English translation

SymBio Pharmaceuticals Limited

Summary of Financial Statements for the first nine months of fiscal year ending December 31, 2019 [Japanese GAAP] (Non-consolidated)

November 8, 2019

Company Name	**SymBio Pharmaceuticals Limited**	Listing: Tokyo Stock Exchange	
Securities Code	4582	URL: https://www.symbiopharma.com/	
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida	
Contact Person	Director, Head of Corporate Planning & Admin. Division and Chief Financial Officer	Kenji Murata	TEL +81-3-5472-1125
Scheduled Date to File Quarterly Report	November 11, 2019	Date of Dividend Payment (plan)	—

Supplementary materials for the quarterly financial statements: Yes ・ No

Holding of quarterly earnings performance review: Yes ・ No

(Values below one million yen are rounded down.)

1. Business results for the first nine months of fiscal year 2019 (January 1, 2019 to September 30, 2019)

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

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss)	
	yen in millions	%	yen in millions	%	yen in millions	%	yen in millions	%
Q3 FY 2019	2,008	(33.8)	(3,536)	—	(3,641)	—	(3,640)	—
Q3 FY 2018	3,032	25.5	(1,907)	—	(1,937)	—	(1,940)	—

	Earnings (Loss) per Share	Diluted Earnings per Share
	yen	yen
Q3 FY 2019	(161.33)	—
Q3 FY 2018	(125.23)	—

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

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

(2) Financial Position

	Total Assets	Net Assets	Equity Ratio
	yen in millions	yen in millions	%
Q3 FY 2019 (as of June 30, 2019)	5,665	3,869	57.7
FY 2018 (as of December 31, 2018)	6,239	4,901	70.1

(Reference) Shareholders' equity: Q3 FY 2019 (as of September 30, 2019) 3,269 million yen

FY 2018 (as of December 31, 2018) 4,371 million yen

2. Dividends

	Annual Dividend per Share				
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year End	Full Year
	yen	yen	yen	yen	yen
FY 2018	—	0.00	—	0.00	0.00
FY 2019	—	0.00	—		
FY 2019 (Forecast)				0.00	0.00

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

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

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss)		Earnings (Loss) per Share
	yen in millions	%	yen in millions	%	yen in millions	%	yen in millions	%	yen
Full Year	3,092	(19.4)	(3,780)	—	(3,856)	—	(3,859)	—	(167.67)

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

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

Notes:

(1) Application of special accounting treatment in preparation of quarterly financial reports: Yes・No

(2) Changes in accounting policies, changes in accounting estimates and restatements after error corrections

(a) Changes in accounting policies due to revision of accounting standards: Yes・No

(b) Changes in accounting policies due to other reasons: Yes・No

(c) Changes in accounting estimates: Yes・No

(d) Restatements after error corrections: Yes・No

(3) Number of shares outstanding (common stock)

(i) Number of issued shares at the end of the period (including treasury shares)	Q3 FY 2019	24,362,681 shares	FY 2018	20,599,731 shares
(ii) Number of treasury shares at the end of the period	Q3 FY 2019	11,143 shares	FY 2018	18 shares
(iii) Average number of shares during the period (cumulative)	Q3 FY 2019	22,565,488 shares	Q3 FY 2018	15,498,539 shares

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

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

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

1. All forecasts presented in this document, including earnings forecasts, are based on the information currently available to management and assumptions judged to be reasonable. Actual results may differ substantially from these forecasts due to various factors. Regarding the assumptions on which the Company's earnings forecasts are based and their usage, please refer to "1. Qualitative Information on Quarterly Financial Results, (3) Explanation of earnings forecasts and other forward-looking information," on Page 8 of the attachment.
2. The Company approved a 1-for-4 consolidation of common stock at the 14th Ordinary General Meeting of Shareholders held on March 28, 2019. This consolidation of shares was carried out with an effective date of July 1, 2019. The earnings forecast for FY 2019, excluding impact from the consolidation of shares, is as follows:
   FY 2019 loss per share forecast (full year): 41.91 yen

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1. Qualitative Information on Quarterly Financial Results

(1) Explanation of business results

Advancements in the Company's business for the first nine months of the fiscal year ending December 31, 2019.

