Note 6) used in combination with BR therapy targeting r/r DLBCL. Similarly, in July 2020 the Company applied for a partial change to the marketing authorization of TREAKISYM® used in combination with polatuzumab vedotin and rituximab and obtained approval in March 2021. On May 19, 2021, polatuzumab vedotin was included in the NHI drug price list, allowing TREAKISYM® to be used in the combination therapy of polatuzumab vedotin and BR therapy (P+BR). Because currently there exists no effective treatment for r/r DLBCL, the newly added indication for TREAKISYM®, combination therapies comprising multiple anticancer drugs are being used as rescue chemotherapy, and the development of highly effective and safe drugs is sorely needed. BR therapy is already being used to treat patients with r/r DLBCL in Europe and the U.S. In Japan, patient organizations and relevant academic societies have submitted a request to the Ministry of Health, Labour and Welfare, asking to make BR therapy available as soon as possible. Going forward, the Company expects TREAKISYM® to be widely available as a treatment option for many patients.

In September 2017, SymBio concluded an exclusive license agreement with Eagle Pharmaceuticals for RTD and RI formulations <sup>(Note 7)</sup> of TREAKISYM<sup>®</sup> in Japan. The RI formulation enables a shortened administration time. The Company obtained marketing approval for the RTD formulation on September 18, 2020, and launched the product in January 2021. For the RI injection, the Company concluded clinical trials aimed at confirming the drug's safety and on May 7, 2021, submitted an approval application. Unlike the FD formulation, RTD formulation of TREAKISYM<sup>®</sup> does not require the cumbersome manual work of dissolving the drug (i.e., drug reconstitution), shortening preparation time and substantially reducing burdens on healthcare providers. Further, the RI injection significantly reduces the infusion time to 10 minutes, down from the one hour required by the currently available FD and RTD formulations. This will greatly reduce burdens on patients and healthcare providers, enabling the Company to provide substantial added value. Further, with exclusive rights to manufacture these liquid formulations, which are patent-protected, the Company is able to extend the life of these products until 2031 and further strengthen the foundation of its 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<sup>®</sup>, 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<sup>®</sup> intravenous infusion (generic name: tisagenlecleucel, marketed by Novartis Pharma K.K.): Kymriah<sup>®</sup> 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<sup>®</sup> for use in the treatment of CD19 positive recurrent/refractory B-cell acute lymphoblastic leukemia (B-ALL) and CD19 positive DLBCL in March 2019. Kymriah<sup>®</sup> 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) Ready-to-dilute (RTD) and rapid infusion (RI) are pre-dissolved liquid formulations that differ from currently available freeze-dried (FD) formulation. The RTD formulation will significantly reduce the preparation time and labor cost for healthcare providers, and the RI injection will substantially reduce infusion duration from the current one hour, 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.) concluded the global Phase III clinical trials (with trial sites in more than 20 countries; INSPIRE study) of the intravenous formulation of rigosertib for patients with higher-risk myelodysplastic syndromes (HR-MDS) who failed to respond to the current standard treatment with hypomethylating agents, relapsed after treatment under the current standard of care, or were intolerant to hypomethylating agents; the primary endpoint of the study was overall survival. In August 2020, Onconova announced that the primary endpoint—improved survival compared to physician's choice of treatment—was not met. The Company is responsible for clinical development in Japan, and is exploring ways to use the findings from the additional analysis of the INSPIRE study in the future development of rigosertib (intravenous formulation).

As for the oral formulation of rigosertib, Onconova completed a Phase I/II clinical trial of the investigational drug (in combination with azacitidine <sup>(Note 8)</sup>) in the U.S. in first-line HR-MDS patients, and the results suggested that the oral formulation of rigosertib used in combination with azacitidine was safe and effective. In June 2017, the Company initiated a Phase I clinical trial in Japan to confirm the safety and tolerability of high-dose monotherapy and tolerance in Japanese patients, and completed patient enrollment in June 2019.

