



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

November 10, 2020

Company Name SymBio Pharmaceuticals Limited Listing: Tokyo Stock Exchange

Securities Code 4582 URL: https://www.symbiopharma.com/

Representative Representative Director, Fuminori Yoshida

President and Chief Executive Officer

Contact Person Corporate Officer and Chief Financial Officer Takaaki Fukushima TEL +81-3-5472-1125

Scheduled Date to File Quarterly November 11, 2020 Date of Dividend —

Report 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 Nine Months of FY 2020 (January 1, 2020 to September 30, 2020)

(1) Operating Results (cumulative)

(Percentages indicate year-on-year changes.)

	Net Sales	3	Operating Prof	it (Loss)	Ordinary Profi	t (Loss)	Profit (Lo	oss)
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Q3 FY 2020	2,332	16.2	(3,142)	_	(3,220)	_	(2,694)	_
Q3 FY 2019	2,008	(33.8)	(3,536)	_	(3,641)	_	(3,640)	_
	Earnings (Loss) per Share		Diluted Earnings	per Share				

	Earnings (Loss) per Share	Diluted Earnings per Share
	Yen	Yen
Q3 FY 2020	(84.59)	
Q3 FY 2019	(161.33)	_

(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	%
Q3 FY 2020 (as of September 30, 2020)	6,232	4,995	70.6
FY 2019 (as of December 31, 2019)	5,273	4,400	71.7

(Reference) Shareholders' equity: Q3 FY 2020 (as of September 30, 2020) 4,397 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			

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

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

(Percentages indicate year-on-year changes.)

	Net Sale	es	Operating (Loss)		Ordinary I (Loss)		Profit (Lo	oss)	Earnings (Loss) per Share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Full Year	3,043	7.2	(4,592)		(4,656)	_	(3,796)	_	(116.13)

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: No Yes •

No Yes •

(b) Changes in accounting policies due to other reasons:

(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)

(ii) Total number of treasury shares at the end of the year

(iii) Average number of shares during the year (cumulative)

Q3 FY 2020	35,198,331 shares	FY 2019	26,437,681 shares
Q3 FY 2020	26,543 shares	FY 2019	22,593 shares
Q3 FY 2020	31,850,674 shares	Q3 FY 2019	22,565,488 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.

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 5 of the attachment.

^{*} 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

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1. Qualitative Information on Quarterly Financial Results

(1) Business results

Progress in the Company's business for the first nine months of the fiscal year under review is as follows.

(i) Domestic business

[Establishment of the Company's own sales force]

SymBio plans to transition to its own sales organization for the sale of TREAKISYM® from January 2021 as its business partnership agreement with Eisai Co., Ltd. ("Eisai") expires in December 2020. Through this transition, the Company aims to achieve profitability in FY 2021 and sustainable growth thereafter.

In the third quarter of the fiscal year under review, the Company began transferring sales operations from Eisai as part of establishing its own sales structure. As planned, the Company assigned 51 medical representatives across Japan and six regional hematology experts to understand the needs of each region and develop plans tailored to address those needs. Through these efforts, the Company expects to enhance the productivity of its sales force.

On September 7, 2020, the Company concluded distribution agreements with Suzuken Co., Ltd. ("Suzuken Group") and Toho Pharmaceutical Co., Ltd. (consolidated subsidiary of Toho Holdings Co., Ltd.; "Kyoso Mirai Group") to establish nationwide product distribution coverage. After the business partnership with Eisai ends, the Suzuken Group and Kyoso Mirai Group will serve as the Company's wholesalers. The Company will also collaborate with S.D. Collabo Co., Ltd. to establish two logistics centers, one in Eastern and one in Western Japan. With its own sales organization in place, the Company is on track to achieve profitability in FY 2021.

