



Summary of Financial Statements for the Fiscal Year Ended December 31, 2019

[Japanese GAAP] (Non-consolidated)

February 6, 2020

Company Name	Symbio Pharmaceuticals Limited	Listing: Tokyo Stock Exchange
Securities Code	4582	URL: https://www.symbiopharma.com/
Representative	Representative Director, President and Chief Executive Officer	Fuminori Yoshida
Contact Person	Corporate Officer, Head of Finance and Accounting Division, and Chief Financial Officer	Takaaki Fukushima TEL +81-3-5472-1125
Ordinary Annual General Meeting of Shareholders	March 26, 2020	Date of Dividend Payment (plan) —
Scheduled Date to File Securities Report	March 27, 2020	

Supplementary materials for the financial statements: Yes No Holding of earnings performance review: Yes No (For securities analysts and institutional investors)

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

1. Business Results for FY 2019 (January 1, 2019 to December 31, 2019)

(1) Operating Results

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss)	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
FY 2019	2,837	(26.0)	(4,301)	—	(4,376)	—	(4,376)	—
FY 2018	3,835	11.4	(2,656)	—	(2,748)	—	(2,752)	—

	Earnings (Loss) per Share	Diluted Earnings per Share	Ratio of Profit (Loss) to Equity (ROE)	Ratio of Ordinary Profit (Loss) to Total Assets (ROA)	Ratio of Operating Profit (Loss) to Net Sales
	Yen	Yen	%	%	%
FY 2019	(189.03)	—	(107.4)	(76.0)	(151.6)
FY 2018	(165.54)	—	(77.8)	(52.4)	(69.2)

(Reference) Equity in earnings of affiliates: FY 2019 — million yen

FY 2018 — million yen

(Note 1) On July 1, 2019, the Company conducted a 1-for-4 reverse stock split of common share. 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	Net Assets per Share
	Millions of yen	Millions of yen	%	Yen
FY 2019 (as of December 31, 2019)	5,273	4,400	71.7	143.07
FY 2018 (as of December 31, 2018)	6,239	4,901	70.1	212.23

(Reference) Shareholders' equity: FY 2019 (as of December 31, 2019) 3,779 million yen

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

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

(3) Cash Flows

	Cash Flows from Operating Activities	Cash Flows from Investing Activities	Cash Flows from Financing Activities	Cash and Cash Equivalents at End of Period
	Millions of yen	Millions of yen	Millions of yen	Millions of yen
FY 2019	(4,350)	(216)	3,740	3,910
FY 2018	(2,324)	(26)	4,272	4,821

2. Dividends

	Annual Dividend per Share					Total Dividends	Payout Ratio	Ratio of Dividends to Net Assets
	1st Quarter	2nd Quarter	3rd Quarter	Fiscal Year End	Full Year			
	Yen	Yen	Yen	Yen	Yen	Millions of yen	%	%
FY 2018	—	0.00	—	0.00	0.00	—	—	—
FY 2019	—	0.00	—	0.00	0.00	—	—	—
FY 2020 (Forecast)	—	0.00	—	0.00	0.00		—	

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

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss)		Earnings (Loss) per Share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Full Year	3,404	20.0	(5,090)	—	(5,134)	—	(4,803)	—	(181.84)

Notes:

(1) 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	•	<input type="checkbox"/> No
(b) Changes in accounting policies due to other reasons:	Yes	•	<input type="checkbox"/> No
(c) Changes in accounting estimates:	Yes	•	<input type="checkbox"/> No
(d) Restatements after error corrections:	Yes	•	<input type="checkbox"/> No

(2) Number of issued shares (common stock)

(i) Total number of issued shares at the end of the year (including treasury shares)	FY 2019	26,437,681 shares	FY 2018	20,599,731 shares
(ii) Total number of treasury shares at the end of the year	FY 2019	22,593 shares	FY 2018	18 shares
(iii) Average number of shares during the year	FY 2019	23,150,655 shares	FY 2018	16,627,778 shares

(Note) On July 1, 2019, the Company conducted a 1-for-4 reverse stock split of common share. 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.

* Summaries of financial statements are not subject to audit through certified public accountants or auditing corporations.

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

(Notes on forward-looking statements)

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. Overview of Business Results, etc. (4) Future outlook," on Page 10 of the attachment.

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1. Overview of Business Results, etc.

(1) Overview of business results for the fiscal year under review

(Business Results for the fiscal year under review)

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

(i) Domestic business

[Issues concerning product defects]

As stated in the reasons for revisions to our earnings forecasts released on August 7, 2019, 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 in our supply agreement with Astellas Deutschland GmbH. Hence, shipments of TREAKISYM® 100 mg vials to the Company's distributor in Japan, Eisai Co., Ltd., faced further delays than originally anticipated. As a result, net sales totaled 2,837,753 thousand yen for the fiscal year ended December 31, 2019, was down 36.4% compared to our initial forecast. Operating loss was 4,301,615 thousand yen (versus our initial forecast of loss of 3,587 million yen).

To prevent similar quality issues from recurring, the Company have filed complaints with Astellas Deutschland GmbH and requested the manufacture and prompt shipment of replacement product batches. Although the Company received the replacement batches, the inventory levels for TREAKISYM® remain low due to unreliable delivery dates and continuing high defect rates for a portion of replacement batches. The Company continues request that Astellas Deutschland GmbH to fulfill its obligations as our supplier. SymBio will continue to negotiate and demand improvement from Astellas Deutschland GmbH and while aiming to provide stable supply of high-quality pharmaceutical products. Astellas Deutschland GmbH has established the corrective and preventive action program (CAPA), but its effectiveness has not yet been confirmed.

[Establishment of the Company's own salesforce]

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

During the fiscal year under review, the Company continued to expand and train its team of TREAKISYM® sales representatives, who would be the core of the Company's own salesforce. Upon completion of their training, sales representatives began conducting regionally focused activities to provide information on July 1, 2019, and the Company made steady progress toward establishing a nationwide salesforce by 1H FY 2022. During the final three months of the fiscal year under review, the Company made significant progress in recruiting the additional regional sales managers and TREAKISYM® sales representatives necessary for a nationwide salesforce and our goal of improving our distribution and logistics capabilities. This achievement is in part due to the formation of business alliances with pharmaceutical wholesalers and division of our logistics center into eastern Japan and western Japan. Furthermore, the Company are diligently preparing for the establishment of information systems incorporating enterprise resource planning (ERP), which is a part of our internal infrastructure. Through these efforts, the Company made steady progress in establishing a high-performance and high-productivity salesforce that is based on extensive expertise and experience.

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

The Company currently sells TREAKISYM®, a drug widely used in the field of malignant lymphoma, 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 (low-grade NHL) ^(Note 1) and mantle cell lymphoma (MCL) in December 2016, for recurrent/refractory low-grade NHL and MCL in October 2010, and for chronic lymphocytic leukemia (CLL) in August 2016. Further, the combination treatment (BR therapy) of TREAKISYM® and rituximab was added to the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues 2018 published by the Japanese Society of Hematology in July 2018, recommending TREAKISYM® as one of standard treatments for all previously approved indications. As a result, TREAKISYM® gained its foothold as the standard treatment for malignant lymphoma. By switching to a highly specialized internal salesforce, the Company aims to achieve a market share that is on par with our market shares in the U.S. and Europe.

In addition to the approved indications, the Company is conducting a Phase III clinical trial for TREAKISYM[®] targeting recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). In November 2019, the Company announced the achievement of a favorable response rate that exceeded expected levels, which represents a primary endpoint. Currently, the Company is preparing to apply for approval for this indication, targeting the second quarter of FY 2020. The above trial is in response to the 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.

The Company entered into an exclusive license agreement (in Japan) for TREAKISYM[®] liquid formulation (RTD and RI liquid formulations) ^(Note 2) with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) in September 2017. Following consultations with the Pharmaceutical and Medical Devices Agency concerning RTD liquid formulation products, the Company completed an application for approval in September 2019 and forecasts a launch in Q1 FY 2021. A clinical trial for RI liquid formulations began in November 2018 primarily to confirm safety. The Company is steadily recruiting patients since the enrollment of the first patient in April 2019. As of January 31, 2020, 31 patients were enrolled. The Company aims to launch these RI liquid formulations in the first half of FY 2022 following a prompt application for approval after the clinical trial. RI liquid formulations significantly reduce the time required for administration to 10 minutes, down from the 60 minutes required by the currently available freeze-dried (“FD”) powder and ready-to-dilute (RTD) formulations. This will greatly lessen the burdens placed on patients and healthcare providers, enabling the Company to add significant value. Furthermore, the protection of multiple patents including the liquid formulation authorization will make it possible to extend the life of this product until 2031 and maximize business value including 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 offered to patients in combination with obinutuzumab ^(Note 3), which was launched in August 2018. In March 2019, the Company received approval for changes to a portion of its application concerning the use of TREAKISYM[®] as a pretreatment agent for tumor-specific T-cell infusion therapy ^(Note 4). This will allow TREAKISYM[®] to be used as a pretreatment for Kymriah[®] intravenous infusion ^(Note 5), which was approved as the first chimeric antigen receptor T-cell (CAR-T) therapy ^(Note 6) in Japan and included in the NHI price listings in May 2019. The status of TREAKISYM[®] as a standard treatment for malignant lymphoma is becoming stronger as its use as a pretreatment for regenerative medicine and other products continues to expand.

Two trials aimed at exploring further possibilities for TREAKISYM[®], a Phase I clinical trial examining TREAKISYM[®] as a treatment for progressive solid tumors and a pre-clinical trial aimed at verifying the therapeutic effects of TREAKISYM[®] on systemic lupus erythematosus (SLE), were concluded and achieved the initial goals. However, the Company suspended further development of TREAKISYM[®] in these areas. In order to best utilize limited management resources, the Company made the strategic decision to prioritize the domestic and overseas development of brincidofovir (mentioned below), an antiviral drug for the treatment of infectious disease, for which the Company have newly acquired a license.

(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) RTD and RI are pre-dissolved liquid formulations that differ from currently available freeze-dried (“FD”) 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.

(Note 3) Obinutuzumab (Gazyva[®], marketed by Chugai Pharmaceutical Co., Ltd.): Like rituximab recommended by treatment guidelines for non-Hodgkin’s lymphoma in Japan and overseas, obinutuzumab is a glycoengineered type II anti-20 monoclonal antibody that directly binds to CD20 (a protein expressed on B-cells other than stem cells or plasma cells) on target B-cells to attack and destroy them along with the body’s immune system.

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

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

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

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

U.S. licensor Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.) (“Onconova”) is conducting a global Phase III clinical trial (with trial sites in more than 20 countries) of the intravenous formulation of rigosertib for higher-risk myelodysplastic syndromes (HR-MDS) in patients who do not respond to the current standard treatment with hypomethylating agents relapse after treatment under the current standard of care, or are intolerant to hypomethylating agents. The Company is responsible for clinical development in Japan and began the trial in December 2015. Forty-eight patients were enrolled as of December 31, 2019, and patient enrollment is in progress. According to an October 2019 announcement from Onconova, global patient enrollment (final target of 360 patients) was more than 90% complete as of November 2019, 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 7)), and results suggested that the oral formulation of rigosertib and azacitidine were safe and effective when combined. The Company started a Phase I clinical trial in Japan in June 2017 to confirm the tolerability and safety of the oral formulation of rigosertib for Japanese patients. We began patient enrollment with the first patient enrolled in October 2017 and completed the enrollment process 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, the Company 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. Data from the global trial was announced at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in December 2019. Based on this data, Onconova announced that it is discussing the design of a Phase II/III adaptive clinical trial testing this combination therapy as a first-line treatment for HR-MDS during the same month.

(Note 7) Azacitidine (Vidaza[®], marketed by Nippon Shinyaku Co., Ltd.): This hypomethylating agent (for injection) was approved in 2011 upon successful confirmation of extended overall survival for the first time in the Phase III clinical trial for the indication of MDS, and is currently used as a first-line drug for MDS patients who have difficulties in hematopoietic stem cell transplantation. MDS is a pre-leukemia, and decreased expression 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 for the treatment of infectious diseases: SyB V-1901 (generic name: brincidofovir)]

On September 30, 2019, the Company entered into an exclusive global licensing agreement for intravenous and oral formulation of brincidofovir^(Note 8), an antiviral drug for the treatment of infectious diseases (SyB V-1901; “BCV IV” and “BCV Oral,” respectively) with Chimerix Inc. (head office: North Carolina, U.S.; “Chimerix”). Under this agreement, the Company acquired the exclusive rights for the worldwide development, marketing, and manufacture of BCV for all human indications, excluding smallpox. With the global rights to BCV, the Company aims to transition into a global specialty pharmaceutical company with an integrated system for supplying high-quality pharmaceutical products.

The Company will first develop BCV IV for the treatment of viral hemorrhagic cystitis^(Note 9) (vHC) that often occurs after hematopoietic stem cell transplantation, which are a niche market with high unmet medical needs. To deliver brincidofovir to

patients who urgently need this treatment, we will conduct clinical development in Japan ahead of the rest of the world, aiming to secure approval for the drug. At the same time, we will conduct global clinical trials of BCV IV that extend to Europe and the U.S targeting a global rollout of the drug. Inspired by its potential wide use throughout the field of surgical transplantation including hematopoietic stem cell transplantation and other organ transplantation, the Company is currently planning clinical development of BCV IV as a treatment for viral infections occurring after kidney transplantation. The Company is currently looking to expand our business in Europe, the U.S. and Asia (including China), where the organ transplant market is larger than Japan. Also, the Company is considering forming partnerships that reflect the regional characteristics of target diseases. We will explore all possible means of maximizing our business value through a variety of measures, including strategically utilizing our wholly owned subsidiary, SymBio Pharma USA, Inc. (head office: Menlo Park, California, U.S.; established May 2016). As for BCV Oral, we will discuss a development plan going forward including efforts to improve its formulation. At present, we are discussing future global development for BCV IV and BCV Oral with prominent overseas researchers in a variety of specialized fields. These formulations have already been found to have highly active antiviral effects, as well as a wide treatment spectrum, through clinical trials conducted by Chimerix, Inc. in the U.S. and Europe. Based on these findings, the Company will discuss the design of global clinical trials.

(Note 8) Brincidofovir (BCV) has a structure in which cidofovir (an antiviral drug for the treatment of infectious disease that is already approved and marketed in the U.S. and Europe, but unapproved in Japan; “CDV”) is bound to a lipid chain (hexadecyloxypropyl; “HDP”). It is quickly absorbed into the lipid bilayer membrane and efficiently transfers into cells, and then the bound lipid chain is metabolized and separated from the structure by intracellular phospholipases. This process generates an activator (CDV-PP; CDV diphosphate) that is retained in the cells for a long period of time, dramatically raising the compound’s antiviral activity. Furthermore, BCV avoids nephrotoxicity, a fundamental issue plaguing CDV, since HDP conjugation prevents the accumulation of the compound in renal tubular epithelial cells through organic anion transporter 1 (OAT1) and CDV is released at low levels in the bloodstream.

