

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 2017	—	0.00	—	0.00	0.00	—	—	—
FY 2018	—	0.00	—	0.00	0.00	—	—	—
FY 2019 (Forecast)	—	0.00	—	0.00	0.00		—	

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

(Percentages indicate year-on-year changes.)

	Net Sales		Operating Profit (Loss)		Ordinary Profit (Loss)		Profit (Loss)		Earnings (Loss) per Share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Full Year	4,465	16.4	(3,587)	—	(3,612)	—	(3,616)	—	(43.88)

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 2018	82,398,924 shares	FY 2017	54,049,224 shares
(ii) Total number of treasury shares at the end of the year	FY 2018	75 shares	FY 2017	75 shares
(iii) Average number of shares during the year	FY 2018	66,511,113 shares	FY 2017	49,857,917 shares

(Note) Refer to “Per share information” on Page 55 for the number of shares that forms the basis for calculating earnings (loss) per share.

* 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 “Overview of Business Results, etc. (4) Future outlook,” on Page 8 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

[Start of preparations for the establishment of the Company's own salesforce]

On October 16, 2018, the Company announced the start of preparations to establish its own salesforce for the sale of TREAKISYM® in Japan. The Company has in place a business partnership agreement with Eisai Co., Ltd. ("Eisai") signed in August 2008 and expiring in December 2020. The Company considered a number of options for developing the business after December 2020, including business partnerships with other companies. However, the Company has now concluded that transitioning to its own salesforce will best serve the interest of patients and maximize business value. Ahead of the transition to such a salesforce in early 2021, the Company will consider the personnel required for an ideal organizational structure and formulate a detailed investment plan for system configuration and preparation of a logistics and distribution infrastructure. In this way, we aim to engage in activities to provide high-quality information and realize a system for providing products, as well as moving toward our topmost management objective of achieving profitability in the fiscal year ending December 31, 2021 and achieving sustainable growth thereafter.

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

The Company markets TREAKISYM® in Japan through its business partner, Eisai. The Company obtained manufacturing and marketing approval for first-line treatment of low-grade NHL and MCL in December 2016, for recurrent/refractory low-grade non-Hodgkin's lymphoma ^(Note 1) (low-grade NHL) and mantle cell lymphoma (MCL) in October 2010, and for chronic lymphocytic leukemia (CLL) in August 2016. Following this indication expansion, TREAKISYM® is steadily increasing its market share in the area of first-line treatment by replacing R-CHOP, the conventional standard treatment, at medical clinics and hospitals. Further, the combination treatment (BR therapy) of TREAKISYM® and rituximab was newly included in the Guidelines for Tumors of Hematopoietic and Lymphoid Tissues 2018 edited and published by the Japanese Society of Hematology in July 2018, becoming recommended as a choice for standard treatment. With this development, TREAKISYM® has been effectively establishing its foothold as the standard treatment for malignant lymphoma. In-market sales at NHI price basis for the fiscal year ended December 31, 2018 posted an increase of 11.6% year on year.

In addition to the three already-approved indications, the Company has started a Phase III clinical trial for TREAKISYM® targeting recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL) and is currently working on patient enrollment toward obtaining approval. The trial is in response to serious need at clinics and hospitals as there is currently no reliable standard treatment. Patient groups have petitioned to the regulatory authorities for the approval of BR therapy. With a view to providing new therapeutic alternatives and maximizing product value, the Company began the Phase III clinical trial in August 2017 and is diligently working to accumulate cases after completing enrollment of the first patient in January 2018.

In addition to these initiatives toward the approval of additional indications, the Company moved forward to further promote the product life cycle management of TREAKISYM®. In September 2017, it entered into an exclusive license agreement with Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.) ("Eagle"), under which Eagle licensed to the Company rights under Eagle's intellectual property to develop, market, and sell Eagle's TREAKISYM® liquid formulation (RTD and RI liquid formulations) ^(Note 2) in Japan. This will further enable the Company to extend the product life until 2031 through patent protection and maximize the value of TREAKISYM®, while bringing significant benefits to patients and healthcare providers by easing their burdens. The Company has already consulted with the Pharmaceutical and Medical Devices Agency regarding approval for the RTD formulation and is currently preparing an application. Clinical trials primarily aimed at confirming the safety of the RI formulation began in November 2018.

Further, the Company acquired approval for the partial revision to the manufacturing and marketing authorization in July 2018. As a result, TREAKISYM® can now be used in combination with not only rituximab but also obinutuzumab ^(Note 3) (launched in August 2018) for the treatment of CD20 positive follicular lymphoma (FL), a common histologic type of low-grade NHL, allowing the Company to provide patients with a new treatment therapy. In September 2018, the Company applied for the

approval of partial revision to the manufacturing and marketing authorization of TREAKISYM[®] regarding its use as a pre-treatment for regenerative medicine products.