[Stable supply]

SymBio currently imports lyophilized injectable formulation of TREAKISYM® from Astellas Deutschland GmbH ("Astellas Deutschland"), a subsidiary of Astellas Pharma Inc., and markets the product in Japan through Eisai. In the third quarter of the fiscal year under review, the Company conducted secondary packaging and quality tests for several imported batches and shipped them to Eisai in accordance with Company plans. The inventory level of TREAKISYM®, which was at a significantly low level in the first half of the fiscal year compared to that a year ago, has stabilized and the Company will continue to work with Astellas Deutschland to maintain a stable supply of the product.

[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®)]

TREAKISYM® is used to treat a wide array of malignant lymphoma. SymBio obtained manufacturing and marketing approval for TREAKISYM® for the indications of first-line treatment of low-grade non-Hodgkin's lymphoma (low-grade NHL) (Note 1) and mantle cell lymphoma (MCL) in December 2016, recurrent/refractory low-grade NHL and MCL in October 2010, and chronic lymphocytic leukemia (CLL) in August 2016. Further, the combination therapy of TREAKISYM® and rituximab (BR therapy) was added to the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues published by the Japanese Society of Hematology in July 2018, and became a standard treatment option for all previously approved indications. With this development, TREAKISYM® 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 for TREAKISYM®, 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. Subsequent to this approval, TREAKISYM® is offered to patients as a new treatment option in combination with obinutuzumab (Note 2). In March 2019, the Company obtained approval of a partial change to allow the use of TREAKISYM® as a pretreatment agent for tumor-specific T-cell infusion therapy, (Note 3) allowing 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. Due to its expanding use as a pretreatment agent for regenerative medicine and other pharmaceutical products, TREAKISYM® has further solidified its position as a standard treatment for malignant lymphoma.

SymBio conducted a Phase III clinical trial of BR therapy targeting recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), an additional indication of the combination therapy following the already-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 a partial change to its marketing authorization in May 2020. Further, the Company is conducting a follow-up study with overall survival as the primary endpoint, since survival data (e.g., overall survival and progression-free survival) for TREAKISYM® administered in combination with rituximab is crucial in establishing the product as a DLBCL treatment. In

June 2020, Chugai Pharmaceutical Co., Ltd. ("Chugai Pharmaceutical") filed for manufacturing and marketing approval for polatuzumab vedotin (Note 6) used in combination with BR therapy targeting r/r DLBCL. In response, in July 2020 the Company applied for approval to partially amend its marketing authorization for TREAKISYM® used in combination with polatuzumab vedotin and rituximab. Once polatuzumab vedotin is included in the NHI drug price list after the Company and Chugai Pharmaceutical obtain approval, TREAKISYM® can be used in the combination therapy of polatuzumab vedotin and BR therapy. Because there is currently no effective treatment for r/r DLBCL, the newly added indication for TREAKISYM®, combination therapies comprising multiple anticancer drugs are used as rescue chemotherapy. However, because these therapies often cause serious adverse effects, patients are in dire need the development of highly effective and safe drugs. BR therapy is already used to treat patients with r/r DLBCL in Europe and the U.S. In Japan, patient organizations and relevant academic societies have requested the Ministry of Health, Labour and Welfare 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 patients.

In September 2017, SymBio concluded a license agreement with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) and obtained exclusive rights to develop and market TREAKISYM® liquid formulation (RTD and RI liquid formulations) (Note 7) in Japan. The Company obtained manufacturing and marketing approval for the RTD liquid formation on September 18, 2020, and plans to launch the product in January 2021. For the RI liquid formulation, the Company commenced a clinical trial with the main goal of confirming safety in November 2018, successfully enrolled the target number of patients, and completed follow-up observation, i.e., reached last-patient-last-visit (LPLV), in September 2020. The Company plans to promptly file for approval once the trial is concluded and expects to obtain approval in the second half of 2022. The RI liquid formulation significantly reduces the infusion time to 10 minutes, down from the 60 minutes required by the currently available lyophilized powder and RTD formulations. This will greatly reduce burden on patients and healthcare providers, enabling the Company to provide substantial value-added. 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®, 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 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") conducted global Phase III clinical trials (with trial sites in more than 20 countries; INSPIRE study) of the intravenous formulation of rigosertib for higher-risk myelodysplastic syndromes (HR-MDS) which 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, with overall survival as the primary endpoint. 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 reviewing ways to use the findings from the genomic analysis of the INSPIRE study in the future development of rigosertib.