(Note 9) Viral hemorrhagic cystitis (vHC): Among viral infections that frequently occur following hematopoietic stem cell transplantation, hemorrhagic cystitis caused by the BK virus or the adenovirus accompanies particularly severe symptoms, including frequent urination, abdominal pain and pain experienced during urination. This type of hemorrhagic cystitis is especially likely to occur in transplantation between unrelated donors and in umbilical cord blood transplantations, which are relatively common in Japan. Its extreme refractory nature is further complicated by the length of time required for reconstruction of the immune system, which hinders treatment in many cases. In severe cases, it can cause disseminated infection and become fatal. There have also been reports of fatal kidney failure cases caused by these viral infections. Drugs currently used in treatment, including cidofovir (CDV), are either unapproved or off-label.

[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 US-based 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 interests of patients, temporarily suspended new patient enrollment for SyB P-1501 from April 21, 2017 due to the concern of the continuity of The Medicines Company’s business regarding the product.

The Company 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 its performance of 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 because the breach of the license agreement by The Medicines Company was not remedied within the stipulated time and ceased the development of SyB P-1501 on February 9, 2018.

Arbitration proceedings against The Medicines Company are still ongoing. Novartis International AG (head office: Switzerland) announced on January 6, 2020 that it had completed the acquisition of The Medicines Company .

(ii) Business outside Japan

SyB L-0501 is also marketed in South Korea, Taiwan, and Singapore, and sales of SyB L-0501 in these countries progressed favorably at a level exceeding the Company’s forecasts.

(iii) Licensing of new drug candidates

The Company conducts ongoing search and evaluation of multiple new drug candidates for potential in-licensing to expand our research and development (“R&D”) pipeline. Our aim is to create long-term business value as a profitable biopharmaceutical company with growth potential.

Additionally, the Company will proceed with the transformation into a global specialty pharmaceutical company with the capacity to develop and commercialize new drugs in the U.S., Japan, Europe, and other major global markets by actively acquiring rights to new drug candidates using wholly owned subsidiary Symbio Pharma USA, Inc. as a global business base.

(iv) Business results

Net sales totaled 2,837,753 thousand yen for the fiscal year ended December 31, 2019, primarily reflecting product sales of TREAKISYM[®], and overall net sales fell 26.0% year on year.

Selling, general and administrative expenses totaled 5,166,366 thousand yen (+34.9% year on year), including R&D expenses of 2,441,552 thousand yen (+33.2% year on year) primarily due to upfront payments for the licensing agreement of brincidofovir, an antiviral drug for the treatment of infectious disease and a new product under development, and expenses associated with clinical trials for the intravenous formulations of TREAKISYM[®] and the intravenous and oral formulations of rigosertib, as well as other selling, general and administrative expenses of 2,724,814 thousand yen (+36.5% year on year).

As a result, an operating loss of 4,301,615 thousand yen was recognized for the fiscal year ended December 31, 2019 (an operating loss of 2,656,072 thousand yen for the previous fiscal year). In addition, non-operating income was 4,331 thousand yen, primarily consisting of insurance claim income of 2,736 thousand yen. Meanwhile, non-operating expenses were 79,372 thousand yen and primarily comprised foreign exchange losses of 54,755 thousand yen, share issuance cost of 13,932 thousand yen, and commission expenses of 10,457 thousand yen. Consequently, ordinary loss totaled 4,376,655 thousand yen (compared to an ordinary loss of 2,748,730 thousand yen in the same period of the previous fiscal year) and bottom-line loss in the fiscal year ended December 31, 2019 totaled 4,376,258 thousand yen (compared to a loss of 2,752,533 thousand yen for the same period of the previous fiscal year).

Segment information is omitted since the Company operates within a single segment, which includes the R&D, manufacturing, and marketing of pharmaceutical drugs and other related activities.

(2) Overview of financial position for the fiscal year under review

(Analysis of assets, liabilities, net assets, and cash flow)

Total assets as of December 31, 2019 stood at 5,273,955 thousand yen, a decrease of 965,467 thousand yen from the previous fiscal year end. This was primarily due to the increase of 150,469 thousand yen in consumption taxes receivable, 137,554 thousand yen in accounts receivable–trade, 125,120 thousand yen in software in progress, 44,028 thousand yen in software, 21,513 thousand yen in construction in progress, 10,644 thousand yen in advances paid, and 10,629 thousand yen in prepaid expenses that were offset by decreases of 910,525 thousand yen in cash and deposits and 533,824 thousand yen in merchandise and finished goods. Total liabilities stood at 873,838 thousand yen, a decrease of 463,784 thousand yen, owing mainly to rises of 135,845 thousand yen in accounts payable–other and 16,506 thousand yen in income taxes payable that were offset by decreases of 605,187 thousand yen in trade payable and 16,427 thousand yen in forward exchange contracts.

Under net assets, increases of 1,898,059 thousand yen in capital stock, 1,898,059 thousand yen in legal capital surplus, and 91,016 thousand yen in share acquisition rights were offset by a decrease of 4,376,258 thousand yen in retained earnings that was due to the recording of bottom-line loss and an increase of 15,059 thousand yen in treasury shares. As a result of these factors, total net assets fell by 501,683 thousand yen from the previous fiscal year end, to 4,400,116 thousand yen. The equity ratio consequently rose 1.6 percentage points from the previous fiscal year end, to 71.7%.

Despite a boost from the issuance of new shares, cash and cash equivalents (“cash”) as of December 31, 2019 stood at 3,910,830 thousand yen, a decrease of 910,525 thousand yen from the previous fiscal year end. This was mainly due to the recording of loss before income taxes.

(Cash flows from operating activities)

Net cash used in operating activities amounted to 4,350,738 thousand yen, compared with 2,324,547 thousand yen in cash used by these activities in the previous fiscal year. Factors having a positive effect on cash included a decrease of 533,824 thousand yen in inventories, the recording of 127,144 thousand yen in share-based compensation expenses, an increase of 124,233 thousand yen in accounts payable–other and the recording of 83,370 thousand yen in foreign exchange losses, 38,085 thousand yen in depreciation, 13,932 thousand yen in share issuance cost, and 10,457 thousand yen in commission expenses. Principal factors having a negative effect on cash were the recording of 4,372,458 thousand yen in loss before income taxes, a decrease of 605,187 thousand yen in accounts payable–trade, an increase of 150,469 thousand yen in consumption taxes receivable, an increase of 137,554 thousand yen in notes and accounts receivable–trade, an increase of 18,649 thousand yen in prepaid expenses, and an increase of 10,644 thousand yen in advances paid.

(Cash flows from investing activities)

Net cash used in investing activities amounted to 216,462 thousand yen, compared with 26,180 thousand yen used in these activities in the previous fiscal year. Principal contributing factors included 192,013 thousand yen in purchase of intangible assets and 24,498 thousand yen in purchase of property, plant and equipment.

(Cash flows from financing activities)

Net cash provided by financing activities was 3,740,045 thousand yen, compared with 4,272,056 thousand yen provided by these activities in the previous fiscal year. This result occurred despite 20,871 thousand yen in purchase of treasury shares and 11,582 thousand yen in payments for issuance of shares and was primarily the result of 3,771,476 thousand yen in proceeds from issuance of shares resulting from the exercise of share acquisition rights.

(3) Overview of cash flows for the fiscal year under review

	11th Term Fiscal year ended December 2015	12th Term Fiscal year ended December 2016	13th Term Fiscal year ended December 2017	14th Term Fiscal year ended December 2018	15th Term Fiscal year ended December 2019
Equity ratio (%)	82.9	73.5	63.6	70.1	71.7
Equity ratio on a fair market value basis (%)	150.8	165.1	278.4	250.9	304.0
Debt redemption period (years)	—	—	—	—	—
Interest coverage ratio	—	—	—	—	—

Equity ratio: Equity (total shareholders' equity)/total assets

Equity ratio on a fair market value basis: Total market value of common stock/total assets

Debt redemption period: Interest-bearing debt/cash flows from operating activities

Interest coverage ratio: Cash flows from operating activities/interest payments

(Notes) 1. Total market value is calculated based on the number of shares issued, excluding treasury shares.

2. Debt redemption period and interest coverage ratio are not available due to negative cash flows from operating activities.

(4) Future outlook

The Company expects net sales of 3,404 million yen in the fiscal year ending December 31, 2020, a 20.0% increase from the fiscal year ended December 31, 2019, mainly as a result of growth in sales of TREAKISYM[®] in Japan. Meanwhile, in R&D, the Company will continue to pursue the development of TREAKISYM[®] for recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL); the RTD and RI liquid formulations of TREAKISYM[®]; intravenous and oral formulations of rigosertib; and a new pipeline product, brincidofovir, an antiviral drug for the treatment of infectious disease.

With the aim of further enhancing corporate value over the long term, the Company will continue to consider in-licensing new drug candidates and will continue to advance the development of its current pipeline as a whole. Simultaneously, it will earnestly promote the construction of its own salesforce and preparations for global business expansion while targeting profitability in the fiscal year ending December 31, 2021 and continued expansion in earnings afterward. To this end, the Company anticipates R&D expenses of 2,679 million yen (2,441 million yen in the fiscal year ended December 31, 2019) and selling, general and administrative expenses of 6,236 million yen (5,166 million yen in the fiscal year ended December 31, 2019), including R&D expenses.

Key development milestones for the Company's current pipeline are as follows:

[TREAKISYM[®]]

Regarding recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), the Company will proceed with the preparation of approval applications.

The Company is making steady progress on both the RTD and RI liquid formulations of TREAKISYM[®], which was in-licensed from Eagle Pharmaceuticals, Inc. In the case of the former, the Company has completed approval applications and is undergoing preparations to launch sales in the first three months of the fiscal year ending December 31, 2021. In the case of the latter, clinical trials aimed primarily at confirming formulation safety are underway.

[Intravenous and oral formulation of rigosertib]

As for the intravenous formulation of rigosertib, the Company is currently accumulating patient enrollments in Japan as part of the global Phase III clinical trial, and will continue to pursue development jointly with Onconova Therapeutics, Inc.

As for the oral formulation of rigosertib, the Company will make preparations in step with Onconova to ensure that it can promptly participate in a joint global Phase III clinical trial for combination therapy with azacytidine.

[Brincidofovir, an antiviral drug for the treatment of infectious disease]

The company plans to conduct clinical development in Japan using the intravenous formulation of brincidofovir (BCV IV) before embarking on global development. We will initially target viral hemorrhagic cystitis occurring after hematopoietic stem cell transplantation, which represents a niche market with high unmet medical demand. Setting our sights on global rollouts and future business expansion for the intravenous and oral formulations of brincidofovir (BCV oral), we will hold discussions with prominent researchers from a number of specialties and review clinical trial designs based on the knowledge we gain from these discussions.

As a result of these planned activities, the Company anticipates net sales of 3,404 million yen, an operating loss of 5,090 million yen, an ordinary loss of 5,134 million yen, and a loss of 4,803 million for the fiscal year ending December 31, 2020.

(5) Basic policies concerning profit distribution and dividends

The Company has not distributed dividends to date.

Although the Company has recorded product sales of its first product, TREAKISYM[®], other pipeline products are still at the investment stage. Therefore, it is our policy to prioritize allocation of funds to strengthen our financial position and continue R&D activities rather than to distribute dividends. However, we recognize that the return of profit to shareholders is an important management issue and will continue to consider the distribution of profits based on future business performance and financial

conditions.

The articles of incorporation state that the Company can pay an interim dividend, based on a corporate resolution by the Board of Directors, on June 30 every year as the record date. The Company can also distribute surplus by designating a record date in addition to year-end and interim dividends. The decision-making body for the interim dividend is the Board of Directors, and for the year-end dividend the shareholders' meeting.

(6) Business risks

Described below are major issues that may lead to potential risks in the Company's business activities. Issues that are not necessarily considered significant by the Company are also disclosed in view of our commitment to actively provide information to investors and shareholders as these issues may carry weight in making investment decisions or in understanding our business activities. The Company is fully aware of the potential risks, and will make utmost efforts to prevent such risks from materializing, but should they occur, we intend to take appropriate action. However, we realize that investment decisions regarding our stock should be made carefully by evaluating the following matters, as well as other matters mentioned in other sections of this document. We would add that the following descriptions do not purport to cover all possible risks associated with investment in our stock. The future perspectives mentioned below reflect our understanding of our business circumstances as of the date of publication of this document.

(i) Risks associated with pharmaceutical development in general

The Company's main business is to in-license new drug candidate compounds created by pharmaceutical and bio venture companies, and to develop these into pharmaceutical products. The R&D field of pharmaceuticals is replete with strong competition, including pharmaceutical giants. In addition, specialty pharmaceutical companies, including the Company, emulate each other in quality and speed within the sector. The process from development to manufacturing and marketing involves many regulatory hurdles, necessitating a vast amount of capital input over a long period of time in business operations. Their future prospects involve uncertainty and these risk factors are associated with the Company's present and future business activities.

a) Uncertainty involved in pharmaceutical development

The pharmaceutical development process leading up to the launch of a drug generally requires a large amount of expenditure over a prolonged period. The probability of success is low. At each stage of development, it is not uncommon to make decisions on discontinuing or delaying product development. In pharmaceutical development, the different stages of development have to be conducted in phases, and at each phase a decision is made regarding whether or not development should continue. It is not unusual for a decision to be made to stop development in mid-process. The probability is low for development to progress successfully through to product launch. Even after a product is successfully developed and launched, reevaluation is conducted periodically or irregularly to confirm efficacy and safety of the product in light of academic standards in medical and pharmaceutical areas at the time of reevaluation. In cases where efficacy is not confirmed or serious side effects could lead to further damage to the health of patients, there remains a risk that approval for the product may be revoked due to concerns over efficacy and side effects (see (f): "risk associated with side effects"). To reduce and disperse these risks, the Company aims to have several drug candidates in its development pipeline and to prioritize insofar as possible the in-licensing of drug candidates with confirmed proof of concept (POC)^(Note 10) in human subjects. For small specialty pharmaceutical business such as the Company, the impact of removing a single drug candidate from the development pipeline is highly material and could have a significant impact on the Company's financial position, business performance, and cash flow.