(i) Licensing of new drug candidates

On September 30, 2019, the Company concluded an exclusive global licensing agreement for the antiviral drug Brincidofovir (Note 1) (SyB V-1901; "BCV") 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. With the global rights to BCV, the Company will transition into a global specialty pharmaceutical company with an integrated system for supplying high-quality pharmaceutical products.

The Company will initially develop BCV for the treatment of viral hemorrhagic cystitis (Note 2) (vHC) and HHV-6 encephalitis (Note 3) occurring after hematopoietic stem cell transplantation and kidney transplantation, which are niche markets with high unmet medical demand. We are promoting rapid commercialization of BCV in Japan to deliver it to patients requiring treatment as promptly as possible. At the same time, the Company is looking to expand its business in Europe, the U.S. and Asia (including China), where organ transplant markets are large, and are considering forming partnerships that take advantage of the regional characteristics of these target diseases. We will explore all possible means of maximizing our business value by applying a variety of measures, including the strategic utilization of wholly owned subsidiary SymBio Pharma USA, Inc. (head office: Menlo Park, California, U.S.; established May 2016; "SymBio Pharma USA"). For more details, please see our October 1, 2019 press release, *SymBio Announces Exclusive Global License Agreement with Chimerix for Antiviral Drug, Brincidofovir: With the development of anti-multiviral agent SymBio transforms into a global business*.

Additionally, we conduct ongoing search and evaluation of new drug candidates for potential in-licensing to expand our R&D pipeline. Through these efforts, our aim is to create long-term business value as a profitable biopharmaceutical company with growth potential.

(Note 1) 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 blood.

(Note 2) Viral hemorrhagic cystitis (vHC): Among viral infections that frequently occur following hematopoietic stem cell transplantation, adenovirus infections causing hemorrhagic cystitis are particularly refractory in nature. They accompany severe symptoms, including frequent urination, abdominal pain and pain experienced during urination. When severe, they can cause disseminated infection and become fatal. Cases in which adenovirus spreads to the kidneys, causing fatal renal failure, have also been reported. These infections are particularly likely to occur in transplantation between unrelated donors and in umbilical cord blood transplantation, which are relatively common in Japan. Their extreme refractory nature is further complicated by the length of time required for reconstruction of the immune system. Drugs currently used in treatment, including cidofovir (CDV), are either unapproved or off-label.

(Note 3) HHV-6 encephalitis: HHV-6 is the sixth human herpesvirus to be discovered. It reactivates in 30–70% of patients after allogeneic hematopoietic stem cell transplantation and can cause HHV-6 encephalitis. Most cases of HHV-6 encephalitis develop within 2–6 weeks, most frequently in the 3rd week after transplantation. It is characterized by its three major symptoms of impaired memory, disordered consciousness and convulsions, which, in typical cases, gradually appear in the same order (convulsions occur in 30–70% of patients). In rapidly progressing cases, neurological symptoms worsen by the hour, often requiring respirator management for repeated convulsions and respiratory depression. The conditions of HHV-6 encephalitis patients often deteriorate rapidly over short periods of time, making early treatment extremely important. According to guidelines edited and released by the Japan Society for Hematopoietic Cell Transplantation (February 2018), the first-line drugs are foscarnet (FOS) and ganciclovir (GCV), followed by cidofovir (CDV). CDV is not preferred as the top drug due to its strong nephrotoxicity and because it transfers poorly into cerebrospinal fluid (CSF). All three of these drugs have been found to be effective in vitro, but, to date, no trials have been conducted to confirm their clinical efficacy in patients with HHV-6 encephalitis.

(ii) Domestic business

[Preparation for the establishment of the Company's own sales organization]

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

During the first nine months of the fiscal year under review, the Company continued to expand and train its team of TREAKISYM® sales representatives, whowill be the core of the Company's own sales organization. These sales representatives began conducting regionally-focussed information-providing activities on July 1, 2019, in order to promote the Company's transition toward a nationwide sales organization. The Company will establish an efficient and highly productive marketing organization with deep expertise and experience. Concurrently, the Company is putting in place the appropriate logistics, distribution, and information systems infrastructure.