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

(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 exclusive rights for the worldwide development, marketing, and manufacture of BCV for all human indications, excluding smallpox.

As a result of the review at the Global Advisory Board meeting convened in February, the Company 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, primarily in Japan, the U.S., and Europe. Leveraging the efficacy and safety data of BCV obtained from clinical trials, the Company intends to investigate the efficacy of the drug against a range of dsDNA 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 of the drug 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. Currently, the Company is diligently preparing to initiate clinical trials to determine the appropriate dose of BCV IV for pediatric use scheduled for 2021.

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 (Note 10), the Company expects BCV IV to also be effective and safe 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 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, 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 include 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]

On October 11, 2017, SymBio initiated an arbitration against The Medicines Company (head office: New Jersey, U.S., "MDCO")—from whom the Company in-licensed SyB P-1501 (IONSYS in the U.S.) in October 2015—under the rules of the International Chamber of Commerce, seeking damages of 82 million US dollars arising from MDCO's decision to discontinue and withdraw IONSYS from the U.S. and European markets and failure to provide adequate assurances of MDCO's performance under the license agreement. On September 1, 2020, the Company announced that the arbitral tribunal did not agree with the Company's claim that MDCO failed to provide adequate assurances of performance under the license agreement and denied the Company's claim for damages. However, the arbitral tribunal awarded the Company 4,950,000 US dollars representing 50% of its legal fees and expenses that it sought to recover in the arbitration.

(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

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

(iv) Business results

Net sales totaled 2,332,601 thousand yen for the first nine months of the FY 2020, primarily reflecting product sales of TREAKISYM®, and overall net sales increased 16.2% year on year.

Selling, general and administrative expenses totaled 3,753,157 thousand yen (-8.4% year on year), including research and development ("R&D") expenses of 1,754,364 thousand yen (-11.0% year on year) primarily due to expenses associated with clinical trials for the intravenous formulation of TREAKISYM® and the intravenous formulations of rigosertib, as well as other selling, general and administrative expenses of 1,998,792 thousand yen (-6.0% year on year), including upfront spending to establish an internal sales structure.

As a result, an operating loss of 3,142,396 thousand yen was recognized in the first nine months of FY 2020 (versus an operating loss of 3,536,352 thousand yen in the same period of FY 2019). Due to non-operating expenses of 81,103 thousand yen, primarily comprising foreign exchange losses of 55,648 thousand yen and share issuance cost of 23,203 thousand yen, ordinary loss totaled 3,220,921 thousand yen (versus an ordinary loss of 3,641,904 thousand yen in the same period of FY 2019). Despite posting 525,145 thousand yen in settlement received, the bottom-line loss in the first nine months of the FY 2020 totaled 2,694,284 thousand yen (versus a loss of 3,640,556 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) Financial position

Total assets as of September 30, 2020 stood at 6,232,069 thousand yen, an increase of 958,114 thousand yen from the previous fiscal year end. This was primarily due to increases of 816,692 thousand yen in cash and deposits, 360,803 thousand yen in merchandise and finished goods, 163,142 thousand yen in software, 17,227 thousand yen in tools, furniture and fixture, 13,012 thousand yen in prepaid expenses, and 10,275 thousand yen in lease and guarantee deposits, offsetting decreases of 296,167 thousand yen in accounts receivable—trade, 94,791 thousand yen in software in progress, 79,114 thousand yen in consumption taxes receivable, 41,791 thousand yen in advances paid, and 17,248 thousand yen in construction in progress.

Total liabilities stood at 1,236,495 thousand yen, an increase of 362,656 thousand yen from the previous fiscal year end, owing mainly to increases of 394,286 thousand yen in accounts payable—other and 20,583 thousand yen in accounts payable—trade, offsetting a decrease of 55,541 thousand yen in income taxes payable.