(Note 10) Proof of concept (POC) means confirming the efficacy and safety of a new drug candidate in clinical trials and verifying its practical potential.

b) Uncertainty of income

In order to generate income from the drugs in development, the Company must succeed at all stages of new drug candidate development, obtain the requisite approvals from regulatory authorities, and successfully manufacture and market the product either on our own or in partnership with a third-party. It is not assured that the Company will succeed in these activities, or even if we do succeed, we may not be able to ensure the margin of profitability needed to continue the business. A Phase III clinical trial is underway for the lyophilized powder formulation of TREAKISYM[®], a product currently in the development pipeline that is designed to treat recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL). The Company has completed

approval applications for the TREAKISYM® RTD liquid formulation and is preparing to launch it for sale during the first three months of the fiscal year ending December 31, 2021. We are also conducting clinical trials primarily aimed at confirming the safety of the TREAKISYM® RI liquid formulation. With respect to rigosertib, we are currently handling clinical development in Japan and are conducting a global Phase III clinical trial with the intravenous formulation for the target indication of recurrent/refractory higher-risk MDS. We are also responsible for the domestic clinical development of the oral formulation of rigosertib and are conducting preparations to enable participation in a global clinical trial regarding its combination with azacitidine as a first-line treatment of higher-risk MDS. Furthermore, we have acquired exclusive rights for the global development, marketing, and manufacture of brincidofovir, an antiviral drug for the treatment of infectious disease. These rights cover all human indications other than smallpox. Moving forward, we will formulate plans aimed at maximizing business value for rollouts in Japan and worldwide. We are promoting the development of these compounds, seeking to successfully launch the products onto the market to obtain income. In some cases, we may consider entering into an alliance with other pharmaceutical companies in development and marketing so as to expedite the inflow of income. Notwithstanding our efforts, the drug candidates in our pipeline will require a considerable amount of time under development before they reach the marketplace. There is no guarantee that they will make it onto the market as viable products, or that an alliance agreement can be signed with other pharmaceutical companies. We are of the opinion that the selection of indications and the methods of alliance and marketing identified thus far promise sufficient future profitability after considering the market size and marketing performance of approved drugs. However, should we prove to be wrong in our assessment, or should there be any change in the conditions on which the assessment is based and we fail to promptly adapt to such changes, there could be a significant impact on our financial position, business performance, and cash flow.

c) Uncertainty in legislation and regulations requiring compliance, and the health insurance system

The pharmaceutical industry, the Company's core business, is subject to various regulatory restrictions in individual countries, which are imposed by laws and administrative guidance related to pharmaceutical drugs as well as other relevant legislation regarding all aspects of business operations (research, development, manufacturing, and marketing). We formulate our business plans in accordance with the Pharmaceuticals and Medical Devices Act (PMD Act) of Japan and other current legislative regulations as well as the health insurance system, together with drug pricing guidelines that derive from this legislation. Notwithstanding, there is a possibility that these regulations, regulatory systems, and pricing will change before the products that we are developing reach the marketplace. If any major change does occur, there may be a significant impact on our financial position, business performance, and cash flow.

d) Risk concerning development and marketing overseas

We conduct our pharmaceutical business in Asian and other countries globally, not exclusively in Japan, where we anticipate the expansion of healthcare needs in accordance with economic growth in these strategic business areas. Currently, the lyophilized powder formulation of TREAKISYM® is being sold in South Korea, Taiwan and Singapore, and we are formulating global business expansion plans related to the future worldwide development, sale, and manufacture of brincidofovir, an antiviral drug for the treatment of infectious disease, including in Asia, Europe, and the United States. In overseas markets, as in Japan, pharmaceutical development and marketing generally require very large expenditure and are associated with various business risks. To reduce investment expenditure and business risk, we out-license the development and marketing rights of some of our drug candidates to other overseas companies. Before out-licensing the rights we possess, we select a licensee after careful due diligence; we conduct monitoring when necessary after out-licensing the rights. The development and sales of out-licensed products are subject to business conditions of the licensee or any changes in the regulatory and competitive environment in respective countries, and may fall below initial expectations, resulting in lower than anticipated milestone revenue or royalty income. In such cases, there may be an impact on our financial position, business performance, and cash flow. Similarly, we regularly consider strategically utilizing partnerships with other pharmaceutical companies through methods such as joint development and sales or insourcing or outsourcing agreements. However, the Company acknowledges the possibility that actual earnings may not reach target levels if development or sales do not progress according to projections due to factors such as economic conditions at partner companies, regulations in various countries, or competitive environments. Such cases could potentially affect the Company's financial position, business performance, and cash flow.

e) Competition in the pharmaceutical industry

The pharmaceutical industry is an intensely competitive sector. A large number of both Japanese and foreign pharmaceutical

companies and research institutions, including giant multinational pharmaceuticals, compete in the arena. Technological innovation is progressing rapidly. Many competitors have a comparative advantage over the Company in terms of technology, marketing, and financial position. Thus, these companies may more efficiently produce and sell competitor products, which are more effective than the Company's developed products. This means that what transpires in the competitive landscape with regards to development, manufacturing, and marketing operations may have a significant impact on our financial position, business performance, and cash flow.

f) Risk associated with side effects

Unexpected side effects may occur from the use of pharmaceutical products, from their clinical trial stage to post-marketing stage. If serious and unexpected side effects occur, compensation claims may be brought against the Company, or depending on the situation, there is the risk of a delay in clinical trial timelines or even discontinuation of product development. In the case where such side effects could lead to further damage to the health of patients, there is the risk of cancellation of approval or discontinuation of sales. Regarding compensation claims, the Company has in place the liability insurance necessary to minimize the financial damage should such claims arise. However, this does not exclude the possibility that the compensation awarded exceeds the amount insured. If this should occur, it could have a significant impact on the Company's financial position, business performance, and cash flow.

g) Product liability

The development and manufacturing of pharmaceutical products involves product liability risk. If in the future any products that the Company developed causes damage to health or any adverse events are discovered during clinical trials, manufacturing, sales, or marketing of the drug, the Company will be subject to product liability. This may have a significant impact on the Company's financial position, business performance, and cash flow. If a product liability suit is filed against the Company, the Company's corporate image could be damaged, leading to a loss of confidence in the Company and the drugs it develops, impacting future business.

h. Risks related to manufacturing and supply stability

After bringing products under development to market, the Company must ensure a stable supply of those products. However, technological or legal issues at a business partner to whom the Company has outsourced production could interrupt or substantially delay the supply of products, as could a fire or other disaster that causes a suspension of operations. Such situations could have a significant impact on the Company's financial position, business performance, and cash flow.

(ii) Risk in business operations

a) Risk concerning the Company's business model

The Company does not own research and manufacturing facilities. Instead, the Company has adopted a business model to raise income and profit from such activities, mainly targeting orphan drugs ^(Note 11) in the areas of oncology and hematology, in-licensing drug candidates from pharmaceutical and bio venture companies with POC established through human subjects, and developing and marketing pharmaceutical products in Japan, Asia (China, Hong Kong, South Korea, Taiwan, Singapore, etc.), and other countries globally. Furthermore, we have acquired exclusive rights for the worldwide development, sale, and manufacture of brincidofovir (BCV; an antiviral drug for the treatment of infectious disease) for all human indications, except smallpox, through an exclusive global licensing agreement with Chimerix Inc. Utilizing these rights, we will promote our own transformation into a specialty pharmaceutical company that is capable of expanding its business into global markets and is equipped with an integrated system for supplying high-quality pharmaceutical products.

In developing and marketing the pipeline products, the Company plans to engage in alliances with other pharmaceutical companies. However, there is no guarantee that the Company can continuously in-license drug candidate compounds that satisfy in-house criteria and secure these partner companies. In addition, as the Company mainly targets orphan drugs for in-licensing ^(Note 12), it may not be able to generate expected sales turnover. Furthermore, in the event that development at a licensor is delayed or fails, there may be impact on the corresponding development in Japan. The Company also acknowledges the possibility that global business expansion may not proceed according to initial projections due to uncontrollable factors that affect the progress of development, sales, and manufacturing plans of either the Company or its corporate partners. These factors could impact the Company's financial position, business performance, and cash flow. Needless to say, intense competition within the pharmaceutical sector and changes in the Company's financial position may force the Company to revise its business model. Should this occur, there may be a significant impact on the Company's business.

(Note 11) The rare-disease field is one in which the number of patients requiring drugs is small. Drugs for this field are termed “orphan drugs.” The Japanese Ministry of Health, Labour and Welfare has established an orphan drug designation system for drugs meeting the criteria of (1) a drug to treat a serious disease that affects less than 50,000 people in Japan, and (2) for which there is a great need for medical treatment. Once designation is obtained, the drug will enjoy various advantages including shortening of the time from regulatory submission for review of the drug to approval and the extension of the re-examination period for up to 10 years.

(Note 12) “In-licensed drug candidates” are compounds or products for which obtaining the rights of development and commercialization from other companies is under consideration.

b) Dependency on specific partners and suppliers

The Company holds exclusive rights to manufacture brincidofovir (antiviral drug for the treatment of infectious disease) for all human indications except for smallpox. As a specialty pharmaceutical company without production facilities, the Company currently needs to depend on the supply of product from other companies when conducting clinical trials and marketing approved drugs. Given this fact, the financial position and production conditions of the product supplier may have a significant impact on the Company’s financial position, business performance, and cash flow. With regard to the development and marketing of pipeline products, while the Company plans to launch sales on its own in the fiscal year ending December 31, 2021, its current business plan focuses on forming alliances with pharmaceutical companies. However, if the partner company’s management situation deteriorates substantially or if management policies change, which are matters beyond the Company’s control, initial business plans may not be realized. Also, if any breach of contract occurs that necessitates the termination of the license agreement as stipulated, the alliance may also end prior to reaching the expiration date. In such cases, there may be a significant impact on the Company’s financial position, business performance, and cash flow. Typically, in-license agreements with partner companies, revenues to be gained before the drug reaches the marketplace will include an upfront payment upon signing the contract, funding for co-development, and milestone payments. Of these, milestone payments are extremely unstable and unpredictable income as they are based on the attainment of predefined results. If development progress is delayed, there may be a significant impact on the Company’s financial position, business performance, and cash flow.

c) Risk concerning intellectual property rights

During drug development activities, the Company makes use of various intellectual property rights which generally have been licensed to the Company by other companies such as pharmaceutical and bio venture companies. In relation to in-licensed drug candidates, there is a risk that patent applications by licensors relating to an out-licensed drug are not approved or are declared invalid. Moreover, it is difficult to completely avoid the possible creation of an intellectual property right by a third-party that supersedes the intellectual property right of the Company’s in-licensed drug candidate. These situations could lead to a significant impact on the Company’s financial position, business performance, and cash flow. As of the submission date of this document, no lawsuit has been filed by a third-party against the Company concerning intellectual property rights, including patents in connection with product development. When in-licensing a drug candidate, the Company will seek advice from lawyers and conducts a thorough due diligence investigation through patent firms in order to prevent such intellectual property risks. Nevertheless, it is difficult to realize full protection from the occurrence of intellectual property right disputes involving the infringement of third-party rights, and these may have a significant impact on the Company’s financial position, business performance, and cash flow. The candidate compounds that the Company in-licenses are not necessarily protected by patents. On the other hand, even if a drug candidate is not protected by a patent, the assignment of the compound for re-examination review by the regulatory authorities would restrict the entry of generic drugs during the review period, giving rise to a limited period of marketing exclusivity.

d) Information protection

To reduce the risk of significant confidential information relating to pipeline development and other business activities leaking outside the Company, the Company engages in rigorous information protection. The Company requires directors and employees, Scientific Advisory Board (SAB) members, outsourcing partners, and other business partners to sign confidentiality agreements. Even with the agreement in place, directors and employees, SAB members, outsourcing partners, and other business partners may not adhere to confidentiality, and should this occur, significant confidential information may be divulged elsewhere, which may impact the Company’s business, financial position, business performance, and cash flow.

e) Risk concerning important contracts

If any contracts that may have a significant impact on conducting the Company's business operations are terminated due to expiration, cancellation, or for any other reason, there may be a significant impact on the Company's financial condition, business performance, and cash flow.

(iii) Risk associated with organization

a) Risk of being a young company

SymBio is a young company founded in March 2005. Since inception, the Company has engaged in in-licensing activities of drug candidates for development. The founding President and CEO built up the pharmaceutical development business from scratch, and the Company recorded income from product sales in August 2010, for the first time in its history. There is the possibility that business issues that SymBio has never encountered arise in the future. At the moment, however, there are difficulties associated with accurately predicting any changes in the external environmental factors that may affect the Company's business results. Therefore, the Company considers business results for the past several years to be an inadequate reference to pass judgment on whether or not the Company can continue to grow.

b) Risk of being a small corporation

The Company uses contract research organizations (CROs ^(Note 13)) in conducting R&D, thereby forming a development framework requiring relatively small staff numbers. With progress in the development of the pipeline (including global expansion) already in place and with newly in-licensed drug candidates coming on line, the Company may need growth in R&D human resources. However, for whatever reason should an alliance with a CRO terminate, or should the Company fail to secure the planned number of staff, or should existing staff decide to leave, the Company's business operations may be hampered, leading to a possible impact on the Company's financial position, business performance, and cash flow.

(Note 13) A contract research organization (CRO) is an organization that provides research and other services to pharmaceutical companies, supporting pharmaceutical companies in their efforts to conduct development activities without delay. The details of the commissioned activities may include monitoring to ensure that clinical studies are carried out in full accordance with study protocols and clinical data management.

c) Dependency on a specific person

Fuminori Yoshida, the Representative Director, founding President and CEO, has played a key role since the Company's foundation in the implementation and execution of all operations in the Company's business management. Thus, in the event that he cannot continue to perform his corporate responsibilities for some unforeseen reason, this could have a significant impact on the Company's business operations.

d) Scientific Advisory Board (SAB)

The Scientific Advisory Board ("SAB") is an advisory panel to the Company's president on the potential in-licensing of new drug candidates. The Company invites members of the panel from clinicians and scientists engaged in basic research who are highly regarded in the healthcare industry due to their successful track records and wealth of experience. The SAB meets two or three times a year to engage in active discussion and debate, with each member giving his/her own perspective on an in-licensed drug candidate in the aim of building a pipeline portfolio with a balanced risk–return trade-off, while taking into consideration the degree of healthcare needs and profitability of in-licensed drug candidates, which are gathered from all over the world. The Company will continue in its efforts to acquire members of excellence for the SAB. However, if difficulty should arise in procuring members for reasons such as the cancellation, expiration, or renewal refusal of contracts with existing members, there may be an impact on the Company's ability to evaluate and in-license quality drug candidates.

(iv) Business results

a) Business performance in previous years

The Company's key business indicators are given below:

Term	11th Term	12th Term	13th Term	14th Term	15th Term
Fiscal Year Ended	December 2015	December 2016	December 2017	December 2018	December 2019
Net sales (thousands of yen)	1,933,241	2,368,112	3,444,206	3,835,530	2,837,753
Operating profit (loss) (thousands of yen)	(2,551,662)	(2,127,049)	(3,947,061)	(2,656,072)	(4,301,615)
Ordinary profit (loss) (thousands of yen)	(2,630,386)	(2,316,806)	(3,976,784)	(2,748,730)	(4,376,655)

To date, with the exception of the 4th Term, the Company's total R&D expenses and other general and administrative expenses exceeded the Company's income, resulting in the posting of an operating loss, an ordinary loss, and a bottom-line loss. For this reason, the Company does not consider the financial statements and indicators of previous years to provide adequate reference data in making period comparisons of business performance or in forecasting future business performance.

b) Expected increase in R&D expenditures

The Company's R&D expenses for the past five fiscal years are provided below:

Term	11th Term	12th Term	13th Term	14th Term	15th Term
Fiscal Year Ended	December 2015	December 2016	December 2017	December 2018	December 2019
R&D expenses (thousands of yen)	2,034,714	1,667,098	3,017,812	1,832,746	2,441,552

The Company intends to continue R&D activities and cumulative loss is currently trending upward. Utilizing our own salesforce, we aim to achieve profitability as a business objective in the fiscal year ending December 31, 2021 through expansion of product sales revenue from additional indications of TREAKISYM[®]. However, the achievement of this objective could potentially be hampered by a variety of factors. Through the recording of product sales revenue upon early approval for the intravenous and oral formulations of rigosertib and brincidofovir, an antiviral drug for the treatment of infectious disease, and the income from alliances with pharmaceutical companies, the Company aims to collect early return on its R&D investment and continuously improve business performance as soon as possible; however, there is no guarantee that the Company will be able to achieve these aims as forecast.

c) Negative retained earnings (accumulated deficits) brought forward

SymBio is a specialty pharmaceutical company. Until products under development at the clinical stage reach the marketplace so that the Company can continuously earn stable income through product sales revenue and royalty income, the Company will continue to carry significant upfront outlay of R&D expenditure. Due to this situation, with the exception of the 4th Term, the Company has posted losses since its foundation. At the end of the 15th Term, the fiscal year ended December 31, 2019, the Company recorded a negative balance of 25,919,496 thousand yen as accumulated deficits brought forward. SymBio aims to become profitable at the earliest possible date by advancing its pipeline development in a rapid, precise, and efficient manner and shifting toward implementing its own internal salesforce. However, the possibility still exists that profits may not be generated in the planned timeframe. Should the Company's business fail to develop and fail to generate profits as planned, the timing of negative retained earnings brought forward becoming positive may considerably be delayed.

d) Fundraising

As a bio venture aiming to transform into a global specialty pharmaceutical company, the Company requires a large amount of funds to cover business expansion, including funds for R&D expenses. If SymBio's business plan does not take shape as planned and it suffers a shortfall in funding, the Company will endeavor to procure funds by changing strategic alliances, securing new alliance contracts, or issuing new shares. However, if the Company fails to generate funds when they are required, there may be serious doubt over the continuation of its business operations.

e) Tax losses carried forward

The Company currently has tax losses carried forward. For this reason, the Company is not subject to corporate income tax, local inhabitant tax, or enterprise tax at the standard rates and expects this to continue for several years into the future. However, if accumulated deficits are written off earlier than expected and can no longer be used as an offset to taxable income due to such reasons as the revision to current tax treatment of losses carried forward, the Company would become liable for the payments of corporate income tax, local inhabitant tax, and enterprise tax at standard rates, which may have an impact on a bottom-line profit (or loss) and cash flow currently planned.