In addition to the intravenous formulation currently under development and on sale, the Company is exploring the potential of TREAKISYM[®] through the development of an oral formulation as the treatment for solid tumors and autoimmune diseases, with an aim to solidify its business through a platform of TREAKISYM[®] products. Amid such initiatives, the Company commenced a Phase I clinical trial for progressive solid tumors in January 2018, with the aims of examining the recommended dosage and administration schedule as well as tolerability and safety of the oral formulation of TREAKISYM[®], and identifying potential target tumor types. After completing enrollment of the first patient in May 2018, the Company is currently working to accumulate cases. Meanwhile, with a view to evaluating the effect of oral administration of TREAKISYM[®] on the immune system, the Company concluded a joint research agreement with Keio University in May 2018 to conduct a pre-clinical trial to verify the therapeutic effect of this product in the treatment of systemic lupus erythematosus (SLE), a form of autoimmune disease with extremely high medical need. The pre-clinical trial is currently underway.

- (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.

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

U.S. licensor Onconova Therapeutics, Inc. (head office: Pennsylvania, U.S.) ("Onconova") is conducting a global Phase III clinical trial (with trial sites in more than 20 countries) of the intravenous formulation of rigosertib for higher-risk myelodysplastic syndromes (HR-MDS) which do not respond to the current standard treatment with hypomethylating agents, which relapse after treatment under the current standard of care, or which are intolerant to hypomethylating agents. The Company is responsible for clinical development in Japan and in December 2015 began the trial. Forty patients were enrolled as of December 31, 2018, and patient enrollment is proceeding. Based on the results of the interim analysis completed in January 2018, the independent Data Monitoring Committee (DMC) recommended that Onconova continues the trial with patient enrollment increased in accordance with statistical criteria in an adaptive design previously agreed upon with the U.S. Food and Drug Administration (FDA). 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 has completed Phase I/II clinical trials in the U.S. for the target indication of first-line HR-MDS (in combination with azacitidine^(Note 4)) and has been conducting a Phase II clinical trial for the target indication of transfusion-dependent lower-risk MDS. The Company started a domestic Phase I clinical trial in June 2017 to confirm the tolerability and safety of the oral formulation of rigosertib for Japanese patients. The first patient was enrolled in October 2017 and patient enrollment is proceeding favorably. After completion of this trial, the Company plans to promptly conduct a Phase I clinical trial for combination therapy with azacitidine and to take part in a global Phase III clinical trial for combination therapy with azacitidine for the first-line treatment of patients with higher-risk MDS, which Onconova currently plans to conduct. The Company also plans and prepares to apply for approval of the oral formulation of rigosertib in Japan in timing alignment with the U.S. and Europe. With respect to the development for the indication of transfusion-dependent lower-risk MDS, the Company will continue to consider participating from Japan in view of the status of development by Onconova.

- (Note 4) About azacitidine (Vidaza[®], marketed by Nippon Shinyaku Co., Ltd.): This hypomethylating agent (for injection) was approved in 2011 upon successful confirmation of extended overall survival for the first time in the Phase III clinical trial for the indication of MDS, and is currently used as a first-line drug for MDS patients who have difficulties in hematopoietic stem cell transplantation. MDS is a preleukemic state, and decrease in tumor suppressor gene due to excessive methylation of DNA is thought to be related to the disease. Hypomethylating agents such as azacitidine are

thought to suppress progress to leukemia by restoring tumor suppressor gene with a deterrent effect against methylation of DNA.

[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 interest of patients, determined to temporarily suspend new patient enrollment for SyB P-1501 from April 21, 2017 due to its concern as to the continuity of The Medicines Company's business regarding the product.

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

Arbitration proceedings against The Medicines Company are still ongoing.

[New drug candidates]

The Company continues to actively seek new drug candidates and in-licensing opportunities globally, aiming to expand both profitability and growth potential over the medium- to long-term, and discussions with multiple potential licensors are ongoing.

In May 2016, the Company established a wholly-owned subsidiary, Symbio Pharma USA, Inc. (head office: Menlo Park, California, U.S., "Symbio Pharma USA"), as the Company's planned strategic base for overseas business development. Acquiring rights to new drug candidates through Symbio Pharma USA as the base of global business will be part of the Company's continued transformation into a global specialty pharmaceutical company with capability to develop and commercialize new drugs in the U.S., Japan, Europe, and other major global markets.