Under net assets, decreases of 23,082 thousand yen in share acquisition rights and 2,694,284 thousand yen in retained earnings due to the recording of a bottom-line loss were offset by increases of 1,658,022 thousand yen in capital surplus and 1,655,936 thousand yen in share capital. As a result, total net assets increased by 595,458 thousand yen from the previous fiscal year end to 4,995,574 thousand yen.

The equity ratio consequently declined 1.1 percentage points from the previous fiscal year end to 70.6%.

(3) Earnings forecasts and other forward-looking information

As of the date of this document, no revision was made to the earnings forecasts for FY 2020 revised on September 17, 2020.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly balance sheet

		(Unit: thousands of yen)
	FY 2019 (as of December 31, 2019)	Q3 FY 2020 (as of September 30, 2020)
Assets		
Current assets		
Cash and deposits	3,910,830	4,727,522
Accounts receivable-trade	549,275	253,107
Merchandise and finished goods	_	360,803
Prepaid expenses	94,002	107,014
Advances paid	41,791	_
Consumption taxes receivable	275,324	196,210
Other	16,267	124,884
Total current assets	4,887,491	5,769,542
Non-current assets		
Property, plant and equipment		
Buildings, net	34,734	32,193
Tools, furniture and fixtures, net	19,242	36,470
Construction in progress	21,513	4,265
Total property, plant and equipment	75,491	72,929
Intangible assets		
Software	94,974	258,116
Software in progress	145,551	50,759
Total intangible assets	240,525	308,876
Investments and other assets		
Shares of subsidiaries	0	0
Leasehold and guarantee deposits	70,446	80,722
Total investments and other assets	70,446	80,722
Total non-current assets	386,463	462,527
Total assets	5,273,955	6,232,069
Liabilities		, ,
Current liabilities		
Accounts payable-trade	120,913	141,496
Accounts payable—other	639,482	1,033,769
Income taxes payable	87,756	32,214
Other	24,066	27,081
Total current liabilities	872,219	1,234,562
Non-current liabilities		, : , ; ; ;
Provision for retirement benefits	1,619	1,933
Total non-current liabilities	1,619	1,933
Total liabilities	873,838	1,236,495
10th Imolition		1,230,473

		(Unit: thousands of yell)
	FY 2019 (as of December 31, 2019)	Q3 FY 2020 (as of September 30, 2020)
Net assets		
Shareholders' equity		
Share capital	14,870,639	16,526,575
Capital surplus	14,843,137	16,501,160
Retained earnings	(25,919,496)	(28,613,781)
Treasury shares	(15,077)	(16,210)
Total shareholders' equity	3,779,202	4,397,744
Share acquisition rights	620,913	597,830
Total net assets	4,400,116	4,995,574
Total liabilities and net assets	5,273,955	6,232,069