(v) Other risks

a) Profit distribution to shareholders

Since the foundation of the Company, dividends have not been distributed. SymBio is currently at the business stage of making upfront investment for the development and commercialization (including global rollout) of pharmaceutical drugs, as well as continuous growth achieved through the application of its own internal salesforce. The Company plan to continue to prioritize using funds to strengthen its financial position, continue its R&D activities, and support in-licensing of new drug candidates. Thus, the Company has at present no plans for making dividend payouts. However, the Company recognizes that the return of profit to shareholders is an important management issue and will consider profit distribution based on future business performance and financial condition.

b) Procurement of funds

The Company may face increases in its capital requirements due to rises in necessary expenses accompanying business expansion through in-licensing of new drug candidates or unpredictable changes in external environment. Fluctuations in estimated earnings may also cause capital requirements to greatly exceed predictions in the Company forecast for the fiscal year ending December 31, 2020 or in the medium- to long-range plan. In either of these cases, the Company may obtain additional financing through means such as the issue of new shares. By doing so, the number of issued shares will increase, potentially diluting the per share value of the Company's stock.

c) Dilution of the Company's shares by the exercise of potential shares

The Company adopted a stock option plan in order to motivate and encourage higher business performance of directors and employees, and to attract human resources of excellence. In accordance with the Commercial Code of 1890 Article 280-19, 280-20, and 280-21, and the Companies Act Article 236, 238, 239, and 240, share acquisition rights are granted to directors and employees.

Additionally, the Company made a resolution at the Board of Directors meeting held on April 6, 2016 to issue the 3rd unsecured convertible bonds with share acquisition rights (total issue price: 3 billion yen) and the 39th warrant (total issue price: 9,776 thousand yen; total issue price of shares when issued through the exercise of share acquisition rights: 943,592 thousand yen) by way of third-party allotment. The Company also made a resolution at the Board of Directors meeting held on August 9, 2017 to issue the 42nd warrant (total issue price: 32,560 thousand yen; total issue price of shares when issued through the exercise of share acquisition rights: 1,892,000 thousand yen) by way of third-party allotment. Furthermore, on April 9, 2018, the Board of Directors resolved to issue the 45th through 47th warrants (total issue price: 23,100 thousand yen; total issue price of shares when issued through the exercise of share acquisition rights: 10,440,000 thousand yen) by way of third-party allotment. Among these warrants, as of December 31, 2019, the following remained unexercised: 1,675,000 shares to be issued upon the exercise of the 47th warrant.

As of December 31, 2019, potential dilutive shares from the abovementioned warrants ("number of potential shares") totaled 1,675,000 shares and comprised 6.3% of total shares issued. There is the possibility that per share value of the Company's stock will be diluted if these potential shares are exercised in the future. To attract talent, the Company may continue to offer similar incentives. This means that if these share acquisition rights are exercised in the future, per share value of the Company's stock may be diluted.

d) Stock holding by venture capitals

In general, venture capitals and investment partnerships own shares for the purpose of realizing capital gains by selling shares after IPO. If venture capitals and investment partnerships that own SymBio shares sell all or a portion of such shares, it could have an impact on the market price of the Company's shares.

e) Risk of loss on foreign exchange

The Company, which does not currently have a production facility, receives its supply of products from other companies and assumes that it will make one-off payments when in-licensing drug candidates to expand its pipeline. Suitable financing for these payments is obtained in advance through the arrangement of deposits denominated in foreign currency or foreign exchange forward contracts. Where such assets denominated in foreign currency are stated at market value in financial statements at every year end, there is a risk of loss on valuation due to foreign currency fluctuations in the future and this may have an impact on the Company's financial position, business performance, and cash flow.

f) Risk associated with natural disasters

Any disasters (earthquake, typhoon, fire, etc.) and pandemic that occur in the Company's geographic business domain could lead to the occurrence of human and material damage, or suspension and delay in business. In such cases, social credibility and compensation issues may have an impact on the Company's financial position, business performance, and cash flow.

2. Status of Corporate Group

SymBio owns one unconsolidated subsidiary. However, because its impact on financial results is insignificant, it is omitted.

3. Management Policies

(1) Basic policy of company management

SymBio Pharmaceuticals Limited was established in March 2005 by Fuminori Yoshida, who previously served concurrently as Corporate VP of Amgen Inc. ^(Note 14) (United States) and President of Amgen K.K., a wholly owned subsidiary of Amgen Inc., (now part of Takeda Pharmaceutical Company Limited) for 12 years since its establishment.

The Company aims to achieve social and management responsibilities by responding to unmet medical needs ^(Note 15) based on the guiding principle of mutual harmony, creating an intricate symbiotic relationship between patients, physicians, scientists, regulators, and investors.

The Company regards underserved therapeutic areas with extremely significant medical needs as a business opportunity and remains focused on the areas of oncology and hematology, where high entry barriers exist due to the high degree of specialization required. In this sense, SymBio is the first specialty pharmaceutical company in Japan. Rather than exploring opportunities to in-license and develop new "blockbuster" drugs (drugs with sales exceeding 100 billion yen), the Company channels its resources into the development of drugs in underserved markets where medical needs are high despite limited patient numbers. Holding multiple drug approvals and new drug candidates in these key therapeutic areas, the Company aims to build a solid pipeline portfolio, achieve high profitability with high-value products and services, and operate sustainable businesses.

(Note 14) Applied Molecular Genetics, or Amgen Inc., the world's largest company in the biopharmaceutical field, was founded in Thousand Oaks, California, in 1980, and started business in Japan as Amgen K.K. on May 1, 1993. After Takeda Pharmaceutical Company Limited ("Takeda") acquired 100% of Amgen K.K.'s stock in February 2008, its operations were merged into Takeda.

(Note 15) "Unmet medical needs" means requirements for medical treatment that have not yet been fulfilled. It refers to a situation in which no effective drugs or treatments are currently available, despite strong demand by patients and/or physicians.

(2) Key performance index

As a pharmaceutical company, SymBio believes that launching new drugs onto the market on an ongoing basis through its own salesforce is an important element of securing higher corporate value. Accordingly, we plan to move ahead with building an integrated sales system that includes a salesforce, as well as logistics and distribution. At the same time, the Company intends to continue in-licensing drug candidates for development and aggressively investing management resources into R&D activities.

Earnings have continued to grow, mainly due to product sales, since SyB L-0501 was approved for manufacture and sale in Japan and Singapore in 2010. Going forward, the Company will continue collaborating with Eisai to expand sales of TREAKISYM[®] in Japan until our business partnership agreement expires in December 2020. From 2021, we aim to switch to our own salesforce and expand earnings further. By obtaining approval for the intravenous and oral formulations of rigosertib and putting this product on the market; launching development of and commercializing brincidofovir, an antiviral drug for the treatment of infectious disease, in Japan and overseas; and working to in-license, promote the development of, and acquire

approval for new pipeline products, we will establish a high level of stable profitability as soon as possible. We will not set performance index targets such as ROE or ROA until profits are recorded in a single year through the transition to our own salesforce in the fiscal year ending December 31, 2021.

(3) Pipeline

The Company currently has the following pipeline products under development: SyB L-0501, SyB L-1101, SyB C-1101, SyB L-1701, SyB L-1702, and SyB V-1901. The Company will continue to in-license candidate drugs to further expand and build its pipeline portfolio with a balanced risk–return trade-off.

(i) [Anticancer agents: SyB L-0501 (lyophilized powder formulation), SyB L-1701 (RTD formulation), SyB L-1702 (RI formulation), (generic name: bendamustine hydrochloride; trade name: TREAKISYM®)]

Bendamustine hydrochloride (the generic name), the active pharmaceutical ingredient of TREAKISYM®, is an anticancer agent that has been in use for a number of years in Germany under the trade name of Ribomustin® for the treatment of non-Hodgkin’s lymphoma, multiple myeloma, and chronic lymphocytic leukemia. The Company decided to in-license this product because there is currently no effective medication for the indications of recurrent/refractory low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma. These are underserved therapeutic areas aligned with the Company’s corporate mission and also fall within one of SymBio’s targeted therapeutic fields (hematologic cancer). Astellas Deutschland GmbH, a German subsidiary of Astellas Pharma Inc., is the worldwide licensor of bendamustine hydrochloride. Cephalon, Inc. (Pennsylvania, United States), a subsidiary of Teva Pharmaceutical Industries Ltd. (Israel), in-licensed rights to bendamustine hydrochloride for North America from Astellas Pharma GmbH and obtained approvals from the U.S. Food and Drug Administration (FDA) to use the drug for the treatment of chronic lymphocytic leukemia and refractory B-cell non-Hodgkin’s lymphoma in March 2008 and October 2008, respectively. Mundipharma International Corporation Limited (United Kingdom) and Janssen-Cilag Limited (United Kingdom) are also licensed from Astellas Pharma GmbH and have obtained exclusive rights for the development and commercialization of bendamustine hydrochloride in Europe and other regions, respectively.

The Company is licensed from Astellas Deutschland GmbH with exclusive rights for the development and commercialization of bendamustine hydrochloride in Japan, China, Hong Kong, South Korea, Singapore, and Taiwan. In Japan, the drug has received approval for the indications of recurrent/refractory low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma (October 27, 2010), and was launched under the trade name TREAKISYM® on December 10, 2010. For additional indications, in December 2015, the Company filed applications for manufacturing and marketing approval in Japan for the target indications of first-line treatment of low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma, and chronic lymphocytic leukemia. The Company received manufacturing and marketing approval for the indication of chronic lymphocytic leukemia in August 2016 and of first-line treatment of low-grade non-Hodgkin’s lymphoma and mantle cell lymphoma in December 2016. TREAKISYM® achieved primary endpoints in its Phase III clinical trial as a treatment for recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), and the Company is currently preparing to apply for its approval. In order to maximize the business value of TREAKISYM® by further promoting product life cycle management, the Company concluded an exclusive license agreement with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) (“Eagle”) in September 2017 to develop, market, and sell Eagle’s ready-to-dilute (“RTD”) and rapid infusion (“RI”) liquid formulation injection products in Japan. Presently, the Company is applying for approval of the RTD formulation, and is proceeding with clinical trials aimed primarily at verifying the safety of the RI formulation.

Eisai has signed an agreement on TREAKISYM® with SymBio for the rights of joint development and exclusive sales in Japan, and is currently selling TREAKISYM®.

In Asia, SyB L-0501 received the approval for the indication of low-grade non-Hodgkin’s lymphoma and chronic lymphocytic leukemia in Hong Kong in December 2009. In Hong Kong, Cephalon, Inc. has the exclusive right to develop and sell bendamustine hydrochloride, and is currently selling the product. In Singapore, approval for the indications of low-grade non-Hodgkin’s lymphoma and chronic lymphocytic leukemia was obtained in January 2010. In South Korea, approval for the indications of chronic lymphocytic leukemia and multiple myeloma was obtained in May 2011, approval for the indication of recurrent/refractory low-grade non-Hodgkin’s lymphoma was achieved in June 2014, and approval for the first-line treatment of CD20 positive follicular lymphoma was obtained in August 2017.

In South Korea and Singapore, Eisai has agreements in place with SymBio for exclusive development and selling rights. Eisai’s subsidiaries launched the product in Singapore and South Korea in September 2010 and October 2011, respectively.

In China, SymBio’s business partner Cephalon, Inc. received approval in December 2018 for the treatment of recurrent B-cell non-Hodgkin lymphoma following treatment with rituximab. In Taiwan, SymBio’s business partner InnoPharmax Inc. (Taiwan)

achieved approval for the indications of low-grade non-Hodgkin's lymphoma and chronic lymphocytic leukemia in October 2011, followed by product launch in February 2012. In November 2017, InnoPharmax Inc. obtained approval for the first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma.

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

Rigosertib is an anticancer agent with a unique type of multikinase inhibitory activity ^(Note 16). It is currently being developed in the U.S., Europe, and elsewhere by a U.S. company, Onconova Therapeutics, Inc. ("Onconova"), for the target indications of myelodysplastic syndromes ("MDS"). MDS is the pre-pathological state for malignant tumors of blood cells, which has shown increasing numbers of patients in recent years; it frequently affects elderly people; and it is a refractory disease, with a high probability of developing into leukemia.

No effective medication is available yet, especially for recurrent/refractory MDS, and it therefore constitutes an underserved therapeutic area. In July 2011, the Company signed a license agreement with Onconova, obtaining the exclusive right to develop and commercialize rigosertib in Japan and South Korea. Based on this agreement, the Company continues to develop the intravenous rigosertib formulation for the target indication of recurrent/refractory higher-risk MDS and the oral formulation for the target indication of first-line higher-risk MDS (in combination with azacitidine).

As for the intravenous formulation of rigosertib, the Company is participating in a global Phase III clinical trial with clinical trial sites in more than 20 countries worldwide, 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 conducting its own clinical trial to participate in the global Phase III clinical trial from Japan.

As for the oral formulation of rigosertib, Onconova has been conducting a Phase II clinical trial for the target indication of transfusion-dependent lower-risk MDS and a clinical trial for the indication of first-line higher-risk MDS (in combination with azacitidine).

The Company has completed its domestic Phase I clinical trial of the oral formulation of rigosertib as a monotherapy for the target indication of lower-risk MDS, and is currently conducting a domestic Phase I clinical trial to confirm the safety of high-dose monotherapy for the target indication of first-line higher-risk MDS. The Company is considering participating in global clinical trials after completing the Phase I clinical trial. The development for the target indication of transfusion-dependent lower-risk MDS will be considered based on the development progress made by Onconova.

While Onconova is making steady progress with development, we will look into the option of developing rigosertib for indications other than MDS. By allocating development of the intravenous and oral formulations to different indications, the Company aims to make progress with development of treatment methods that are easy for patients to use, and that place sufficient importance on patient compliance.