(ii) Markets outside Japan

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

(iii) Business results

As a result of the above, net sales totaled 3,835,530 thousand yen for the fiscal year ended December 31, 2018, primarily reflecting product sales of TREAKISYM[®]. Product sales showed a year-on-year increase of 10.6%. Accordingly, overall net sales rose 11.4% year on year.

Selling, general and administrative expenses totaled 3,828,941 thousand yen (a year-on-year decrease of 23.1%), including research and development ("R&D") expenses of 1,832,746 thousand yen (a year-on-year decrease of 39.3%) primarily due to such factors as expenses related to intravenous and oral formulations of TREAKISYM[®], and expenses associated with clinical trials on the intravenous and oral formulations of rigosertib, and other selling, general and administrative expenses of 1,996,195 thousand yen (a year-on-year increase of 1.8%).

As a result, an operating loss of 2,656,072 thousand yen was recognized for the fiscal year ended December 31, 2018 (an operating loss of 3,947,061 thousand yen for the previous fiscal year). In addition, the Company recorded non-operating expenses totaling 94,854 thousand yen, primarily comprising foreign exchange losses of 54,103 thousand yen, share issuance cost of 29,650 thousand yen, and commission fee of 11,100 thousand yen, and non-operating income totaling 2,196 thousand yen primarily due to dividend income of insurance of 1,501 thousand yen and interest income of 525 thousand yen. This resulted in an ordinary loss of 2,748,730 thousand yen (an ordinary loss of 3,976,784 thousand yen for the previous fiscal year) and a loss of 2,752,533 thousand yen (a loss of 3,977,862 thousand yen for the previous fiscal year).

Segment information has been omitted since the Company operates within a single segment, which includes the research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities.

(2) 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, 2018 stood at 6,239,423 thousand yen, an increase of 1,987,138 thousand yen from the previous fiscal year end. This was primarily due to increases of 1,874,296 thousand yen in cash and deposits, 171,310 thousand yen in merchandise and finished goods, 26,414 thousand yen in consumption taxes receivable, 17,135 thousand yen in software in progress, and 12,386 thousand yen in advances paid, offsetting decreases of 78,154 thousand yen in accounts receivable–trade, 15,844 thousand yen in forward exchange contracts, 14,637 thousand yen in software, 14,420 thousand yen in lease and guarantee deposits, and 12,983 thousand yen in long-term prepaid expenses. Total liabilities stood at 1,337,623 thousand yen, an increase of 324,741 thousand yen, owing mainly to rises of 172,770 thousand yen in accounts payable–other, 121,718 thousand yen in accounts payable–trade, 16,436 thousand yen in income taxes payable, and 16,427 thousand yen in forward exchange contracts.

Under net assets, the decrease of 2,752,533 thousand yen in retained earnings (accumulated deficits) due to the recording of a loss was offset mainly by an increase of 2,210,903 thousand yen in capital stock, and a rise of 2,210,903 thousand yen in legal capital surplus. As a result, total net assets grew by 1,662,397 thousand yen from the previous fiscal year end, to 4,901,799 thousand yen. The equity ratio consequently rose 6.5 percentage points from the previous fiscal year end, to 70.1%.

Cash and cash equivalents (“cash”) as of December 31, 2018 stood at 4,821,355 thousand yen, an increase of 1,874,296 thousand yen from the previous fiscal year end. This was mainly due to a cash increase resulting from the issuance of new shares, despite recording a loss before income taxes.

(Cash flows from operating activities)

Net cash used in operating activities amounted to 2,324,547 thousand yen, compared with 3,816,793 thousand yen in cash used by these activities in the previous fiscal year. Factors having a positive effect on cash included an increase of 155,185 thousand yen in accounts payable–other, share-based compensation expenses of 122,944 thousand yen, an increase of 121,718 thousand yen in accounts payable–trade, a decrease of 78,154 thousand yen in notes and accounts receivable–trade, foreign exchange losses of 47,032 thousand yen, depreciation of 34,699 thousand yen, share issuance cost of 29,650 thousand yen, and 11,100 thousand yen in commission fee. Principal factors having a negative effect on cash were a loss before income taxes of 2,748,733 thousand yen, an increase in inventories of 171,310 thousand yen, an increase in consumption taxes receivable of 26,414 thousand yen, and an increase in advances paid of 12,386 thousand yen.

(Cash flows from investing activities)

Net cash used in investing activities amounted to 26,180 thousand yen, compared with 77,507 thousand yen used in these activities in the previous fiscal year. The principal factor having a positive impact on cash was proceeds from collection of lease and guarantee deposits of 13,747 thousand yen, while the purchase of property, plant and equipment used 31,932 thousand yen.