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

The Company markets TREAKISYM® in Japan through its business partner, Eisai. The Company obtained manufacturing and marketing approval for first-line treatment of low-grade non-Hodgkin's lymphoma (Note 4) (low-grade NHL) and mantle cell lymphoma (MCL) in December 2016, for recurrent/refractory low-grade NHL and MCL in October 2010, and for chronic lymphocytic leukemia (CLL) in August 2016. Following this indication expansion, TREAKISYM® is steadily increasing its market share in the area of first-line treatment by replacing R-CHOP, the conventional standard treatment, at medical clinics and hospitals. Further, the combination treatment (BR therapy) of TREAKISYM® and rituximab was newly included in the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues 2018 edited and published by the Japanese Society of Hematology in July 2018, becoming recommended as a choice for standard treatment for all previously approved indications. TREAKISYM® has established its foothold as the standard treatment for malignant lymphoma with this development, and surveys conducted by the Company indicate that its share of first-line treatment has risen to above 55%.

In addition to the three already-approved indications, the Company is conducting a Phase III clinical trial for TREAKISYM® targeting recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). The trial is in response to serious need at clinics and hospitals as there is currently no reliable standard treatment. Patient groups and relevant academic societies have petitioned to the regulatory authorities for the approval of BR therapy. With a view to providing new therapeutic alternatives, the Company began the Phase III clinical trial in August 2017 and, after enrolling its first patient in January 2018, steadily continued to accumulate cases, finally completing the enrollment process in April 2019. In September of the same year, the observation periods for all subjects came to an end (last patient, last visit; "LPLV"), and in November, we achieved a favorable response rate that exceeded expected levels, which represent a primary endpoint. Moving forward, the Company will continue preparations to apply for the approval of the additional indication in Q2 FY 2020.

The Company concluded an exclusive license agreement (in Japan) for TREAKISYM® liquid formulation (RTD and RI liquid formulations) (Note 5) with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) ("Eagle") in September 2017. Following consultations with the Pharmaceutical and Medical Devices Agency concerning RTD liquid formulation products, the Company submitted an application for their approval in September 2019 and is currently working diligently to prepare for their launch in Q1 FY 2021. A clinical trial for RI liquid formulations began in November 2018, with the primary goal of confirming their safety. The Company had been steadily acquiring patients since the enrollment of the first patient began in April 2019. As of October 31, 2019, 26 patients were enrollment. The Company aims to launch these RI liquid formulations as products in 1H FY 2022 following a prompt application for approval after this clinical trial has ended. This drug will provide added value by greatly reducing the burdens placed on patients and healthcare providers, and liquid formula patent protection will enable the extension of its product life until 2031. Moving forward, the Company is aiming to maximize business value with this drug while focusing on further development strategies.

Further, as a result of the approval obtained in July 2018 of a partial change application to the Company's TREAKISYM® marketing authorization, TREAKISYM® can now be used in combination with not only rituximab but also other new anti-CD20 antibodies for the treatment of CD20 positive follicular lymphoma (FL), a common histologic type of low-grade NHL. As a new treatment option, it is being offered to patients in combination with obinutuzumab (Note 6), which was launched in August 2018. In March 2019, the Company received approval for changes to a portion of its application concerning the use of TREAKISYM® as

a pretreatment agent for tumor-specific T-cell infusion therapy (Note 7). This will allow TREAKISYM® to be used as a pretreatment for Kymriah® intravenous infusion (Note 8), which was approved as the first chimeric antigen receptor T-cell (CAR-T) therapy (Note 9) in Japan and included in the NHI price listings in May 2019. The status of TREAKISYM® as a standard treatment for malignant lymphoma is becoming stronger as its use as a pretreatment used with regenerative medicine and other products continues to spread.