(Note 16) Multikinase inhibitors impede the proliferation, infiltration, and metastasis of cancer cells, thereby eradicating them.

(iii) [Antiviral drug and treatment for infectious disease: SyB V-1901 (generic name: brincidofovir)]

On September 30, 2019, the Company entered into an exclusive global licensing agreement for brincidofovir ("BCV"; an antiviral drug for the treatment of infectious disease) with Chimerix Inc. 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 (vHC) occurring after hematopoietic stem cell transplantation, which are niche markets with high unmet medical demand. To deliver BCV to patients requiring treatment as promptly as possible, we will conduct clinical development in Japan ahead of the rest of the world and secure approval for the drug. At the same time, we will conduct global clinical trials that extend to Europe and the United States while targeting a global rollout of the drug. Additionally, we are currently planning clinical development of BCV as a treatment for viral infections occurring after kidney transplantation. We are also looking to expand our business in Europe, the U.S. and Asia (including China), where organ transplant markets are large, and are considering forming partnerships that reflect the regional characteristics of 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.

(4) Medium- to long-term strategy

The Company is pursuing primarily the following five strategies in order to achieve its mid-range plan.

(i) De-risking by post-POC strategy

We in-license drug candidates for which proof of concept (POC) is already confirmed in human subjects in principle. Accordingly, they should be drugs that are in a relatively late stage of clinical development or already on the market overseas. The advanced development is already conducted overseas for these drug candidates and their efficacy and safety are already confirmed in human subjects, thereby reducing the development risk. We utilize existing clinical data available overseas so as to compress development timelines, reduce the development costs, and increase the likelihood of regulatory approvals in Japan and Asian markets.

(ii) Building a high-quality pipeline with exceptional search and evaluation capabilities

Our new drug search engine is connected to the diverse network of pharmaceutical and bio venture companies, and enables us to select promising drug candidates from the vast number of chemical compounds after the careful review by internal experts. Using their wealth of experience at the forefront of R&D, Scientific Advisory Board (SAB) members carefully evaluate and render final judgment on each drug candidate. The highly established screening process up to the final selection of drug candidates, coupled with the post-POC strategy (in which we in-license drug candidates whose efficacy and safety are already confirmed overseas), alleviates development risk and reduces development timelines. It also helps to understand how satisfactorily the drug candidates meet the healthcare needs and to improve the accuracy of revenue projections after the product launch.

(iii) Containment of fixed costs by labless/fabless strategy

The Company does not own any research or production facilities, which are often regarded as the main cause of fixed costs. Once drug candidates are searched and in-licensed, we focus on value-added activities such as the formulation and implementation of development strategy and outsource other necessary routine procedures. This enables us to reduce development costs of pharmaceutical drugs and secure a flexible financial strategy.

(iv) Realization of high business efficiency by “Blue Ocean strategy” (Note 17)

There are many cases that the standard drug used overseas cannot be prescribed in Japan or a new drug is launched in Japan five years behind its initial approval overseas. This problem is called “drug lag” and is becoming aggravated, while the term “cancer patient refugee” has been created. This drug lag is particularly conspicuous in our strategic drug development areas of refractory cancer and hematological diseases. There is a large market of anticancer agents that continues to grow with the aging population. However, anticancer agents have a wide range of indications and they are fragmented by the type of tumor, and in some therapeutic areas there are a limited number of patients. Although an extremely high degree of specialization is required and developing new agents in these therapeutic areas is highly difficult, it is often financially unattractive for larger pharmaceutical companies to pursue due to the small size of the potential market. This is part of the cause of the delay in drugs coming to market. On the other hand, obtaining approval and launching a new drug in one of these less competitive therapeutic areas creates an opportunity to achieve superior growth and profitability by continuous indication expansion and bringing new products into the market.

(Note 17) “Blue Ocean strategy” means a strategy of redefining the market, avoiding marketplaces with fierce competition in which competitors seek to gain limited market shares (termed “red oceans”), and instead creating a “blue ocean,” an unexploited market with reduced competition, enabling profits to be maximized while providing customers with high-value products and services.

(v) Going global beyond Asia

The Company has thus far been operating its businesses in Asia centered on Japan. However, major development is unachievable if we remained in Asia, as the environment surrounding Japanese healthcare is changing drastically. Moving forward, the Company will carry out search and evaluation activities to advance new drug candidates with a view to global development. On September 30, 2019, the Company entered into an exclusive global licensing agreement for the antiviral drug brincidofovir with Chimerix Inc. (head office: North Carolina, U.S.). Under this agreement, the Company acquired the exclusive

rights for the worldwide development, marketing, and manufacture of brincidofovir, an antiviral drug for the treatment of infectious disease, for all human indications, excluding smallpox.

(5) Issues to be addressed by the Company

The Company is committed to focusing on the following key management objectives.

(i) Further expansion of the pipeline

In order to enhance the enterprise value as a specialty pharmaceutical company, we need to expand the pipeline through ongoing in-licensing of new drug candidates for development.

The Company is conducting or planning development of the following anticancer agents: SyB L-0501, SyB L-1101, SyB C-1101, SyB L-1701, SyB L-1702, and SyB V-1901, an antiviral drug for the treatment of infectious disease. Currently we are in discussion with counterparties regarding the in-licensing of several new drug candidates, and will continue with active efforts to in-license new drug candidates for development in order to further expand our pipeline.

(ii) Life cycle management of products in the existing pipeline

In order to enhance the enterprise value, not only in-licensing new drug candidates but also promoting product life cycle management is important. Therefore, it is critical to maximize returns from each drug under development through indication expansion after the in-licensed drugs' initial approval.

TREAKISYM® is approved for manufacturing and marketing in Japan for the indications of recurrent/refractory low-grade non-Hodgkin's lymphoma and mantle cell lymphoma, chronic lymphocytic leukemia, and first-line treatment of low-grade non-Hodgkin's lymphoma and mantle cell lymphoma. TREAKISYM® also achieved primary endpoints in its Phase III clinical trial for the indication of recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL), and the Company is currently preparing to apply for its approval. In addition, the Company intends to maximize the business value of TREAKISYM® by promoting the product life cycle management of the product and is developing the TREAKISYM® liquid formulation (RTD and RI liquid formulations) in-licensed from Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.).

The development of intravenous and oral formulations of rigosertib for the indication of myelodysplastic syndromes (MDS) is currently progressing. Few useful therapeutic agents are currently available for MDS, so it is an area with very high unmet medical need. With respect to the global Phase III clinical trial of the intravenous formulation for the target indication of recurrent/refractory higher-risk MDS conducted by Onconova, the Company is conducting its clinical trial in Japan. As for the oral formulation, the Company has completed a domestic Phase I clinical trial as a monotherapy for the target indication of lower-risk MDS, and is currently conducting a domestic Phase I clinical trial to confirm the safety of high-dose monotherapy for the target indication of first-line higher-risk MDS. The Company is considering participating in global clinical trials after completing the Phase I clinical trial. The development for the target indication of transfusion-dependent lower-risk MDS will be considered based on the status of development by Onconova.

The Company is focused on maximizing the business value of TREAKISYM® and rigosertib by promoting product life cycle management through further indication expansion. Furthermore, we will aim to maximize earnings by pursuing life cycle management related to brincidofovir, an antiviral drug for the treatment of infectious disease, while transforming into a specialty pharmaceutical company with the capacity to expand into global markets.

(iii) Preparation for the establishment of the Company's own salesforce

Domestic sales of TREAKISYM® are currently handled through Eisai, in accordance with the business partnership agreement the Company concluded in August 2008. This agreement is set to expire in December 2020 and, looking ahead to the fiscal year ending December 31, 2021, the Company is planning to transition to its own salesforce.

Providing specialized medical drugs information will enable the Company to more accurately understand the needs of the market and respond more swiftly, allowing it to contribute to the benefit of patients while aiming to maximize the business value of TREAKISYM®. Furthermore, the Company strives to build a consistent salesforce with a high level of specialization in the field of hematological diseases. Through this effort, the Company aims to achieve high business efficiency, ensure sustainable earnings growth, and maximize shareholder value once the intravenous and oral formulations of rigosertib, which are currently under development to treat myelodysplastic syndromes (MDS), join TREAKISYM® in the product lineup.

With regard to brincidofovir, an antiviral drug for the treatment of infectious disease, we will not only pursue domestic sales,

but also consider global business development in all parts of the world, including Europe and the United States.

(iv) Global expansion for further growth

In addition to Japan, the Company identifies China, Hong Kong, South Korea, Taiwan, and Singapore as strategic regions and has moved forward with business development in Asia.

However, with expanding medical expenditures due to the aging population in Japan, and the advent of the “era of generic drugs comprising 80% of all drugs dispensed” as a governmental policy of Japan, the business environment for innovative drug developers is expected to remain extremely challenging. Such a policy may also be implemented by other Asian countries.

Under these circumstances, the Company will promote global expansion aiming for further growth. Utilizing its experience fostered through its business in Asia, the Company will search, evaluate, and negotiate concerning new drug candidates that can follow brincidofovir, an antiviral drug for the treatment of infectious disease, in order to acquire their rights on a global scale.

(v) Securing personnel

The Company places the highest priority on personnel as the Company’s principal management resource. Without talent, we cannot make superior achievements in terms of exploring, developing, and providing information concerning new drugs; nor can we roll out these new drugs on a global scale. We have been continually recruiting talented people; especially after being listed, we have recruited the best and brightest people in order to strengthen the management organization. Going forward, we plan to continue to further strengthen our human resources by providing on-the-job training and employee development programs.

(vi) Financial issue

It is necessary for the Company to raise funds required for business activities such as R&D expenditures as pipeline development and global business expansion progress and as drug candidates increase in number.

Therefore, we make every effort to further strengthen the financial base by continually diversifying the method of fund raising and curtailing costs through tight budget control.

(6) Other important matters concerning the Company’s management

Issuance of 45th through 47th warrants

In order to secure the funds necessary for R&D, construction of its own internal salesforce, and licensing of new drug candidates, the Company made a resolution at the Board of Directors meeting held on April 9, 2018 to issue the 45th through 47th warrants (with Exercise Price Revision Clauses) by way of third-party allotment, and completed the payment of 6,383,225 thousand yen as of December 31, 2019.

4. Basic Views on Selection of Accounting Standards

Over the near term, the Company will prepare its financial statements based on Japanese generally accepted accounting principles (GAAP), taking into account the inter-period comparability of financial statements and comparability across companies.

In terms of the application of International Financial Reporting Standards (IFRS), the Company will take appropriate measures in light of the existing circumstances in Japan and overseas.

5. Financial Statements and Primary Notes

(1) Balance sheet

(Unit: thousands of yen)

	FY 2018 (as of December 31, 2018)	FY 2019 (as of December 31, 2019)
Assets		
Current assets		
Cash and deposits	4,821,355	3,910,830
Accounts receivable–trade	411,720	549,275
Merchandise and finished goods	533,824	—
Supplies	589	640
Prepaid expenses	83,372	94,002
Advances paid	31,147	41,791
Consumption taxes receivable	124,855	275,324
Other	31,624	15,626
Total current assets	6,038,490	4,887,491
Non-current assets		
Property, plant and equipment		
Buildings	46,198	47,486
Accumulated depreciation	(9,427)	(12,751)
Buildings, net	36,771	34,734
Tools, furniture and fixtures	59,541	66,241
Accumulated depreciation	(39,361)	(46,998)
Tools, furniture and fixtures, net	20,180	19,242
Construction in progress	—	21,513
Total property, plant and equipment	56,951	75,491
Intangible assets		
Software	50,946	94,974
Software in progress	20,430	145,551
Total intangible assets	71,376	240,525
Investments and other assets		
Shares of subsidiaries	0	0
Long-term prepaid expenses	1,225	—
Lease and guarantee deposits	71,378	70,446
Total investments and other assets	72,604	70,446
Total non-current assets	200,932	386,463
Total assets	6,239,423	5,273,955
Liabilities		
Current liabilities		
Accounts payable–trade	726,100	120,913
Accounts payable–other	503,637	639,482
Income taxes payable	71,249	87,756
Forward exchange contracts	16,427	—
Other	18,926	24,066
Total current liabilities	1,336,342	872,219
Non-current liabilities		
Provision for retirement benefits	1,281	1,619
Total non-current liabilities	1,281	1,619
Total liabilities	1,337,623	873,838

(Unit: thousands of yen)

	FY 2018 (as of December 31, 2018)	FY 2019 (as of December 31, 2019)
Net assets		
Shareholders' equity		
Capital stock	12,972,579	14,870,639
Capital surplus		
Legal capital surplus	12,942,579	14,840,639
Other capital surplus	—	2,498
Total capital surplus	12,942,579	14,843,137
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(21,543,238)	(25,919,496)
Total retained earnings	(21,543,238)	(25,919,496)
Treasury shares	(17)	(15,077)
Total shareholders' equity	4,371,902	3,779,202
Share acquisition rights	529,897	620,913
Total net assets	4,901,799	4,400,116
Total liabilities and net assets	6,239,423	5,273,955

(2) Statement of income

(Unit: thousands of yen)

	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Net sales		
Net sales of goods	3,809,874	2,811,272
Rights income	25,656	26,481
Total net sales	3,835,530	2,837,753
Cost of sales		
Beginning merchandise inventory	362,514	533,824
Cost of purchased goods	2,968,586	1,684,453
Purchase allowance and returns	134,614	245,276
Total	3,196,486	1,973,002
Ending merchandise inventory	*1 533,824	*1 —
Cost of goods sold	2,662,661	1,973,002
Gross profit	1,172,869	864,751
Selling, general and administrative expenses	*2 *3 3,828,941	*2 *3 5,166,366
Operating profit (loss)	(2,656,072)	(4, 301,615)
Non-operating income		
Interest income	525	235
Insurance claim income	—	2,736
Dividend income of insurance	1,501	1,282
Interest on tax refund	116	76
Other	54	0
Total non-operating income	2,196	4,331
Non-operating expenses		
Commission expenses	11,100	10,457
Share issuance costs	29,650	13,932
Foreign exchange losses	54,103	54,755
Other	—	227
Total non-operating expenses	94,854	79,372
Ordinary profit (loss)	(2,748,730)	(4,376,655)
Extraordinary income		
Gain on reversal of share acquisition rights	9,826	4,197
Total extraordinary income	9,826	4,197
Extraordinary losses		
Loss on retirement of non-current assets	*4 9,829	—
Total extraordinary losses	9,829	—
Profit (loss) before income taxes	(2,748,733)	(4,372,458)
Income taxes—current	3,800	3,800
Total income taxes	3,800	3,800
Profit (loss)	(2,752,533)	(4,376,258)

(3) Statement of changes in equity

FY 2018 (from January 1, 2018 to December 31, 2018)

(Unit: thousands of yen)

	Shareholders' equity						
	Capital stock	Capital surplus			Retained earnings		Treasury shares
		Legal capital surplus	Other capital surplus	Total capital surplus	Other retained earnings Retained earnings brought forward	Total retained earnings	
Balance at beginning of current period	10,761,676	10,731,676	—	10,731,676	(18,790,705)	(18,790,705)	(17)
Changes of items during period							
Issuance of new shares (exercise of share acquisition rights)	2,210,903	2,210,903		2,210,903			1,626,756
Profit (loss)					(2,752,533)	(2,752,533)	
Net changes of items other than shareholders' equity							
Total changes of items during period	2,210,903	2,210,903	—	2,210,903	(2,752,533)	(2,752,533)	—
Balance at end of current period	12,972,579	12,942,579	—	12,942,579	(21,543,238)	(21,543,238)	(17)