With the aim of maximizing the business value of TREAKISYM<sup>®</sup> and rigosertib, the Company intends to conduct joint research with the Institute of Medical Science, the University of Tokyo, to investigate the efficacy of the drugs used in combination as well as used in combination with other existing drugs and look for new indications.

(Note 8) Azacitidine (Vidaza<sup>®</sup>, 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 <sup>(Note 9)</sup> (SyB V-1901; "BCV IV" and "BCV Oral," respectively) with Chimerix Inc. (head office: North Carolina, U.S.). Under this agreement, the Company acquired exclusive rights for the worldwide development, marketing, and manufacturing of BCV for all human indications, excluding orthopox viruses.

The Company determined to prioritize the 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, primarily in Japan, the U.S., and Europe. In March 2021, the Company submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate a Phase II clinical trial targeting AdV infections primarily in pediatric patients (also including adult patients). In April 2021, the FDA granted the development program a fast-track designation.

Based on the efficacy and safety findings from clinical trials targeting AdV infections, the Company plans to investigate the efficacy of BCV against a range of dsDNA<sup>(Note 10)</sup> viral infections and expand target indications to include multiple viral infections occurring after hematopoietic stem cell transplantation. It also intends to pursue the possibility of expanding target indications to viral infections after kidney or other organ transplantation. Through these efforts, the Company aims to expand the market for BCV and maximize its business value. BCV Oral demonstrated highly active antiviral effects in clinical trials conducted by Chimerix in Europe and the U.S. These trials also confirmed that BCV Oral had broad-spectrum antiviral effects. Based on these extensive antiviral effects of BCV Oral against various dsDNA viruses, the Company expects BCV IV to be also effective and safe in the treatment and prevention of various viral infections occurring after hematopoietic stem cell transplantation.

In December 2020, Chimerix announced that the U.S. FDA accepted its New Drug Application (NDA) for BCV Oral as a medical countermeasure for smallpox. Chimerix subsequently obtained approval on June 4, 2021.

- (Note 9) Brincidofovir is a lipid conjugate of cidofovir (CDV). CDV is an antiviral drug already approved and marketed in the United States and the European Union, but unapproved in Japan. It is quickly absorbed into the lipid bilayer membrane and efficiently transferred into cells, and 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, significantly raising the compound's antiviral activity. Furthermore, BCV avoids nephrotoxicity, a fundamental issue plaguing CDV, as the lipid 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 include herpesviridae, adenoviridae, polyomaviridae, papillomaviridae, poxviridae families of viruses, such as cytomegalovirus (CMV), adenovirus (AdV), human herpesvirus 6 (HHV-6), herpes simplex virus type 1 or 2 (HSV-1/2), BK virus (BKV), varicella zoster virus (VZV), human papillomavirus (HPV), JC virus, and small pox virus.

#### (ii) Business outside Japan

SyB L-0501 is also marketed in China and Hong Kong, and sales of SyB L-0501 in these countries were in line with the Company's forecasts.

#### (iii) Licensing of new drug candidates

SymBio plans to focus on the global development of the antiviral drug brincidofovir in-licensed in September 2019. The Company will continue its ongoing search and evaluation activities seeking new drug candidates for potential in-licensing. Through these efforts, it aims to create long-term business value as a profitable biopharmaceutical company with growth potential.

#### (iv) Business results

Net sales for the first six months of FY 2021 increased to 3,146,608 thousand yen (+131.3% year on year), as the transition to in-house sales led to sharp growth. However, sales growth was limited due to the residual inventories of TREAKISYM<sup>®</sup> FD formulation in the market sold by Eisai before the transition to in-house sales in December 2020. Another factor contributing to subdued sales growth was the impact of the resurgence of COVID-19 cases since the end of 2020, which resulted in postponed treatments or changes of regimen, as well as constricted sales activities due to tighter restrictions on visitations to facilities. However, from the third quarter of FY 2021, the Company expects sales of TREAKISYM<sup>®</sup> for r/r DLBCL to increase due to the following factors: gradual resumption of treatments which had thus far been postponed due to COVID-19 vaccination of the elderly patients; approval of BR and P-BR therapies for the additional indication of r/r DLBCL granted on March 23, 2021; and inclusion of Chugai Pharmaceutical's polatuzumab vedotin in the NHI drug price list on May 19, 2021.