In addition, the Company is exploring the potential of TREAKISYM® as the treatment for solid tumors and autoimmune diseases, with an aim to solidify its business through a platform of TREAKISYM® products. Amid such initiatives, the Company commenced a Phase I clinical trial for progressive solid tumors in January 2018, with the aims of examining the recommended dosage and administration schedule as well as tolerability and safety of the oral formulation of TREAKISYM®, and identifying potential target tumor types. After completing enrollment of the first patient in May 2018, the Company is currently accumulating cases. Meanwhile, with a view to evaluating the effect of oral administration of TREAKISYM® on the immune system, the Company concluded a joint research agreement with Keio University in May 2018 to verify the therapeutic effect of this product in the treatment of systemic lupus erythematosus (SLE), an autoimmune disease that is giving rise to extremely high treatment demand. The Company later conducted a preclinical trial with Keio University. Currently, the results of this trial are being collected and, once they have been evaluated, the Company will decide upon its plans moving forward, including future clinical trials.

(Note 4) Non-Hodgkin's lymphoma (NHL) is a generic term of all types of malignant lymphoma other than Hodgkin's lymphoma. Malignant lymphoma refers to malignant growths that form when the lymphatic corpuscles inside of white blood cells become cancerous. The majority of malignant lymphoma identified in Japanese patients is non-Hodgkin's lymphoma.

(Note 5) RTD and RI are predissolved liquid formulations that differ from the currently available freeze-dried ("FD") powder formulation. RTD (ready-to-dilute) will significantly reduce the preparation time and labor cost for healthcare providers, and RI (rapid infusion) will reduce infusion duration to 10 minutes from the current 60 minutes, greatly reducing the burdens placed on patients and providing significant added value to healthcare providers.

(Note 6) Obinutuzumab (Gazyva®, marketed by Chugai Pharmaceutical Co., Ltd.): Like rituximab recommended by treatment guidelines for non-Hodgkin's lymphoma in Japan and overseas, obinutuzumab is a glycoengineered type II anti-20 monoclonal antibody that directly binds to CD20 (a protein expressed on B-cells other than stem cells or plasma cells) on target B-cells, and attacks and destroys them along with the body's immune system.

(Note 7) 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 8) Kymriah® intravenous infusion (generic name: tisagenlecleucel; marketed by Novartis Pharma K.K.): Kymriah® intravenous infusion is the first chimeric antigen receptor T-cell (CAR-T) therapy approved within Japan. The Company received manufacturing and marketing approval for Kymriah® for use in the treatment of CD19 positive recurrent/refractory B-cell acute lymphoblastic leukemia (B-ALL) and CD19 positive recurrent/refractory diffuse large B-cell lymphoma (DLBCL) in March 2019. Kymriah® intravenous infusion was included in NHI price listings in May 2019.

(Note 9) Chimeric antigen receptor T-cell (CAR-T) therapy is a type of tumor-specific T-cell infusion therapy that introduces genes that code chimeric antigen receptors (CARs) into T-cells, amplifies these cells and then infuses them. These chimeric antigen receptors are produced by combining the intracellular domains of T-cell receptors with the antigen-binding sites of antibodies capable of recognizing membrane antigens attached to tumor cells. In clinical trials using CARs to target CD19 that expresses on B-cells, CD19-targeting CARs were introduced into T-cells that were later administered to patients with B-cell tumors. These modified cells produced clear clinical effects.

[Anticancer agents: SyB L-1101 (intravenous formulation) and SyB C-1101 (oral formulation) (generic name: rigosertib sodium)]

U.S. Licensor Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.) ("Onconova") is conducting a global Phase III clinical trial (with trial sites in more than 20 countries) of the intravenous formulation of rigosertib for higher-risk myelodysplastic syndromes (HR-MDS) which do not respond to the current standard treatment with hypomethylating agents, which relapse after treatment under the current standard of care, or which are intolerant to hypomethylating agents. The

Company is responsible for clinical development in Japan and in December 2015 began the trial. Forty-eight patients were enrolled as of October 31, 2019. According to an October 2019 announcement from Onconova, global patient enrollment (final target of 360 patients) is approaching 90% completion, and top-line results (primary endpoints) are expected to be released in 1H FY 2020. Based on the results of the trial, the Company is planning to apply for approval in Japan at the same time as in the U.S. and Europe.