	Shareholders' equity	Share acquisition rights	Total net assets
	Total shareholders' equity		
Balance at beginning of current period	2,702,629	536,772	3,239,402
Changes of items during period			
Issuance of new shares (exercise of share acquisition rights)	4,421,806		4,421,806
Profit (loss)	(2,752,533)		(2,752,533)
Net changes of items other than shareholders' equity		(6,875)	(6,875)
Total changes of items during period	1,669,273	(6,875)	1,662,397
Balance at end of current period	4,371,902	529,897	4,901,799

FY 2019 (from January 1, 2019 to December 31, 2019)

(Unit: thousands of yen)

	Shareholders' equity						
	Capital stock	Capital surplus			Retained earnings		Treasury shares
		Legal capital surplus	Other capital surplus	Total capital surplus	Other retained earnings Retained earnings brought forward	Total retained earnings	
Balance at beginning of current period	12,972,579	12,942,579	—	12,942,579	(21,543,238)	(21,543,238)	(17)
Changes of items during period							
Issuance of new shares (exercise of share acquisition rights)	1,898,059	1,898,059		1,898,059			
Profit (loss)					(4,376,258)	(4,376,258)	
Purchase of treasury shares							(20,871)
Disposal of treasury shares			2,498	2,498			5,811
Net changes of items other than shareholders' equity							
Total changes of items during period	1,898,059	1,898,059	2,498	1,900,558	(4,376,258)	(4,376,258)	(15,059)
Balance at end of current period	14,870,639	14,840,639	2,498	14,843,137	(25,919,496)	(25,919,496)	(15,077)

	Shareholders' equity	Share acquisition rights	Total net assets
	Total shareholders' equity		
Balance at beginning of current period	4,371,902	529,897	4,901,799
Changes of items during period			
Issuance of new shares (exercise of share acquisition rights)	3,796,119		3,796,119
Profit (loss)	(4,376,258)		(4,376,258)
Purchase of treasury shares	(20,871)		(20,871)
Disposal of treasury shares	8,310		8,310
Net changes of items other than shareholders' equity		91,016	91,016
Total changes of items during period	(592,699)	91,016	(501,683)
Balance at end of current period	3,779,202	620,913	4,400,116

(4) Statement of cash flows

(Unit: yen in thousands)

	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Cash flows from operating activities		
Profit (loss) before income taxes	(2,748,733)	(4,372,458)
Depreciation	34,699	38,085
Amortization of guarantee deposits	1,186	881
Share-based remuneration expenses	122,944	127,144
Increase (decrease) in provision for retirement benefits	(111)	338
Interest income	(525)	(235)
Insurance claim income	—	(2,736)
Foreign exchange losses (gains)	47,032	83,370
Commission expenses	11,100	10,457
Share issuance cost	29,650	13,932
Gain on reversal of share acquisition rights	(9,826)	(4,197)
Loss on retirement of non-current assets	9,829	—
Decrease (increase) in trade receivables	78,154	(137,554)
Decrease (increase) in inventories	(171,310)	533,824
Decrease (increase) in prepaid expenses	(9,696)	(18,649)
Decrease (increase) in advances paid	(12,386)	(10,644)
Decrease (increase) in consumption taxes refund receivable	(26,414)	(150,469)
Decrease (increase) in other current assets	30,366	15,946
Decrease (increase) in long-term prepaid expenses	4,928	1,225
Increase (decrease) in notes and accounts payable—trade	121,718	(605,187)
Increase (decrease) in accounts payable—other	155,185	124,233
Increase (decrease) in other current liabilities	13,935	5,219
Subtotal	(2,318,271)	(4,347,472)
Interest and dividends received	524	235
Proceeds from insurance income	—	2,736
Commitment fee paid	(3,000)	(2,438)
Income taxes paid	(3,800)	(3,800)
Net cash provided by (used in) operating activities	(2,324,547)	(4,350,738)
Cash flows from investing activities		
Purchase of property, plant and equipment	(31,932)	(24,498)
Purchase of intangible assets	(7,837)	(192,013)
Payments of leasehold and guarantee deposits	(159)	—
Proceeds from refund of leasehold and guarantee deposits	13,747	50
Net cash provided by (used in) investing activities	(26,180)	(216,462)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	4,278,712	3,771,476
Proceeds from issuance of share acquisition rights	23,100	—
Payments for issuance of shares	(29,755)	(11,582)
Purchase of treasury shares	—	(20,871)
Proceeds from disposal of treasury shares	—	(1,022)
Net cash provided by (used in) financing activities	4,272,056	3,740,045
Effect of exchange rate change on cash and cash equivalents	(47,032)	(83,370)
Net increase (decrease) in cash and cash equivalents	1,874,296	(910,525)
Cash and cash equivalents at beginning of period	2,947,059	4,821,355

(Unit: yen in thousands)

	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Cash and cash equivalents at end of period	*1 4,821,355	*1 3,910,830

(5) Notes to going concern assumptions

None to be reported.

(6) Significant accounting policies

1. Valuation basis and method of marketable and investment securities

(1) Shares of subsidiaries

Shares of subsidiaries are stated at cost determined by the moving-average method.

(2) Other marketable and investment securities

Available-for-sale securities with determinable market value

Available-for-sale securities with a determinable market value are stated at fair value based on marketable value on the closing date and other premises. Any valuation differences are included directly in shareholders' equity. Cost of securities sold is calculated by the moving-average method.

Available-for-sale securities without determinable market value

Available-for-sale securities without determinable market value are stated at cost determined by the moving-average method.

2. Valuation basis and method of derivative transactions

Derivative financial instruments are stated at fair value.

3. Valuation basis and method of inventories

Inventories are stated at cost determined by the weighted-average method. The amount on the balance sheet is calculated by reducing book value when the contribution of inventories to profitability declines.

4. Depreciation and amortization of non-current assets

(1) Property, plant and equipment (excluding lease assets)

Depreciation of property, plant and equipment is computed by the straight-line method.

The useful lives of major property, plant and equipment are summarized as follows:

Buildings 3 to 18 years

Tools, furniture and fixtures 4 to 20 years

(2) Intangible assets (excluding lease assets)

Amortization of intangible assets is computed by the straight-line method.

Capitalized software costs are being amortized over the period of the internal use of five years.

(3) Lease assets

Depreciation of lease assets is computed by the straight-line method over the lease term with no residual value.

5. Deferred assets

Share issuance costs and bond issuance costs are recorded as expenses in full at the time of expenditure.

6. Basis for translating assets and liabilities denominated in foreign currencies into Japanese yen

Monetary assets and liabilities denominated in foreign currencies are translated into yen at the spot exchange rates prevailing on the closing date, and resulting gains or losses are credited or charged to income.

7. Basis for reserves and provisions

(1) Allowance for doubtful accounts

The allowance for doubtful accounts is provided at an amount determined based on the historical experience of bad debt with respect to ordinary receivables and an estimate of uncollectible amounts determined by reference to specific doubtful receivables from customers which are experiencing financial difficulties.

For the fiscal year ended December 31, 2018, no allowance for doubtful accounts is provided due to no historical experience of bad debt and no receivable balances that are deemed uncollectible.

(2) Provision for retirement benefits

The provision for retirement benefits is provided based on an estimated amount for retirement benefit obligations as of December 31, 2018.

The Company applies the simplified method to calculate amounts of provision for retirement benefits and retirement benefit expenses. That is, the amount of retirement benefit obligations are the payments required for voluntary retirement as of each fiscal year end.

8. Cash and cash equivalents in the statement of cash flows

Cash and cash equivalents consist of cash on hand, cash in banks which can be withdrawn at any time, and short-term investments with a maturity of three months or less that can easily be converted to cash and are subject to little risk of change in value.

9. Other significant basis for the preparation of financial statements

Accounting for consumption tax

Transactions are recorded at amounts exclusive of consumption tax.

(7) Notes to financial statements

(Balance sheet)

The Company has overdraft and commitment line contracts with three banks in a business relationship to efficiently procure working capital. The status of the bank overdraft and loan commitments based on these contracts at the end of each fiscal year is as follows:

	(Unit: thousands of yen)	
	FY 2018 (as of December 31, 2018)	FY 2019 (as of December 31, 2019)
Total amounts of bank overdraft limit and loan commitment line	1,350,000	1,350,000
Balance of borrowing outstanding	—	—
Unused balance	1,350,000	1,350,000

(Statement of income)

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

	(Unit: thousands of yen)	
	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
	121,317 ^(Note 1)	187,840 ^(Note 2)

(Note 1) A certain batch of TREAKISYM® 25 mg was determined to be unsalable due to its poor external appearance, which resulted in an inventory valuation loss.

(Note 2) A batch of TREAKISYM® 100 mg was determined to be unsalable due to quality issues, resulting in an inventory valuation loss.

- * 2 The selling expenses ratio is roughly 10.6% and 14.2% for the fiscal years ended December 31, 2018 and 2019, respectively, and the general and administrative expenses ratio is roughly 89.4% and 85.8% for the fiscal years ended December 31, 2018 and 2019, respectively.

Major expense items and amounts are as follows:

	(Unit: thousands of yen)	
	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Remuneration for directors (and other officers)	163,971	166,833
Salaries and allowance	339,859	338,543
Retirement benefit expenses	663	555
R&D expenses	1,832,746	2,441,552
Depreciation	18,787	19,362
Fee expenses	443,679	711,781
Promotion expenses	405,467	733,688

- * 3 Total amounts of R&D expenses included in general and administrative expenses

	(Unit: thousands of yen)	
	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
	1,832,746	2,441,552

- * 4 Details of loss on retirement of non-current assets

	(Unit: thousands of yen)	
	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Facilities attached to buildings	9,829—	—

(Statement of changes in equity)

FY 2018 (from January 1, 2018 to December 31, 2018)

1. Type and number of shares issued and treasury shares

(Unit: number of shares)

	At beginning of current period	Increase	Decrease	At end of current period
Shares issued				
Common stock	54,049,224	28,349,700	—	82,398,924
Total	54,049,224	28,349,700	—	82,398,924
Treasury shares				
Common stock	75	—	—	75
Total	75	—	—	75

(Note) Increase of 28,349,700 issued shares of common stock is due to the exercise of share acquisition rights.

2. Share acquisition rights

Company	Description	Type of shares to be issued	Number of shares to be issued				Balance as of December 31, 2018 (thousands of yen)
			At beginning of current period	Increase	Decrease	At end of current period	
SymBio Pharmaceuticals Limited	The 39th warrant	Common stock	4,171,000	—	4,171,000	—	—
	The 42nd warrant	Common stock	3,765,200	—	3,765,200	—	—
	The 45th warrant	Common stock	—	20,000,000	20,000,000	—	—
	The 46th warrant	Common stock	—	15,000,000	—	15,000,000	6,600
	The 47th warrant	Common stock	—	15,000,000	—	15,000,000	5,700
	Share acquisition rights as stock options	—	—	—	—	—	517,597
Total			7,936,200	50,000,000	27,936,200	30,000,000	529,897

(Note) The information about the type and number of shares to be issued pertaining to share acquisition rights as stock options is described in “Stock options.”

(Main reasons for increase/decrease)

Decrease due to exercise of the 39th warrant: 4,171,000 shares

Decrease due to exercise of the 42nd warrant: 3,765,200 shares

Increase due to issuance of the 45th warrant: 20,000,000 shares

Decrease due to exercise of the 45th warrant: 20,000,000 shares

Increase due to issuance of the 46th warrant: 15,000,000 shares

Increase due to issuance of the 47th warrant: 15,000,000 shares

3. Dividends

None to be reported.

FY 2019 (from January 1, 2019 to December 31, 2019)

1. Type and number of shares issued and treasury shares

(Unit: number of shares)

	At beginning of current period	Increase	Decrease	At end of current period
Shares issued				
Common stock	82,398,924	17,126,800	73,088,043	26,437,681
Total	82,398,924	17,126,800	73,088,043	26,437,681
Treasury shares				
Common stock	75	31,050	8,532	22,593
Total	75	31,050	8,532	22,593

- (Notes)
1. Increase of 17,126,800 issued shares of common stock is due to the exercise of share acquisition rights
 2. Decrease of 73,088,043 issued shares of common stock is due to the 1-for-4 reverse stock split of common share conducted on July 1, 2019.
 3. Increase of 31,050 issued shares of common stock is due to the purchase of fractional shares.
 4. Of the decrease of 8,532 common treasury shares, 57 were due to the 1-for-4 reverse stock split of common share conducted on July 1, 2019, 6,775 were due to exercise of share acquisition rights, and 1,700 were sold to owners of fractional shares.

2. Share acquisition rights

Company	Description	Type of shares to be issued	Number of shares to be issued				Balance as of December 31, 2018 (thousands of yen)
			At beginning of current period	Increase	Decrease	At end of current period	
SymBio Pharmaceuticals Limited	The 46th warrant	Common stock	15,000,000	—	15,000,000	—	—
	The 47th warrant	Common stock	15,000,000	—	13,325,000	1,675,000	2,546
	Share acquisition rights as stock options	—	—	—	—	—	618,367
Total			30,000,000	—	28,325,000	1,675,000	620,913

(Note) The information about the type and number of shares to be issued pertaining to share acquisition rights as stock options is described in “Stock options.”

(Main reasons for increase/decrease)

Decrease due to exercise of the 46th warrant: 15,000,000 shares

Decrease due to the 1-for-4 consolidation of the common shares of the 47th warrant conducted on July 1, 2019: 11,250,000 shares

Decrease due to exercise of the 47th warrant: 2,075,000 shares

3. Dividends

None to be reported.

(Statement of cash flows)

*1. Cash and cash equivalents as of the fiscal year end are reconciled to the accounts reported in the balance sheet as follows:

	(Unit: thousands of yen)	
	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Cash and deposits	4,821,355	3,910,830
Cash and cash equivalents	4,821,355	3,910,830

(Financial instruments)

1. Financial instruments

(1) Policies for financial instruments

The Company procures the funds necessary in light of the pipeline development plan (primarily by third-party allotment and offering by new share issuance). A temporary surplus fund is invested in financial instruments which are highly safe and liquid.

As a principle, the Company does not enter into derivative transactions for speculative trading purposes but uses them within the scope prescribed in the Company's internal rules.

(2) Types of financial instruments and related risks

Operating receivables such as accounts receivable—trade and advances paid in connection with joint development are exposed to the credit risk of customers and joint development partners. Operating receivables denominated in foreign currencies are exposed to foreign exchange fluctuation risk.

The Company intends to invest in marketable and investment securities which have a relatively low risk of falling below initial investments, however, it might entail a finite risk.

Operating payables such as accounts payable—trade and accounts payable—other are mostly due within 75 days. Operating payables denominated in foreign currencies are exposed to foreign exchange fluctuation risk.

The Company uses derivative transactions to avoid foreign exchange fluctuation risks and enters into forward exchange contracts within the scope prescribed in the internal rules based on balances of receivables and payables denominated in foreign currencies as well as the actual volume of export and import transactions denominated in foreign currencies.

Lease and guarantee deposits are mostly security deposits related to leased office premises and their refunds are subject to the credit risk of the lessor.