(Cash flows from financing activities)

Net cash provided by financing activities was 4,272,056 thousand yen, compared with 1,164,230 thousand yen provided by these activities in the previous fiscal year. Proceeds from issuance of shares resulting from exercise of share acquisition rights provided 4,278,712 thousand yen, and proceeds from issuance of share acquisition rights provided 23,100 thousand yen, while payments for issuance of common shares used 29,755 thousand yen.

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

	10th Term Fiscal year ended December 2014	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
Equity ratio (%)	90.7	82.9	73.5	63.6	70.1
Equity ratio on a fair market value basis (%)	155.1	150.8	165.1	278.4	250.9
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 4,465 million yen in the fiscal year ending December 31, 2019, a 16.4% increase from the fiscal year ended December 31, 2018, 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[®], and the oral formulation of TREAKISYM[®], as well as intravenous and oral formulations of rigosertib.

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. To this end, the Company anticipates R&D expenses of 2,508 million yen (1,832 million yen in the fiscal year ended December 31, 2018) and selling, general and administrative expenses of 5,053 million yen (3,828 million yen in the fiscal year ended December 31, 2018), 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 continue to accumulate patient enrollments in the Phase III clinical trial that is already underway.

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 is currently preparing approval applications, and clinical trials aimed primarily at confirming formulation safety are underway in the case of the latter.

Regarding the oral formulation of TREAKISYM[®], the Company will continue to proceed diligently with a Phase I clinical trial that is currently in progress.

[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 trial, and will continue to actively pursue development.

As for the oral formulation of rigosertib, after safety has been confirmed through the domestic Phase I clinical trial as a monotherapy, for which patient enrollment is currently underway, the Company will make preparations to ensure that it can promptly participate in a global Phase III clinical trial for combination therapy with azacitidine, which is currently being planned by Onconova Therapeutics, Inc.

As a result of these planned activities, the Company anticipates net sales of 4,465 million yen, an operating loss of 3,587 million yen, an ordinary loss of 3,612 million yen, and a loss of 3,616 million for the fiscal year ending December 31, 2019.

(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 POC^(Note 5) 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 5) 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 is presently preparing approval applications for the TREAKISYM[®] RTD liquid formulation and has begun clinical trials primarily aimed at confirming the safety of the TREAKISYM[®] RI liquid formulation. With respect to rigosertib, we are currently conducting a global Phase III clinical trial in Japan with the intravenous formulation for the target indication of recurrent/refractory higher-risk MDS and a domestic Phase I clinical trial with the oral formulation as a monotherapy with consideration of targeting the indication of first-line treatment of higher-risk MDS. We are promoting the development of these compounds, aiming 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. 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.

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 we have developed cause 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 6) 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. 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 7), 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. 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 6) 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 7) "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

As a specialty pharmaceutical company without production facilities, the Company 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 has plans to conduct sales on its own in the future, 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, breach of contract, 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, it is difficult to accurately predict 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 8)) in conducting R&D, thereby forming a development framework requiring relatively small staff numbers. With progress in the development of the pipeline 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 8) 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 of contracts with existing members, retirement, or refusal to renew, or should a brain drain occur, 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	10th Term	11th Term	12th Term	13th Term	14th Term
Fiscal Year Ended	December 2014	December 2015	December 2016	December 2017	December 2018
Business revenue (thousands of yen)	1,955,027	1,933,241	2,368,112	3,444,206	3,835,530
Operating profit (loss) (thousands of yen)	(1,303,279)	(2,551,662)	(2,127,049)	(3,947,061)	(2,656,072)
Ordinary profit (loss) (thousands of yen)	(1,110,316)	(2,630,386)	(2,316,806)	(3,976,784)	(2,748,730)

To date, with the exception of the 4th Term, the Company's total R&D expenses and other general 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	10th Term	11th Term	12th Term	13th Term	14th Term
Fiscal Year Ended	December 2014	December 2015	December 2016	December 2017	December 2018
R&D expenses (thousands of yen)	774,103	2,034,714	1,667,098	3,017,812	1,832,746

The Company intends to continue R&D activities, resulting in an increase of cumulative loss for the foreseeable future. With future increases in product sales revenue from additional indications of TREAKISYM[®], the recording of product sales revenue upon early approval for the intravenous and oral formulations of rigosertib, and the income from alliances with pharmaceutical companies, the Company intends to improve business performance as soon as possible; however, there is no guarantee that such assumptions will materialize and swift performance improvement will be realized.