As for the oral formulation of rigosertib, Onconova completed Phase I/II clinical trials in the U.S. for the target indication of first-line HR-MDS (in combination with azacitidine (Note 10)) and is conducting a Phase II clinical trial for the target indication of transfusion-dependent lower-risk MDS. The Company started a domestic Phase I clinical trial in June 2017 to confirm the tolerability and safety of the oral formulation of rigosertib for Japanese patients. The Company continued to steadily accumulate cases since the first patient was enrolled in October 2017 and completed patient enrollment in June 2019. After completion of this trial, the Company plans to promptly conduct a Phase I clinical trial for combination therapy with azacitidine. Further, to apply for approval of the oral formulation of rigosertib in Japan no later than in the U.S. and Europe, it plans to take part in a global trial for combination therapy with azacitidine for the first-line treatment of patients with higher-risk MDS, which Onconova is currently considering conducting. In order to accelerate this global clinical trial's examination process, Onconova applied for a Special Protocol Assessment (SPA) (Note 11) with the US Food and Drug Administration (FDA) in December 2018. Following negotiations with the FDA concerning the SPA, Onconova announced in October 2019 that it will consider a Phase II controlled study comparing the effects of rigosertib combined with azacitidine as a first-line treatment for HR-MDS with the effects of azacitidine alone. With respect to the development for the target indication of transfusion-dependent lower-risk MDS, the Company will continue to consider participating from Japan in view of the status of the development by Onconova.

(Note 10) Azacitidine (Vidaza®: marketed by Nippon Shinyaku Co., Ltd.): This hypomethylating agent (for injection) was approved in 2011 upon successful confirmation of extended overall survival for the first time in the Phase III clinical trial for the indication of MDS. It is currently used as a first-line drug for MDS patients who have difficulties in hematopoietic stem cell transplantation. MDS is a preleukemic state, and decrease in tumor suppressor gene due to excessive methylation of DNA is thought to be related to the disease. Hypomethylating agents such as azacitidine are thought to suppress progress to leukemia by restoring tumor suppressor gene with a deterrent effect against methylation of DNA.

(Note 11) Special Protocol Assessment (SPA): A system under which after completion of a phase II trial and prior to the launch of phase III trial, sponsors can reach an agreement with the FDA regarding the phase III trial protocol such as target illness, purpose, trial design, primary and secondary endpoints, and method of data analysis. The agreement indicates that the FDA concurs with the adequacy of the overall protocol design and the design can be used (without changing the terms) in the approval filing process when the phase III trial is completed. The SPA is intended to shorten FDA's review period of new drug application, as it boosts the possibility of drug approval provided the trial endpoints are achieved.

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

In October 2015, the Company entered into an agreement with Incline Therapeutics, Inc., a wholly owned subsidiary of The Medicines Company (head office: New Jersey, U.S.) for an exclusive license to develop and commercialize SyB P-1501 in Japan. The Company, acting in the best interest of patients, determined to temporarily suspend new patient enrollment for SyB P-1501 from April 21, 2017 due to its recently arising concern as to the continuity of The Medicines Company's business regarding the product.

The Company later initiated arbitration against The Medicines Company on October 11, 2017 under the rules of the International Chamber of Commerce, seeking damages of 82 million U.S. dollar (approximately 9.0 billion yen) arising from The Medicines Company's repudiation of the license agreement. The Company claims that The Medicines Company was not able to provide the Company with adequate assurance of performance of its contractual obligations under the license agreement in light of its decision to discontinue commercialization activities regarding the product and withdraw from markets in the U.S. and Europe, and that such failure by The Medicines Company is a material breach of the license agreement. Furthermore, the Company terminated the license agreement on November 30, 2017, based on the fact that the breach of the license agreement by The Medicines Company was not remedied within the stipulated time, and terminated the development of SyB P-1501 on February 9, 2018.

Arbitration proceedings against The Medicines Company are still ongoing.