(3) Risk management for financial instruments

(i) Monitoring of credit risks (the risk that customers or counterparties may default on obligations)

In accordance with the Company's internal credit policies for managing credit risk arising from operating receivables, the Company's marketing department periodically monitors the creditworthiness of major customers and monitors due dates and outstanding balances by individual customers. In addition, the Company is making efforts to promptly identify and mitigate risks of bad debts from customers who are having financial difficulties.

The Company enters into derivative transactions only with financial institutions which have a sound credit profile in order to mitigate the counterparty risk.

(ii) Monitoring of market risk (the risk arising from fluctuations in foreign exchange rates, interest rates, and others)

The Company deposits cash primarily with financial institutions with high credit ratings.

For marketable and investment securities, the Company intends to avoid risks of falling below initial investments by investing in securities with a satisfactory credit rating and investment period in accordance with the Company's internal investment policies.

The Company enters into forward exchange contracts in order to avoid foreign exchange fluctuation risks in connection with receivables and payables denominated in foreign currencies.

Followed by appropriate authorization procedures prescribed in the Company's internal rules, the Finance & Accounting department executes and monitors derivative transactions. Monthly transaction performances are reported to the executive management committee.

(iii) Monitoring of liquidity risks (the risk that the Company may not be able to meet its obligations on the scheduled due date)

Based on the report from each department, the responsible department of the Company prepares and updates its cash flow plans on a timely basis and ensures to maintain the liquidity on hand to manage liquidity risk.

(4) Supplementary explanation of the estimated fair value of financial instruments

The fair value of financial instruments is based on their quoted market price, if available. When there is no quoted market price available, fair value is reasonably estimated. Since various assumptions and factors are reflected in

estimating the fair value, different assumptions and factors could result in different fair value. In addition, the notional amounts of derivatives in notes to “Derivative transactions” are not necessarily indicative of the actual market risk involved in derivative transactions.

(5) Concentration of credit risk

As of December 31, 2018, all operating receivables are from one particular major customer.

2. Fair value of financial instruments

The carrying value on the balance sheet, fair values, and their differences are as follows. The financial instruments whose fair value is extremely difficult to determine are not included. (See Note 2.)

FY 2018 (as of December 31, 2018)

(Unit: thousands of yen)

	Carrying value on the balance sheet	Fair value	Differences
(1) Cash and deposits	4,821,355	4,821,355	—
(2) Accounts receivable—trade	411,720	411,720	—
(3) Advances paid	31,147	31,147	—
Assets, total	5,264,223	5,264,223	—
(1) Accounts payable—trade	726,100	726,100	—
(2) Accounts payable—other	503,637	503,637	—
(3) Income taxes payable	71,249	71,249	—
Liabilities, total	1,300,988	1,300,988	—
Derivative transactions, total (*)	(16,427)	(16,427)	—

(*) Receivables and liabilities arising from derivative transactions are presented on a net basis and net liabilities are shown in parentheses.

FY 2019 (as of December 31, 2019)

(Unit: thousands of yen)

	Carrying value on the balance sheet	Fair value	Differences
(1) Cash and deposits	3,910,830	3,910,830	—
(2) Accounts receivable—trade	549,275	549,275	—
(3) Advances paid	41,791	41,791	—
Assets, total	4,501,897	4,501,897	—
(1) Accounts payable—trade	120,913	120,913	—
(2) Accounts payable—other	639,482	639,482	—
(3) Income taxes payable	87,756	87,756	—
Liabilities, total	848,153	848,153	—
Derivative transactions, total (*)	—	—	—

(*) Receivables and liabilities arising from derivative transactions are presented on a net basis and net liabilities are shown in parentheses.

(Notes)

1. Fair value measurement of financial instruments and other matters related to securities and derivative transactions

Assets

(1) Cash and deposits, (2) Accounts receivable—trade, and (3) Advances paid

The carrying value is deemed as the fair value since these are scheduled to be settled in a short period of time.

Liabilities

(1) Accounts payable—trade, (2) Accounts payable—other, and (3) Income taxes payable

The carrying value is deemed as the fair value since these are scheduled to be settled in a short period of time.

Derivative transactions

See notes to “Derivative transactions.”

2. Financial instruments whose fair value is extremely difficult to determine

(Unit: thousands of yen)

	FY 2018 (as of December 31, 2018)	FY 2019 (as of December 31, 2019)
Lease and guarantee deposits	71,378	70,446

Lease and guarantee deposits are not included in the above table since no market quote is available and their fair value is extremely difficult to determine.

3. The redemption schedule for monetary assets and securities with maturities after the closing date

FY 2018 (as of December 31, 2018)

(Unit: thousands of yen)

	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Deposits	4,821,265	—	—	—
Accounts receivable–trade	411,720	—	—	—
Advances paid	31,147	—	—	—
Total	5,264,133	—	—	—

FY 2019 (as of December 31, 2019)

(Unit: thousands of yen)

	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Deposits	3,910,739	—	—	—
Accounts receivable–trade	549,275	—	—	—
Advances paid	41,791	—	—	—
Total	4,501,806	—	—	—

(Derivative transactions)

1. Derivative transactions to which hedge accounting is not applied

Currency-related transactions

FY 2018 (as of December 31, 2018)

(Unit: thousands of yen)

Classification	Type	Notional amount	Portion due after one year included herein	Fair value	Unrealized gain (loss)
OTC transactions	Forward exchange contract Buy Euro	578,438	—	(16,427)	(16,427)
Total		578,438	—	(16,427)	(16,427)

(Note) Fair value measurement

The fair value is measured based on the quoted prices obtained from financial institutions with which the Company has a business relationship.

FY 2019 (as of December 31, 2019)

None to be reported.

2. Derivative transactions to which hedge accounting is applied

None to be reported.

(Retirement benefits)

1. Outline of retirement benefit plans

The Company has adopted a defined contribution pension plan. A lump-sum payment plan (non-contributory plan) is applied for certain employees based on the Company's internal rules for retirement benefits.

The simplified method is applied to calculate amounts of provision for retirement benefits and retirement benefit expenses.

2. Retirement benefit plan under the simplified method

(1) The reconciliation of provision for retirement benefits at the beginning and the end of the fiscal year under the simplified method is as follows:

	(Unit: thousands of yen)	
	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Provision for retirement benefits at beginning of period	1,392	1,281
Retirement benefit expenses	325	431
Paid amount of retirement benefits	(436)	(93)
Provision for retirement benefits at end of period	1,281	1,619

(2) The reconciliation of retirement benefit obligations or pension assets at the end of the fiscal year and provision for retirement benefits and the prepaid pension cost on the balance sheet is as follows:

	(Unit: thousands of yen)	
	FY 2018 (as of December 31, 2018)	FY 2019 (as of December 31, 2019)
Retirement benefit obligations under non-contributory plan	1,281	1,619
Net defined benefit liability or asset on the balance sheet	1,281	1,619
Provision for retirement benefits	1,281	1,619
Net defined benefit liability or asset on the balance sheet	1,281	1,619

(3) Retirement benefit expenses

Retirement benefit expenses calculated under the simplified method FY 2018: 325 thousand yen
FY 2019: 431 thousand yen

3. Defined contribution pension plan

The amount of the Company's contribution to the defined contribution pension plan for the fiscal years ended December 31, 2018 and 2019 were 1,942 thousand yen and 1,024 thousand yen, respectively.

(Stock options)

1. The account title and the amount of stock options charged as expenses

(Unit: thousands of yen)

	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Selling, general and administrative expenses	122,944	127,144

2. The account title and the amount of income recognized for vested shares that expired unexercised

(Unit: thousands of yen)

	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Gain on reversal of share acquisition rights	9,826	4,197

3. Description of stock options and changes in the size of stock options

The following information is based on stock options that were available in the fiscal year ended December 31, 2019.

The number of stock options is converted into the number of shares.

On July 1, 2019, we conducted a 1-for-4 reverse stock split of common share reverse stock split of common share, and figures below reflect its impact.

(1) Description of stock options

	The 17th Warrant	The 19th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 3 Audit & Supervisory Board member of the Company 1 Total 4	External collaborators 2
Class and number of shares to be issued upon the exercise of the stock options	Common stock 18,000 shares	Common stock 3,125 shares
Grant date	March 18, 2009	March 18, 2009
Vesting conditions	1. A person to whom these stock options are granted (hereinafter, "Person Granted") must have the status as the Company's director, Audit & Supervisory Board member, advisor, or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or compulsory retirement; if otherwise the Board of Directors approves; or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	The vesting period is not fixed.	Same as on the left
Exercise period	From March 19, 2011 to March 18, 2019	From March 19, 2011 to March 18, 2019

	The 20th Warrant	The 21st Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 6 Audit & Supervisory Board member of the Company 1 Total 7	Employees of the Company 50
Class and number of shares to be issued upon the exercise of the stock options	Common stock 90,250 shares	Common stock 81,625 shares
Grant date	March 31, 2010	March 31, 2010
Vesting conditions	1. The Person Granted must have the status as the Company's director, Audit & Supervisory Board member, advisor, or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or compulsory retirement; if otherwise the Board of Directors approves; or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	The vesting period is not fixed.	Same as on the left
Exercise period	From April 1, 2012 to March 31, 2020	From April 1, 2012 to March 31, 2020

	The 22nd Warrant	The 23rd Warrant
Individuals covered by the plan and number of persons granted stock options	External collaborators 13	Employees of the Company 9
Class and number of shares to be issued upon the exercise of the stock options	Common stock 38,250 shares	Common stock 8,000 shares
Grant date	March 31, 2010	October 15, 2010
Vesting conditions	1. The Person Granted must have the status as the Company's director, Audit & Supervisory Board member, advisor, or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or compulsory retirement; if otherwise the Board of Directors approves; or if the Person Granted is an external collaborator. 2. The Company's stock must be listed on a stock exchange.	Same as on the left
Vesting period	The vesting period is not fixed.	Same as on the left
Exercise period	From April 1, 2012 to March 31, 2020	From October 15, 2012 to October 14, 2020

	The 24th Warrant	The 25th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 5	Employees of the Company 59
Class and number of shares to be issued upon the exercise of the stock options	Common stock 48,000 shares	Common stock 48,750 shares
Grant date	March 31, 2011	March 31, 2011
Vesting conditions	<p>1. The Person Granted must have the status as the Company's director, Audit & Supervisory Board member, advisor, or employee at the time of exercise. However, this is not necessarily the case if the Person Granted retires due to the expiry of her/his term or compulsory retirement; or if otherwise the Board of Directors approves or if the Person Granted is an external collaborator.</p> <p>2. The Company's stock must be listed on a stock exchange.</p>	Same as on the left
Vesting period	The vesting period is not fixed.	Same as on the left
Exercise period	From March 31, 2013 to March 30, 2021	From March 31, 2013 to March 30, 2021

	The 26th Warrant	The 27th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 4	Employees of the Company 70
Class and number of shares to be issued upon the exercise of the stock options	Common stock 90,625 shares	Common stock 107,675 shares
Grant date	May 2, 2012	May 2, 2012
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1) to (6).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise conditions *(2) and (5).	Same as on the left
Exercise period	From April 18, 2014 to April 17, 2022	From April 18, 2014 to April 17, 2022

	The 30th Warrant	The 31st Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 5	Employees of the Company 68
Class and number of shares to be issued upon the exercise of the stock options	Common stock 29,000 shares	Common stock 31,000 shares
Grant date	May 29, 2013	May 29, 2013
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1) to (6).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise conditions *(2) and (5).	Same as on the left
Exercise period	From May 15, 2015 to May 14, 2023	From May 15, 2015 to May 14, 2023

	The 32nd Warrant	The 33rd Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 5	Employees of the Company 68
Class and number of shares to be issued upon the exercise of the stock options	Common stock 63,000 shares	Common stock 82,500 shares
Grant date	April 30, 2014	April 30, 2014
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1), (3), (4), (7), and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(7).	Same as on the left
Exercise period	From April 16, 2017 to April 15, 2024	From April 16, 2017 to April 15, 2024

	The 35th Warrant	The 36th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 6	Employees of the Company 61
Class and number of shares to be issued upon the exercise of the stock options	Common stock 51,050 shares	Common stock 78,000 shares
Grant date	April 10, 2015	April 10, 2015
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1), (3), (4), (7), and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(7).	Same as on the left
Exercise period	From March 27, 2018 to March 26, 2025	From March 27, 2018 to March 26, 2025

	The 37th Warrant	The 38th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 6	Employees of the Company 73
Class and number of shares to be issued upon the exercise of the stock options	Common stock 59,125 shares	Common stock 98,750 shares
Grant date	April 14, 2016	April 14, 2016
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1), (3), (4), (7), and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(7).	Same as on the left
Exercise period	From March 31, 2019 to March 30, 2026	From March 31, 2019 to March 30, 2026

	The 40th Warrant	The 41st Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 6	Employees of the Company 71
Class and number of shares to be issued upon the exercise of the stock options	Common stock 70,000 shares	Common stock 112,800 shares
Grant date	April 24, 2017	April 24, 2017
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1), (3), (4), (7), and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(7).	Same as on the left
Exercise period	From March 30, 2020 to March 29, 2027	From March 30, 2020 to March 29, 2027

	The 43rd Warrant	The 44th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 6	Employees of the Company 74
Class and number of shares to be issued upon the exercise of the stock options	Common stock 76,250 shares	Common stock 116,200 shares
Grant date	April 26, 2018	April 26, 2018
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1), (3), (4), (7), and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(7).	Same as on the left
Exercise period	From March 30, 2021 to March 29, 2028	From March 30, 2021 to March 29, 2028

	The 48th Warrant	The 49th Warrant
Individuals covered by the plan and number of persons granted stock options	Directors of the Company 6	Employees of the Company 92
Class and number of shares to be issued upon the exercise of the stock options	Common stock 78,750 shares	Common stock 179,125 shares
Grant date	April 22, 2019	April 22, 2019
Vesting conditions	No specific conditions are prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted, except for certain vesting conditions stipulated in the exercise conditions. The exercise conditions are described in *(1), (3), (4), (7), and (8).	Same as on the left
Vesting period	The period that fulfills the requirement of the exercise condition *(7).	Same as on the left
Exercise period	From March 30, 2022 to March 29, 2029	From March 30, 2022 to March 29, 2029

*(1) Fractions less than one unit of a share acquisition right shall be unexercisable.

(2) The Person Granted may exercise all or part of the rights in accordance with the following classifications:

The 26th and the 27th warrants

- (a) Those who were granted the share acquisition rights may exercise the rights within the limit of one-fourth (1/4) from April 18, 2014 to April 17, 2015.
- (b) Those who were granted the share acquisition rights may exercise the rights within the limit of one-half (1/2) from April 18, 2015 to April 17, 2016.
- (c) Those who were granted the share acquisition rights may exercise the rights within the limit of three-fourths (3/4) from April 18, 2016 to April 17, 2017.
- (d) Those who were granted the share acquisition rights may exercise all the rights from April 18, 2017 to April 17, 2022.