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 14th Term, the fiscal year ended December 31, 2018, the Company recorded a negative balance of 21,543,238 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. 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 specialty pharmaceutical company, the Company requires a large amount of R&D funding. 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 of pharmaceutical drugs and continues to prioritize the use of funds for strengthening its financial position and for continued R&D activities. 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, 2019 or in the medium- to long-term strategy. 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, 2018 the following remained unexercised: 15,000,000 shares of the number of shares issued upon the exercise of the 46th warrant and 15,000,000 shares of the number of shares issued upon the exercise of the 47th warrant.

As of December 31, 2018, the number of potential dilutive shares from the abovementioned warrants ("number of potential

shares”) totaled 33,758,300 shares and comprised 41.0% of the total number of 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 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 plague 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, fall in 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

None to be reported.

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 9) (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 10) 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 ^(Note 11) 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 9) 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 10) "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.

(Note 11) "Specialty pharmaceutical company" refers to a company that develops new drugs and receives a consistently high international reputation for its R&D ability in a particular field of expertise. This is based on the definition in the Ministry of Health, Labour and Welfare's "New vision for the pharmaceutical industry" (2007).

(2) Key performance index

The Company believes that for a pharmaceutical company, building its own salesforce is an important element in the process of bringing new drugs into the market on an ongoing basis and thereby further enhancing corporate value. Accordingly, we plan to move ahead with building an integrated sales system that includes a sales organization, 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, and by working to in-license, promote the development of, and acquire approval for new pipeline products, the Company will establish a high level of stable profitability as soon as possible. The Company 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 C-0501, SyB L-1101, SyB C-1101, SyB L-1701, and SyB L-1702. 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), and SyB C-0501 (oral 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 (Note 11), 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. (PA, 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 sNDAs 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 of an sNDA 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. The Phase II clinical trial for recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL) has been completed, and the Phase III clinical trial is currently being conducted. 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 preparing approval applications for the RTD formulation, and has begun a clinical trial aimed primarily at verifying the safety of the RI formulation.

In addition to the indications of these intravenous formulation products, the Company is exploring the development of an oral formulation of TREAKISYM[®] with a focus on the treatment of solid tumors and autoimmune diseases, further expanding the business potential. To this end, the Company has commenced a Phase I clinical trial for progressive solid tumors with the aim of examining the recommended dosage and schedule as well as tolerability and safety of the oral formulation of TREAKISYM[®], and narrowing down the types of target tumors. Meanwhile, with a view to evaluating the effect of oral administration of TREAKISYM[®] on the immune system, the Company concluded a joint research agreement with Keio University to conduct a pre-clinical trial to verify the therapeutic value of this product in the treatment of systemic lupus erythematosus (SLE), a form of autoimmune disease. Both parties are working on the pre-clinical trial.

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 patients with indolent B-cell non-Hodgkin lymphoma that has progressed following treatment with rituximab or a rituximab-containing regimen. 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 12). It is currently being developed in the U.S. and Europe 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 participating 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 Phase I/II clinical trials 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 as a monotherapy, in order to conduct a Phase I clinical trial in combination with azacitidine 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 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 the need for compliance.

(Note 12) Multikinase inhibitors impede the growth, proliferation, and metastasis of cancer cells, thereby eradicating them.

(4) Medium- to long-term strategy

The Company is pursuing primarily the following five strategies in order to achieve our long range plan (LRP).

(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 amount of chemical compounds after the careful review by internal experts. Using their wealth of experience at the forefront of research and development, 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 13)

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 13) “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

Although the Company has been operating its businesses in Asia centered on Japan, major development is unachievable given the changing environment surrounding Japanese healthcare. Moving forward, it will carry out search and evaluation activities to advance new drug candidates with a view to global development.

(5) Issues to be addressed by the Company

The Company is committed to making improvements in the following areas.

(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 C-0501, SyB L-1101, SyB C-1101, SyB L-1701, and SyB L-1702. 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. The Company has completed a Phase II clinical trial for recurrent/refractory

diffuse large B-cell lymphoma (r/r DLBCL), and a Phase III clinical trial is currently underway. In addition, the Company intends to maximize business value of TREAKISYM[®] by promoting the product life cycle management of the product, and pursue the development of TREAKISYM[®] liquid formulation (RTD and RI liquid formulations) in-licensed from Eagle Pharmaceuticals, Inc. (head office: New Jersey, U.S.). In addition to the intravenous formulation, the Company is also exploring the development of an oral formulation of TREAKISYM[®] with a focus on the treatment of solid tumors and autoimmune diseases, further expanding the business potential. To this end, the Company has commenced a Phase I clinical trial for progressive solid tumors with the aim of examining the recommended dosage and schedule as well as tolerability and safety of the oral formulation of TREAKISYM[®], and narrowing down the types of target tumors.