(iii) Business outside Japan

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

(iv) Business results

As stated in the reasons for revisions to our earnings forecasts that we released on August 7, 2019, issues involving foreign matter contamination and appearance defects were discovered in lyophilized injection agents imported from Astellas Deutschland GmbH, a subsidiary of Astellas Pharma Inc. The ratio of contamination and appearance defects significantly exceeded limits permitted by quality standards included in our supply agreement with Astellas Deutschland. As a result, shipments of TREAKISYM® 100mg vials to its seller in Japan, Eisai Co., Ltd., will face further delays than originally anticipated.

As a result of the above, net sales totaled 2,008,048 thousand yen for the first nine months of the fiscal year ending December 31, 2019, primarily reflecting product sales of TREAKISYM®. Overall net sales fell 33.8% year on year.

Selling, general and administrative expenses totaled 4,099,251 thousand yen (+44.8% year on year), including research and development ("R&D") expenses of 1,971,788 thousand yen (+52.5% year on year) primarily due to upfront payments for the licensing agreement of antiviral drug Brincidofovir, a new drug candidate, and expenses associated with clinical trials for the intravenous and oral formulations of TREAKISYM® and the intravenous and oral formulations of rigosertib, as well as other selling, general and administrative expenses of 2,127,462 thousand yen (+38.3% year on year).

As a result, an operating loss of 3,536,352 thousand yen was recognized for the first nine months of the fiscal year ending December 31, 2019 (compared to an operating loss of 1,907,504 thousand yen for the first nine months of the previous fiscal year). In addition, including non-operating expenses totaling 109,850 thousand yen primarily comprised of foreign exchange losses, ordinary loss totaled 3,641,904 thousand yen (compared to an ordinary loss of 1,937,509 thousand yen for the first nine months of the previous fiscal year) and a bottom-line loss totaled 3,640,556 thousand yen (compared to a loss of 1,940,842 thousand yen for the first nine months of the previous fiscal year).

Segment information has been omitted as the Company operates within a single segment, 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 September 30, 2019 stood at 5,665,800 thousand yen, down 573,622 thousand yen from December 31, 2018. This primarily reflected decreases of 365,222 thousand yen in accounts receivable–trade, 224,980 thousand yen in merchandise and finished goods and 196,185 thousand yen in cash and deposits that offset increases of 115,570 thousand yen in software in progress, 58,740 thousand yen in consumption taxes receivable, 29,428 thousand yen in software and 22,858 thousand yen in prepaid expenses.

Total liabilities came to 1,796,650 thousand yen, up 459,026 thousand yen from December 31, 2018. This was mainly due to an increase of 1,000,772 thousand yen in accounts payable–other that offset decreases of 502,256 thousand yen in accounts payable–trade and 23,901 thousand yen in income taxes payable.

Net assets totaled 3,869,150 thousand yen, down 1,032,649 thousand yen from December 31, 2018. This was mainly attributable to a decrease of 3,640,556 thousand yen in retained earnings that was caused by quarterly loss and offset increases of 1,273,471 thousand yen in capital surplus, 1,271,770 thousand yen in share capital and 69,672 thousand yen in share acquisition rights.

As a result, the equity ratio fell by 12.4 percentage points from December 31, 2018 to 57.7%.

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

As of the date of this document, no revision to the revised earnings forecast for FY 2019 (released on August 7, 2019) is anticipated.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly balance sheet

(Thousands of yen)

	FY 2018 (as of December 31, 2018)	Q3 FY 2019 (as of September 30, 2019)
Assets		
Current assets		
Cash and deposits	4,821,355	4,625,170
Accounts receivable–trade	411,720	46,497
Merchandise and finished goods	533,824	308,844
Prepaid expenses	83,372	106,230
Advances paid	31,147	33,927
Consumption taxes receivable	124,855	183,596
Other	32,214	17,810
Total current assets	6,038,490	5,322,077
Non-current assets		
Property, plant and equipment		
Buildings, net	36,771	35,582
Tools, furniture and fixtures, net	20,180	21,047
Total property, plant and equipment	56,951	56,629
Intangible assets		
Software	50,946	80,374
Software in progress	20,430	136,001
Total intangible assets	71,376	216,376
Investments and other assets		
Shares of subsidiaries	0	0
Long-term prepaid expenses	1,225	—
Leasehold and guarantee deposits	71,378	70,717
Total investments and other assets	72,604	70,717
Total non-current assets	200,932	343,722
Total assets	6,239,423	5,665,800
Liabilities		
Current liabilities		
Accounts payable–trade	726,100	223,844
Accounts payable–other	503,637	1,504,409
Income taxes payable	71,249	47,347
Other	35,354	19,544
Total current liabilities	1,336,342	1,795,147
Non-current liabilities		
Provision for retirement benefits	1,281	1,503
Total non-current liabilities	1,281	1,503
Total liabilities	1,337,623	1,796,650