The 30th and the 31st warrants

- (a) Those who were granted the share acquisition rights may exercise the rights within the limit of one-fourth (1/4) from May 15, 2015 to May 14, 2016.
 - (b) Those who were granted the share acquisition rights may exercise the rights within the limit of one-half (1/2) from May 15, 2016 to May 14, 2017.
 - (c) Those who were granted the share acquisition rights may exercise the rights within the limit of three-fourths (3/4) from May 15, 2017 to May 14, 2018.
 - (d) Those who were granted the share acquisition rights may exercise all the rights from May 15, 2018 to May 14, 2023.
- (3) The Person Granted shall exercise the rights starting from the date of resolution by the below-mentioned shareholders' meeting or the Board of Directors' meeting until one day before the effective date of the Organizational Restructuring as followed, regardless of the conditions of the exercise period originally stipulated, when the Organizational Restructuring is approved by the resolution of the Company's shareholders' meeting (including the case where resolution of a shareholders' meeting is deemed to exist pursuant to the provision of Article 319 of the Companies Act) or the Board of Directors' meeting (limited to the case where no shareholders' meeting is required for the said Organizational Restructuring) before the exercise period of the share acquisition rights comes into effect: an absorption-type merger or an incorporation-type merger where the Company becomes a dissolving company and an absorption-type split or an incorporation-type company split where the Company becomes a split company, or a share exchange or a share transfer where the Company becomes a wholly-owned subsidiary (collectively, "Organizational Restructuring" as mentioned above).
- (4) The share acquisition rights shall not be offered for pledge or disposed of in any other way.
- (5) A person to whom these stock options are granted ("Person Granted") must have the status as the Company's director, Audit & Supervisory Board member, or employee of the Company or its affiliates at the time of exercise. However, this is not necessarily the case where:
- (a) The Person Granted is a director or Audit & Supervisory Board member of the Company or its affiliates and retires due to the expiry of her/his term.

- (b) The Person Granted is an employee of the Company or its affiliates and retires due to compulsory retirement.
 - (c) The Person Granted is a director, Audit & Supervisory Board member, or employee of the Company or its affiliates and the Board of Directors resolves that he/she has resigned or retired with honorable recognition.
- (6) In the event that:
- (a) The Person Granted dies before the exercise period comes into effect, the beneficiary/ies shall exercise the rights of up to one-half (1/2) within six (6) months from the date of inheritance, or
 - (b) The Person Granted dies during the exercise period, the beneficiary/ies shall exercise all the rights within six (6) months from the date of inheritance. However, in the event that the beneficiary/ies dies, the rights shall be discarded and shall not be exercised by his/her beneficiary/ies.
- (7) The Person Granted must have the status as a director or employee of the Company or its affiliates at the time of exercise. However, this is not necessarily the case where:
- (a) The Person Granted is a director of the Company or its affiliates and retires due to the expiry of her/his term.
 - (b) The Person Granted is an employee of the Company or its affiliates and retires due to compulsory retirement.
 - (c) The Person Granted is a director or employee of the Company or its affiliates and the Board of Directors resolves that he/she has resigned or retired with honorable recognition.
- (8) In the event that the Person Granted dies, the beneficiary/ies shall be able to succeed and exercise the share acquisition rights as prescribed in the allotment agreement for share acquisition rights entered into between the Company and the Person Granted. However, in the event that the beneficiary/ies dies, the rights shall be discarded and shall not be exercised by his/her beneficiary/ies.

(2) Changes in the size of stock options

(a) Number of stock options

(Unit: number of shares)

	The 17th Warrant	The 19th Warrant	The 20th Warrant	The 21st Warrant
Grant date	March 18, 2009	March 18, 2009	March 31, 2010	March 31, 2010
Non-vested shares:				
At the beginning of the year	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	1,000	625	86,125	33,375
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	1,000	625	—	750
At the end of the year	—	—	86,125	32,625

(Unit: number of shares)

	The 22nd Warrant	The 23rd Warrant	The 24th Warrant	The 25th Warrant
Grant date	March 31, 2010	October 15, 2010	March 31, 2011	March 31, 2011
Non-vested shares:				
At the beginning of the year	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	38,250	2,500	48,000	20,875
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	—	—	—	375
At the end of the year	38,250	2,500	48,000	20,500

(Unit: number of shares)

	The 26th Warrant	The 27th Warrant	The 30th Warrant	The 31st Warrant
Grant date	May 2, 2012	May 2, 2012	May 29, 2013	May 29, 2013
Non-vested shares:				
At the beginning of the year	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	90,625	48,825	29,000	13,500
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	—	2,625	—	700
At the end of the year	90,625	46,200	29,000	12,800

(Unit: number of shares)

	The 32nd Warrant	The 33rd Warrant	The 35th Warrant	The 36th Warrant
Grant date	April 30, 2014	April 30, 2014	April 10, 2015	April 10, 2015
Non-vested shares:				
At the beginning of the year	—	—	—	—
Granted	—	—	—	—
Expired	—	—	—	—
Vested	—	—	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	17,250	22,025	14,050	33,750
Vested	—	—	—	—
Exercised	—	1,275	—	6,875
Expired	—	—	—	—
At the end of the year	17,250	20,750	14,050	26,875

(Unit: number of shares)

	The 37th Warrant	The 38th Warrant	The 40th Warrant	The 41st Warrant
Grant date	April 14, 2016	April 14, 2016	April 24, 2017	April 24, 2017
Non-vested shares:				
At the beginning of the year	46,750	48,675	60,000	68,550
Granted	—	—	—	—
Expired	—	—	—	9,500
Vested	46,750	48,675	23,750	—
At the end of the year	—	—	36,250	59,050
Vested shares:				
At the beginning of the year	12,375	9,625	10,000	6,500
Vested	46,750	48,675	23,750	—
Exercised	4,125	7,450	—	—
Expired	—	450	—	—
At the end of the year	55,000	50,400	33,750	6,500

(Unit: number of shares)

	The 43rd Warrant	The 44th Warrant	The 48th Warrant	The 49th Warrant
Grant date	April 26, 2018	April 26, 2018	April 22, 2019	April 22, 2019
Non-vested shares:				
At the beginning of the year	76,250	93,575	—	—
Granted	—	—	78,750	179,125
Expired	—	15,250	5,000	24,500
Vested	33,750	—	—	—
At the end of the year	42,500	78,325	73,750	154,625
Vested shares:				
At the beginning of the year	—	7,500	—	—
Vested	33,750	—	—	—
Exercised	—	—	—	—
Expired	—	—	—	—
At the end of the year	33,750	7,500	—	—

(b) Per share prices

	The 17th Warrant	The 19th Warrant	The 20th Warrant	The 21st Warrant
Grant date	March 18, 2009	March 18, 2009	March 31, 2010	March 31, 2010
Exercise price (yen) (Note 1)	4,676	4,676	2,340	2,340
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	0	0	0	0

	The 22nd Warrant	The 23rd Warrant	The 24th Warrant	The 25th Warrant
Grant date	March 31, 2010	October 15, 2010	March 31, 2011	March 31, 2011
Exercise price (yen) (Note 1)	2,340	2,340	2,728	2,728
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	0	0	0	0

	The 26th Warrant	The 27th Warrant	The 30th Warrant	The 31st Warrant
Grant date	May 2, 2012	May 2, 2012	May 29, 2013	May 29, 2013
Exercise price (yen) (Note 1)	2,220	2,220	3,196	3,196
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen) (Note 2)	(a) 716 (b) 748 (c) 780 (d) 808	(a) 716 (b) 748 (c) 780 (d) 808	(a) 2,344 (b) 2,408 (c) 2,468 (d) 2,524	(a) 2,344 (b) 2,408 (c) 2,468 (d) 2,524

	The 32nd Warrant	The 33rd Warrant	The 35th Warrant	The 36th Warrant
Grant date	April 30, 2014	April 30, 2014	April 10, 2015	April 10, 2015
Exercise price (yen) (Note 1)	1	1	1	1
Average stock price at the time of exercise (yen)	—	656	—	705
Fair value price at grant date (yen) (Note 2)	916	916	1,224	1,224

	The 37th Warrant	The 38th Warrant	The 40th Warrant	The 41st Warrant
Grant date	April 14, 2016	April 14, 2016	April 24, 2017	April 24, 2017
Exercise price (yen)	1	1	1	1
Average stock price at the time of exercise (yen)	728	674	—	—
Fair value price at grant date (yen)	1,088	1,088	812	812

	The 43rd Warrant	The 44th Warrant	The 48th Warrant	The 49th Warrant
Grant date	April 26, 2018	April 26, 2018	April 22, 2019	April 22, 2019
Exercise price (yen)	1	1	1	1
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	792	792	776	776

(Notes) 1. The Company increased its capital through the public offering on December 4, 2013 and through the third-party allotment on December 25, 2013, at the per share amount less than the exercise price of options. Thus, the exercise amounts above are stated after applying the price adjustments clause.

2. (a), (b), (c), and (d) above correspond to each of (a), (b), (c), and (d) of the exercise periods as previously described in 3. (1) *(2).

4. Method for estimating the fair value of the stock options

The fair value of the stock options that were granted during this fiscal year is estimated based on the following method:

(1) Estimate technique used: Black-Scholes Option Pricing Model

(2) Major assumptions and estimate method

	The 48th Warrant	The 49th Warrant
Volatility of stock price ^(Note 1)	58.09%	58.09%
Estimated remaining period ^(Note 2)	2.9 years	2.9 years
Estimated dividend ^(Note 3)	0 yen per share	0 yen per share
Risk-free interest rate ^(Note 4)	(0.154)%	(0.154)%

(Notes) 1. The volatility was calculated based on the actual stock prices from May 14, 2016 to April 22, 2019.

2. The period from the allotment date to the start date of the exercise period is used.

3. The Company estimates dividends to be zero since no dividends have been paid in the past.

4. This represents yields of Japanese government bonds corresponding to the estimated remaining outstanding period.

5. Estimate of the number of stock options vested

The number of expired shares is estimated based on the historical turnover ratio.

(Asset retirement obligations)

The Company has future restoration obligations related to leasehold contracts for office premises. Carrying the balance of lease and guarantee deposits as an asset, the Company reasonably estimates non-recoverable amounts of lease and guarantee deposits under lease contracts and records the amount attributable to the respective fiscal year as expenses, instead of accounting for asset retirement obligations by recognizing a liability and an associated asset.

(Segment information)

[Segment information]

FY 2018 (from January 1, 2018 to December 31, 2018) and FY 2019 (from January 1, 2019 to December 31, 2019)

Segment information is omitted since the Company operates within a single segment, which includes the R&D, manufacturing, and marketing of pharmaceutical drugs and other related activities.

[Related information]

FY 2018 (from January 1, 2018 to December 31, 2018)

1. Information by product and service

Information by product and service is omitted since external sales of a single service category account for more than 90% of net sales stated in the statement of income.

2. Information about geographical areas

(1) Net sales

Net sales information about geographical areas is omitted since external sales to Japanese customers account for more than 90% of net sales stated in the statement of income.

(2) Property, plant and equipment

None to be reported as all property, plant and equipment are located in Japan.

3. Information by the major customer

(Unit: thousands of yen)

Name of customer	Net sales	Name of related segment
Eisai Co., Ltd.	3,648,493	Pharmaceutical businesses including the research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities

FY 2019 (from January 1, 2019 to December 31, 2019)

1. Information by product and service

Information by product and service is omitted since external sales of a single service category account for more than 90% of net sales stated in the statement of income.

2. Information about geographical areas

(1) Net sales

Net sales information about geographical areas is omitted since external sales to Japanese customers account for more than 90% of net sales stated in the statement of income.

(2) Property, plant and equipment

None to be reported as all property, plant and equipment are located in Japan.

3. Information by the major customer

(Unit: thousands of yen)

Name of customer	Net sales	Name of related segment
Eisai Co., Ltd.	2,831,272	Pharmaceutical businesses including the research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities

[Information about impairment loss on non-current assets by reportable segment]

FY 2018 (from January 1, 2018 to December 31, 2018) and FY 2019 (from January 1, 2019 to December 31, 2019)

Information by segment is omitted since the Company operates within a single segment.

[Information about the amortization and unamortized balance of goodwill by reportable segment]

FY 2018 (from January 1, 2018 to December 31, 2018) and FY 2019 (from January 1, 2019 to December 31, 2019)

None to be reported.

[Information about the gain on bargain purchase by reportable segment]

FY 2018 (from January 1, 2018 to December 31, 2018) and FY 2019 (from January 1, 2019 to December 31, 2019)

None to be reported.

(Affiliated party information)

Transactions with affiliated parties

Officer(s) and major individual shareholder(s) of the Company

FY 2018 (from January 1, 2018 to December 31, 2018)

Category	Name of company or person	Location	Capital or investment (thousands of yen)	Business details or profession	Ratio of voting rights and other forms of ownership (ownership) (%)	Relationships with affiliated parties	Transaction details	Transaction amount (thousands of yen)	Account title	Year-end balance (thousands of yen)
Executive	Fuminori Yoshida	—	—	Representative Director, President and Chief Executive Officer of the Company	(Ownership) Direct: 4.18	—	Exercise of share acquisition rights	87,526 (331 thousand shares)	—	—

(Note) This information describes the exercise during the fiscal year under review of share acquisition rights granted based on resolutions at Board of Directors meetings on April 15, 2014 and March 26, 2015.

FY 2019 (from January 1, 2019 to December 31, 2019)

None to be reported.

(Per share information)

	FY 2018 (from January 1, 2018 to December 31, 2018)		FY 2019 (from January 1, 2019 to December 31, 2019)
Net assets per share	212.23 yen	Net assets per share	143.07 yen
Loss per share	(165.54) yen	Loss per share	(189.03) yen

(Notes) 1. While having potential dilutive shares, diluted earnings per share is not provided since the Company reported loss per share.

2. The Company conducted a 1-for-4 consolidation of common shares on July 1, 2019. Net assets per share and loss per share have been calculated based on the assumption that this consolidation was conducted at the beginning of FY 2018.

3. The basis for calculating loss per share is as follows:

	FY 2018 (from January 1, 2018 to December 31, 2018)	FY 2019 (from January 1, 2019 to December 31, 2019)
Loss (thousands of yen)	(2,752,533)	(4,376,258)
Amount not attributable to the shareholders of common stock (thousands of yen)	—	—
Loss attributable to the shareholders of common stock (thousands of yen)	(2,752,533)	(4,376,258)
Average number of shares outstanding during the year (shares)	16,627,779	23,150,655
Description of potential dilutive shares not included in	24 types of share	2 types of share

the earning-per-share calculation due to anti-dilution	acquisition rights (33,758,300 units) in accordance with the Commercial Code of 1890 Article 280 (20) and (21), and the Companies Act Article 236, 238, and 239.	acquisition rights (228,375 units) in accordance with the Commercial Code of 1890 Article 280 (20) and (21), and the Companies Act Article 236, 238, and 239.
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4. The basis for calculating net assets per share is as follows:

	FY 2018 (as of December 31, 2018)	FY 2019 (as of December 31, 2019)
Net assets (thousands of yen)	4,901,799	4,400,116
Amount to be deducted from net assets (thousands of yen)	529,897	620,913
(Of which, share acquisition rights herein [thousands of yen])	(529,897)	(620,913)
Net assets attributable to the shareholders of common stock (thousands of yen)	4,371,902	3,779,202
Number of shares used in the calculation of net assets per share (shares)	20,599,713	26,415,088

(Significant subsequent events)

None to be reported.

6. Other

(1) Change in officers

For information regarding change in officers, see the “Notice of Appointment of Corporate Officer” released on December 19, 2019.

(2) Other

None to be reported.