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 as a monotherapy, in order to conduct a Phase I clinical trial in combination with azacitidine 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.

(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 technical 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 sales organization 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 gains once the intravenous and oral formulations of rigosertib, which are currently under development to treat myelodysplastic syndromes (MDS), join TREAKISYM[®] in the product lineup.

(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. The Company will carry out the search, evaluation, and negotiation activities for new drug candidates, in order to acquire global rights on such candidates, utilizing its experience fostered through its business in Asia.

(v) Securing personnel

The Company places the highest priority on personnel as the Company's principal management resource. We cannot make superior achievements in exploring and developing new drugs without talent. 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 the pipeline development progresses and the number of drug candidates increases.

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 its research and development activities, preparation for establishing its sales organization, and new licensing opportunities, the Company made a resolution at the Board of Directors meeting held on April 9, 2018 to issue the 45th through 47th warrant with Exercise Price Revision Clauses by way of third-party allotment, and received the payment of 2,611,800 thousand yen as of December 31, 2018.

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 2017 (as of December 31, 2017)	FY 2018 (as of December 31, 2018)
Assets		
Current assets		
Cash and deposits	2,947,059	4,821,355
Accounts receivable–trade	489,874	411,720
Merchandise and finished goods	362,514	533,824
Supplies	558	589
Prepaid expenses	73,720	83,372
Advances paid	18,760	31,147
Consumption taxes receivable	98,440	124,855
Forward exchange contracts	15,844	—
Other	29,749	31,624
Total current assets	4,036,522	6,038,490
Non-current assets		
Property, plant and equipment		
Buildings	35,521	46,198
Accumulated depreciation	(7,034)	(9,427)
Buildings, net	28,486	36,771
Tools, furniture and fixtures	49,291	59,541
Accumulated depreciation	(30,968)	(39,361)
Tools, furniture and fixtures, net	18,322	20,180
Construction in progress	64	—
Total property, plant and equipment	46,873	56,951
Intangible assets		
Software	65,583	50,946
Software in progress	3,295	20,430
Total intangible assets	68,878	71,376
Investments and other assets		
Shares of subsidiaries	0	0
Long-term prepaid expenses	14,209	1,225
Lease and guarantee deposits	85,799	71,378
Total investments and other assets	100,008	72,604
Total non-current assets	215,761	200,932
Total assets	4,252,284	6,239,423
Liabilities		
Current liabilities		
Accounts payable–trade	604,382	726,100
Accounts payable–other	330,867	503,637
Income taxes payable	54,813	71,249
Forward exchange contracts	—	16,427
Other	21,427	18,926
Total current liabilities	1,011,490	1,336,342
Non-current liabilities		
Provision for retirement benefits	1,392	1,281
Total non-current liabilities	1,392	1,281
Total liabilities	1,012,882	1,337,623

(Unit: thousands of yen)

	FY 2017 (as of December 31, 2017)	FY 2018 (as of December 31, 2018)
Net assets		
Shareholders' equity		
Capital stock	10,761,676	12,972,579
Capital surplus		
Legal capital surplus	10,731,676	12,942,579
Total capital surplus	10,731,676	12,942,579
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(18,790,705)	(21,543,238)
Total retained earnings	(18,790,705)	(21,543,238)
Treasury shares	(17)	(17)
Total shareholders' equity	2,702,629	4,371,902
Share acquisition rights	536,772	529,897
Total net assets	3,239,402	4,901,799
Total liabilities and net assets	4,252,284	6,239,423

(2) Statement of income

(Unit: thousands of yen)