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

Q3 FY 2019 (from January 1, 2019) (from January 1, 2019) to September 30, 2019) Q3 FY 2020 (from January 1, 2019) to September 30, 2019) Net sales 2,008,048 2,332,601 Cost of sales *1,445,149 *1,721,840 Gross profit 562,899 610,760 Selling, general and administrative expenses 4,099,251 3,753,157 Operating profit (loss) 3,536,352 3,142,396 Non-operating income 201 130 Interest income 201 130 Interest on tax refund 76 120 Dividend income of insurance 2,732 2,734 Insurance claim income 2,732 2,578 Non-operating expenses 7,904 — Non-operating expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 5,5648 Other 227 2,251 Total non-operating expenses 10,985 81,103 Ordinary profit (loss) 3,104 3,104 Gain on reversal of share acquisition rights			(Unit: thousands of yen)
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Net sales 2,008,048 2,332,601 Cost of sales *1,445,149 *1,721,840 Gross profit 562,899 610,760 Selling, general and administrative expenses 4,099,251 3,753,157 Operating profit (loss) (3,536,352) (3,142,396) Non-operating income 201 130 Interest on tax refund 76 120 Dividend income of insurance 1,282 2,324 Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Total non-operating expenses 1,949 4,341 Settlement received			(from January 1, 2020 to September 30, 2020)
Gross profit 562,899 610,760 Selling, general and administrative expenses 4,099,251 3,753,157 Operating profit (loss) (3,536,352) (3,142,396) Non-operating income 201 130 Interest income 201 130 Interest on tax refund 76 120 Dividend income of insurance 1,282 2,324 Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary in	Net sales	<u> </u>	
Selling, general and administrative expenses 4,099,251 3,753,157 Operating profit (loss) (3,536,352) (3,142,396) Non-operating income 201 130 Interest income 201 130 Interest on tax refund 76 120 Dividend income of insurance 1,282 2,324 Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (lo	Cost of sales	*1,445,149	*1,721,840
Operating profit (loss) (3,536,352) (3,142,396) Non-operating income 201 130 Interest income 201 130 Interest on tax refund 76 120 Dividend income of insurance 1,282 2,324 Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—curr	Gross profit	562,899	610,760
Non-operating income 201 130 Interest income 201 130 Interest on tax refund 76 120 Dividend income of insurance 1,282 2,324 Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes	Selling, general and administrative expenses	4,099,251	3,753,157
Interest income 201 130 Interest on tax refund 76 120 Dividend income of insurance 1,282 2,324 Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Operating profit (loss)	(3,536,352)	(3,142,396)
Interest on tax refund 76 120 Dividend income of insurance 1,282 2,324 Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Non-operating income		
Dividend income of insurance 1,282 2,324 Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Interest income	201	130
Insurance claim income 2,736 — Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Interest on tax refund	76	120
Other 0 2 Total non-operating income 4,297 2,578 Non-operating expenses - - Commission expenses 7,904 - Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received - 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes-current 2,850 2,850 Total income taxes 2,850 2,850	Dividend income of insurance	1,282	2,324
Total non-operating income 4,297 2,578 Non-operating expenses 7,904 — Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Insurance claim income	2,736	<u> </u>
Non-operating expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Other	0	2
Commission expenses 7,904 — Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Total non-operating income	4,297	2,578
Share issuance costs 9,440 23,203 Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Non-operating expenses		
Foreign exchange losses 92,277 55,648 Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Commission expenses	7,904	_
Other 227 2,251 Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Share issuance costs	9,440	23,203
Total non-operating expenses 109,850 81,103 Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Foreign exchange losses	92,277	55,648
Ordinary profit (loss) (3,641,904) (3,220,921) Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Other	227	2,251
Gain on reversal of share acquisition rights 4,197 4,341 Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Total non-operating expenses	109,850	81,103
Settlement received — 525,145 Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Ordinary profit (loss)	(3,641,904)	(3,220,921)
Total extraordinary income 4,197 529,486 Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Gain on reversal of share acquisition rights	4,197	4,341
Profit (loss) before income taxes (3,637,706) (2,691,434) Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Settlement received	_	525,145
Income taxes—current 2,850 2,850 Total income taxes 2,850 2,850	Total extraordinary income	4,197	529,486
Total income taxes 2,850 2,850	Profit (loss) before income taxes	(3,637,706)	(2,691,434)
<u> </u>	Income taxes-current	2,850	2,850
Profit (loss) (3,640,556) (2,694,284)	Total income taxes	2,850	2,850
	Profit (loss)	(3,640,556)	(2,694,284)

(3) 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)
Q3 FY 2019	Q3 FY 2020
(from January 1, 2019 to September 30, 2019)	(from January 1, 2020 to September 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 nine 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 1,655,936 thousand yen. The total value of treasury shares increased 4,917 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 525 thousand yen in the total value of treasury shares and 91 thousand yen in other capital surplus.

As a result, as of September 30, 2020 share capital was 16,526,575 thousand yen, capital surplus 16,501,160 thousand yen, and the total value of treasury shares 16,210 thousand yen.

(Significant subsequent events)

None to be reported.