Selling, general and administrative expenses totaled 2,469,708 thousand yen (+13.8% year on year), including research and development expenses of 912,268 thousand yen (+9.4% year on year) primarily due to expenses associated with clinical trials for the intravenous formulation of TREAKISYM<sup>®</sup> and the intravenous formulation of brincidofovir, as well as other selling, general and administrative expenses of 1,557,439 thousand yen (+16.6% year on year), including higher selling expenses due to the transition to in-house sales.

As a result, an operating loss of 194,941 thousand yen was recognized in the first six months of FY 2021 (versus an operating loss of 1,839,942 thousand yen in the same period of FY 2020). Although the Company recorded non-operating income of 14,858

thousand yen, consisting mostly of 14,757 thousand yen in commission income, it also recorded non-operating expenses of 23,774 thousand yen, primarily comprising foreign exchange losses of 17,991 thousand yen and commission expenses of 4,487 thousand yen. As a result, ordinary loss totaled 203,858 thousand yen (versus an ordinary loss of 1,883,076 thousand yen in the same period of FY 2020) and bottom-line loss in the first six months of the FY 2021 totaled 205,560 thousand yen (versus a loss of 1,884,976 thousand yen in the same period of FY 2020).

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, 2021 stood at 5,493,642 thousand yen, a decrease of 781,064 thousand yen from the previous fiscal year end. This was primarily due to decreases of 1,521,796 thousand yen in cash and deposits, 314,761 thousand yen in consumption taxes receivable, and 26,030 thousand yen in software, offsetting increases of 653,113 thousand yen in accounts receivable–trade, 259,927 thousand yen in merchandise and finished goods, 101,116 thousand yen in prepaid expenses, and 92,658 thousand yen in semi-finished goods.

Total liabilities stood at 1,042,581 thousand yen, a decrease of 574,807 thousand yen from the previous fiscal year end, due mainly to decreases in accounts payable–trade by 528,282 thousand yen and accounts payable–other by 154,305 thousand yen, offsetting increases of 128,029 thousand yen in accrued consumption taxes and 9,725 thousand yen in income taxes payable.

Total net assets stood at 4,451,060 thousand yen, a decrease 206,257 thousand yen from the previous fiscal year end. This was mainly owed to decreases of 205,560 thousand yen in retained earnings due to the recording of a bottom-line loss and 145,552 thousand yen in share acquisition rights, which offset increases of 102,113 thousand yen in capital surplus and 101,889 thousand yen in share capital.

The equity ratio consequently rose 8.0% from the previous fiscal year end to 72.4%.

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

In the first six month of FY 2021, the Company recorded an operating loss of 194,941 thousand yen, an ordinary loss of 203,858 thousand yen, and a bottom-line loss of 205,560 thousand yen. However, in the second quarter (three months) alone, the Company achieved profitability with operating profit of 15,577 thousand yen, ordinary profit of 5,049 thousand yen, and bottom-line profit of 4,099 thousand yen. With the approval of TREAKISYM<sup>®</sup> for the additional indication of r/r DLBCL and the inclusion of polatuzumab vedotin in the NHI drug price list from the third quarter onward, the probability of the Company achieving profitability at all profit categories for FY 2021 has further increased. However, that no change had been made to the full-year forecast as of the date of this document.