	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Net sales		
Net sales of goods	3,444,206	3,809,874
Rights income	—	25,656
Total net sales	3,444,206	3,835,530
Cost of sales		
Beginning goods	272,725	362,514
Cost of purchased goods	2,588,681	2,968,586
Purchase allowance and returns	85,951	134,614
Total	2,775,455	3,196,486
Ending goods	362,514	*1 533,824
Cost of goods sold	2,412,940	2,662,661
Gross profit	1,031,266	1,172,869
Selling, general and administrative expenses	*2 *3 4,978,327	*2 *3 3,828,941
Operating profit (loss)	(3,947,061)	(2,656,072)
Non-operating income		
Interest on refund	—	116
Interest income	3,092	525
Dividend income of insurance	1,339	1,501
Other	75	54
Total non-operating income	4,506	2,196
Non-operating expenses		
Commission fee	9,090	11,100
Share issuance cost	14,477	29,650
Foreign exchange losses	10,421	54,103
Other	240	—
Total non-operating expenses	34,229	94,854
Ordinary profit (loss)	(3,976,784)	(2,748,730)
Extraordinary income		
Gain on reversal of share acquisition rights	17,414	9,826
Total extraordinary income	17,414	9,826
Extraordinary losses		
Loss on retirement of non-current assets	—	*4 9,829
Impairment loss	*5 14,692	—
Total extraordinary losses	14,692	9,829
Profit (loss) before income taxes	(3,974,062)	(2,748,733)
Income taxes—current	3,800	3,800
Total income taxes	3,800	3,800
Profit (loss)	(3,977,862)	(2,752,533)

(3) Statement of changes in equity

FY 2017 (from January 1, 2017 to December 31, 2017)

(Unit: thousands of yen)

	Shareholders' equity						
	Capital stock	Capital surplus		Retained earnings		Treasury shares	Total shareholders' equity
		Legal capital surplus	Total capital surplus	Other retained earnings	Total retained earnings		
				Retained earnings brought forward			
Balance at beginning of current period	9,948,298	9,918,298	9,918,298	(14,812,843)	(14,812,843)	(17)	5,053,735
Changes of items during period							
Issuance of new shares (exercise of share acquisition rights)	813,378	813,378	813,378				1,626,756
Profit (loss)				(3,977,862)	(3,977,862)		(3,977,862)
Net changes of items other than shareholders' equity							
Total changes of items during period	813,378	813,378	813,378	(3,977,862)	(3,977,862)	—	(2,351,105)
Balance at end of current period	10,761,676	10,731,676	10,731,676	(18,790,705)	(18,790,705)	(17)	2,702,629

	Share acquisition rights	Total net assets
Balance at beginning of current period	431,135	5,484,870
Changes of items during period		
Issuance of new shares (exercise of share acquisition rights)		1,626,756
Profit (loss)		(3,977,862)
Net changes of items other than shareholders' equity	105,637	105,637
Total changes of items during period	105,637	(2,245,468)
Balance at end of current period	536,772	3,239,402

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

(Unit: thousands of yen)

	Shareholders' equity						
	Capital stock	Capital surplus		Retained earnings		Treasury shares	Total shareholders' equity
		Legal capital surplus	Total capital surplus	Other retained earnings	Total retained earnings		
				Retained earnings brought forward			
Balance at beginning of current period	10,761,676	10,731,676	10,731,676	(18,790,705)	(18,790,705)	(17)	2,702,629
Changes of items during period							
Issuance of new shares (exercise of share acquisition rights)	2,210,903	2,210,903	2,210,903				4,421,806
Profit (loss)				(2,752,533)	(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)	—	1,669,273
Balance at end of current period	12,972,579	12,942,579	12,942,579	(21,543,238)	(21,543,238)	(17)	4,371,902

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

(4) Statement of cash flows

(Unit: yen in thousands)

	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Cash flows from operating activities		
Profit (loss) before income taxes	(3,974,062)	(2,748,733)
Depreciation	29,569	34,699
Amortization of guarantee deposits	1,117	1,186
Share-based compensation expenses	121,205	122,944
Impairment loss	14,692	—
Increase (decrease) in provision for retirement benefits	(4)	(111)
Interest income	(3,092)	(525)
Foreign exchange losses (gains)	42,195	47,032
Commission fee	9,090	11,100
Share issuance cost	14,477	29,650
Gain on reversal of share acquisition rights	(17,414)	(9,826)
Loss on retirement of non-current assets	—	9,829
Decrease (increase) in notes and accounts receivable—trade	(2,403)	78,154
Decrease (increase) in inventories	(89,789)	(171,310)
Decrease (increase) in prepaid expenses	7,437	(9,696)
Decrease (increase) in advances paid	47,705	(12,386)
Decrease (increase) in consumption taxes refund receivable	(63,674)	(26,414)
Decrease (increase) in other current assets	(21,038)	30,366
Decrease (increase) in long-term prepaid expenses	5,495	4,928
Increase (decrease) in notes and accounts payable—trade	282,522	121,718
Increase (decrease) in accounts payable—other	(208,540)	155,185
Increase (decrease) in other current liabilities	7,274	13,935
Other, net	309	—
Subtotal	(3,796,925)	(2,318,271)
Interest and dividend income received	3,132	524
Commitment fee paid	(19,200)	(3,000)
Income taxes paid	(3,800)	(3,800)
Net cash provided by (used in) operating activities	(3,816,793)	(2,324,547)
Cash flows from investing activities		
Purchase of property, plant and equipment	(10,657)	(31,932)
Purchase of intangible assets	(46,364)	(7,837)
Payments for lease and guarantee deposits	(23,550)	(159)
Proceeds from collection of lease and guarantee deposits	3,065	13,747
Net cash provided by (used in) investing activities	(77,507)	(26,180)
Cash flows from financing activities		
Proceeds from issuance of shares resulting from exercise of share acquisition rights	1,146,042	4,278,712
Proceeds from issuance of share acquisition rights	32,560	23,100
Payments for issuance of common shares	(14,372)	(29,755)
Net cash provided by (used in) financing activities	1,164,230	4,272,056
Effect of exchange rate change on cash and cash equivalents	(42,195)	(47,032)
Net increase (decrease) in cash and cash equivalents	(2,772,266)	1,874,296
Cash and cash equivalents at beginning of period	5,719,325	2,947,059
Cash and cash equivalents at end of period	*1 2,947,059	*1 4,821,355