(Thousands of yen)

	FY 2018 (as of December 31, 2018)	Q3 FY 2019 (as of September 30, 2019)
Net assets		
Shareholders' equity		
Share capital	12,972,579	14,244,349
Capital surplus	12,942,579	14,216,051
Retained earnings	(21,543,238)	(25,183,795)
Treasury shares	(17)	(7,024)
Total shareholders' equity	4,371,902	3,269,580
Share acquisition rights	529,897	599,569
Total net assets	4,901,799	3,869,150
Total liabilities and net assets	6,239,423	5,665,800

(2) Quarterly statement of income

Q3 FY 2019

(Thousands of yen)

	Q3 FY 2018 (from January 1, 2018 to September 30, 2018)	Q3 FY 2019 (from January 1, 2019 to September 30, 2019)
Net sales	3,032,365	2,008,048
Cost of sales	2,108,138	1,445,149
Gross profit	924,227	562,899
Selling, general and administrative expenses	2,831,731	4,099,251
Operating profit (loss)	(1,907,504)	(3,536,352)
Non-operating income		
Interest income	491	201
Interest on tax refund	116	76
Dividend income of insurance	1,501	1,282
Insurance claim income	—	2,736
Foreign exchange gains	1,466	—
Other	54	0
Total non-operating income	3,629	4,297
Non-operating expenses		
Commission expenses	8,302	7,904
Share issuance cost	25,332	9,440
Foreign exchange losses	—	92,277
Other	—	227
Total non-operating expenses	33,634	109,850
Ordinary profit (loss)	(1,937,509)	(3,641,904)
Extraordinary income		
Gain on reversal of share acquisition rights	9,346	4,197
Total extraordinary income	9,346	4,197
Extraordinary losses		
Loss on retirement of non-current assets	9,829	—
Total extraordinary losses	9,829	—
Profit (loss) before income taxes	(1,937,992)	(3,637,706)
Income taxes–current	2,850	2,850
Total income taxes	2,850	2,850
Profit (loss)	(1,940,842)	(3,640,556)

(3) Notes to quarterly financial statements

(Notes to going concern assumptions)

None to be reported.

(Quarterly statement of income)

* 1 Inventory values at quarter-end are stated after inventory loss write downs.
The following amount is included within cost of sales as loss on valuation of inventories.

(Unit: yen in thousands)

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

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

(Notes to significant changes in shareholders' equity)

During the first nine months of the fiscal year ending December 31, 2019, new shares were issued upon the exercise of parts of the 36th, 37th, 38th, and 46th warrants. As a result, during the first nine months of the fiscal year under review, share capital and legal capital surplus increased by 1,271,770 thousand yen and 1,271,770 thousand yen, respectively, and the value of the Company's treasury shares rose by 10,949 thousand yen due to share buybacks.

Furthermore, the Company disposed of treasury shares due to the exercise of parts of the 33rd, 36th and 38th warrants. As a result, treasury shares fell 3,163 thousand yen and other capital surplus rose 1,817 thousand yen.

The Company disposed of further treasury shares due to demand for sale to holder of shares less than one unit. As a result, treasury shares fell 779 thousand yen and other capital surplus decreased by 116 thousand yen.

Due to the above factors, share capital as of September 30, 2019 was 14,244,349 thousand yen, while legal capital surplus was 14,216,051 thousand yen and treasury shares were 7,024 thousand yen.

(Significant subsequent events)

None to be reported