# 2. Quarterly Financial Statements and Primary Notes

(1) Quarterly balance sheet

		(Unit: thousands of yen)
	FY 2020 (as of December 31, 2020)	1H FY 2021 (as of June 30, 2021)
Assets		
Current assets		
Cash and deposits	3,848,626	2,326,829
Accounts receivable-trade	406,988	1,060,101
Merchandise and finished goods	271,550	531,478
Semi-finished goods	672,891	765,549
Prepaid expenses	80,645	181,761
Consumption taxes receivable	314,761	—
Other	219,828	200,613
Total current assets	5,815,292	5,066,335
Non-current assets		
Property, plant and equipment		
Buildings, net	42,735	40,936
Tools, furniture and fixtures, net	33,966	29,094
Total property, plant and equipment	76,701	70,031
Intangible assets		
Software	296,005	269,974
Software in progress	5,836	
Total intangible assets	301,841	269,974
Investments and other assets		
Shares of subsidiaries	0	0
Leasehold and guarantee deposits	80,871	87,301
Total investments and other assets	80,871	87,301
Total non-current assets	459,415	427,307
Total assets	6,274,707	5,493,642
Liabilities		
Current liabilities		
Accounts payable-trade	665,460	137,177
Accounts payable-other	645,813	491,508
Income taxes payable	81,928	91,653
Accrued consumption taxes		128,029
Other	222,137	191,834
Total current liabilities	1,615,339	1,040,203
Non-current liabilities		.,,
Provision for retirement benefits	2,050	2,378
Total non-current liabilities	2,050	2,378
Total liabilities	1,617,389	1,042,581
Total fidefitues	1,017,389	1,042,301

		(Unit: thousands of yen)
	FY 2020 (as of December 31, 2020)	1H FY 2021 (as of June 30, 2021)
Net assets		
Shareholders' equity		
Share capital	17,044,943	17,146,833
Capital surplus	17,019,485	17,121,599
Retained earnings	(30,009,713)	(30,215,273)
Treasury shares	(17,538)	(76,686)
Total shareholders' equity	4,037,177	3,976,472
Share acquisition rights	620,140	474,588
Total net assets	4,657,318	4,451,060
Total liabilities and net assets	6,274,707	5,493,642

# (2) Quarterly statement of income

(For the first six months of FY 2021)

		(Unit: thousands of yen)
	1H FY 2020 (from January 1, 2020 to June 30, 2020)	1H FY 2021 (from January 1, 2021 to June 30, 2021)
Net sales	1,360,648	3,146,608
Cost of sales	1,030,749	871,841
Gross profit	329,898	2,274,767
Selling, general and administrative expenses	2,169,841	2,469,708
Operating profit (loss)	(1,839,942)	(194,941)
Non-operating income		
Interest income	120	32
Interest on tax refund	120	68
Commission income		14,757
Other	2	0
Total non-operating income	244	14,858
Non-operating expenses		
Commission expenses	1,495	4,487
Share issuance costs	22,896	1,296
Foreign exchange losses	18,985	17,991
Total non-operating expenses	43,377	23,774
Ordinary profit (loss)	(1,883,076)	(203,858)
Extraordinary income		
Gain on reversal of share acquisition rights		198
Total extraordinary income		198
Profit (loss) before income taxes	(1,883,076)	(203,660)
Income taxes-current	1,900	1,900
Total income taxes	1,900	1,900
Profit (loss)	(1,884,976)	(205,560)

## (3) Quarterly statement of cash flows

	1H FY 2020 (from January 1, 2020 to June 30, 2020)	(Unit: thousands of yen) 1H FY 2021 (from January 1, 2021 to June 30, 2021)
Cash flows from operating activities		
Loss before income taxes	(1,883,076)	(203,660)
Depreciation	20,405	45,710
Share-based payment expenses	55,106	58,194
Increase (decrease) in provision for retirement benefits	177	328
Interest income	(120)	(32)
Foreign exchange losses (gains)	20,272	(14,239)
Commission expenses	1,495	4,487
Share issuance costs	22,896	1,296
Gain on reversal of share acquisition rights		(198)
Decrease (increase) in trade receivables	314,728	(653,113)
Decrease (increase) in inventories	(151,893)	(352,586)
Decrease (increase) in prepaid expenses	(45,249)	(101,116)
Decrease (increase) in advances paid	27,066	_
Decrease (increase) in consumption taxes refund receivable	139,809	314,761
Decrease (increase) in other current assets	(32,022)	19,215
Increase (decrease) in trade payables	72,990	(528,282)
Increase (decrease) in accounts payable-other	(155,565)	(152,360)
Increase (decrease) in other current liabilities	1,536	109,352
Other, net	440	582
Subtotal	(1,591,002)	(1,451,660)
Interest and dividends received	121	32
Income taxes paid	(1,900)	(3,800)
Commitment fees paid		(4,487)
Net cash provided by (used in) operating activities	(1,592,780)	(1,459,916)
Cash flows from investing activities		
Purchase of property, plant and equipment	(9,955)	(3,464)
Purchase of intangible assets	(68,451)	(3,627)
Payments of leasehold and guarantee deposits	(11,377)	(7,011)
Net cash provided by (used in) investing activities	(89,785)	(14,104)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	3,215,468	230
Proceeds from issuance of share acquisition rights	10,540	—
Payments for issuance of shares	(20,494)	(3,321)
Purchase of treasury shares	(4,129)	(59,336)
Proceeds from disposal of treasury shares	321	413
Net cash provided by (used in) financing activities	3,201,706	(62,015)
Effect of exchange rate change on cash and cash equivalents	(20,272)	14,239
Net increase (decrease) in cash and cash equivalents	1,498,867	(1,521,796)
Cash and cash equivalents at beginning of period	3,910,830	3,848,626
Cash and cash equivalents at end of period	5,409,697	2,326,829

## (4) Notes to quarterly financial statements

(Notes to going concern assumptions) None to be reported.

(In case of significant changes to shareholders' equity)

In the first six months of FY 2021, the Company issued new shares due to the exercise of some of share acquisition rights pertaining to the 32nd, 33rd, 35th, 36th, 37th, 38th, 40th, 41st, 43rd, and 44th warrants. As a result, share capital increased by 101,889 thousand yen and capital surplus increased by 101,890 thousand yen. The total value of treasury shares increased 59,337 thousand yen as a result of share repurchases.

The disposal of treasury shares in response to the request to sell shares by shareholders of less-than-one unit of shares led to a decrease of 189 thousand yen in the total value of treasury shares and an increase of 224 thousand yen in other capital surplus.

As a result, as of June 30, 2021, share capital was 17,146,833 thousand yen, capital surplus 17,121,599 thousand yen, and the total value of treasury shares 76,686 thousand yen.

## (Accounting policy changes)

(Change in inventory valuation methods)

The Company has up till now used the weighted average method for inventory valuation. However, as of Q1 FY 2021, the Company has changed to the first in, first out (FIFO) method for merchandise and finished goods and the weighted average method for semi-finished goods. Occasioned by the transition to its own sales force, the Company studied the adoption of new definitions and valuation methods for inventories to enable more detailed tracking of inventory movement, and more accurate inventory valuation and periodic profit calculation.

As a result, the Company determined that the use of the FIFO method for merchandise and finished goods and the weighted average method for semi-finished goods to achieve greater consistency with inventory movement would be a rational choice in terms of inventory valuation and periodic profit calculation and that it would more appropriately reflect the state of the Company's business administration.

Because this change has only a miniscule effect on monetary figures, the Company has not restated historical financial statements.

#### (Changes in statement methods)

(Balance sheets)

Occasioned by the transition to its own sales force, the Company revised its definitions of merchandise and finished goods and semi-finished goods to enable more detailed ascertainment of inventory movement, and more accurate inventory valuation and periodic profit calculation.

As a result, 944,442 thousand yen stated for the "merchandise and finished goods" under current assets in the previous year end balance sheet has been revised as 672,891 thousand yen in "semi-finished goods" and 271,550 thousand yen in "merchandise and finished goods."

(Significant subsequent events) None to be reported.