(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 5 to 15 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 2017 (as of December 31, 2017)	FY 2018 (as of December 31, 2018)
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 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
	—	121,317

A certain batch of TREAKISYM[®] 25mg was determined to be unsalable due to its poor external appearance, which resulted in an inventory valuation loss. Inventory at fiscal year-end reflects their book value, taking this inventory valuation loss into account.

- * 2 The selling expenses ratio is roughly 6.1% and 10.6% for the fiscal years ended December 31, 2017 and 2018, respectively, and the general and administrative expenses ratio is roughly 93.9% and 89.4% for the fiscal years ended December 31, 2017 and 2018, respectively.

Major expense items and amounts are as follows:

	(Unit: thousands of yen)	
	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Directors' compensations	166,292	163,971
Salaries and allowance	387,415	339,859
Retirement benefit expenses	769	663
Research and development expenses	3,017,812	1,832,746
Depreciation	11,322	18,787
Compensations	567,117	443,679
Promotion expenses	303,867	405,467

- * 3 Total amounts of research and development expenses included in general and administrative expenses

	(Unit: thousands of yen)	
	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
	3,017,812	1,832,746

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

	(Unit: thousands of yen)	
	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Facilities attached to buildings	—	9,829

- * 5 Impairment loss

FY 2017 (from January 1, 2017 to December 31, 2017)

For the fiscal year ended December 31, 2017, the Company has recorded impairment loss for the following asset:

(Unit: thousands of yen)			
Location	Use	Category	Impairment loss
Head office (Minato-ku, Tokyo)	Idle asset	Tools, furniture and fixtures	14,692

Impairment loss has been recognized for tools, furniture and fixtures with no prospect to be used in the future, writing down the carrying value of the asset to the recoverable amount. The recoverable amount of the asset is zero; therefore, its total carrying value has been recorded as impairment loss under extraordinary loss.

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

None to be reported.

(Statement of changes in equity)

FY 2017 (from January 1, 2017 to December 31, 2017)

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	46,530,824	7,518,400	—	54,049,224
Total	46,530,824	7,518,400	—	54,049,224
Treasury shares				
Common stock	75	—	—	75
Total	75	—	—	75

(Note) Increase of 7,518,400 shares in 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, 2017 (thousands of yen)
			At beginning of current period	Increase	Decrease	At end of current period	
SymBio Pharmaceuticals Limited	The 34th warrant	Common stock	975,800	—	975,800	—	—
	The 39th warrant	Common stock	4,472,000	—	301,000	4,171,000	9,118
	The 42nd warrant	Common stock	—	8,800,000	5,034,800	3,765,200	13,931
	The 3rd unsecured bonds with convertible bond type share acquisition rights	Common stock	2,132,708	—	2,132,708	—	(Note 2)
	Share acquisition rights as stock options	—	—	—	—	—	513,723
Total			7,580,508	8,800,000	8,444,308	7,936,200	536,772

(Notes) 1. 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.”

2. The 3rd unsecured bonds with convertible bond type share acquisition rights are computed by the lump-sum method.

(Main reasons for increase/decrease)

Decrease due to expiration of exercise period of the 34th warrant: 975,800 shares

Decrease due to exercise of the 39th warrant: 301,000 shares

Increase due to issuance of the 42nd warrant: 8,800,000 shares

Decrease due to exercise of the 42nd warrant: 5,034,800 shares

Decrease due to exercise of share acquisition rights for the 3rd unsecured bonds with convertible bond type share acquisition rights: 2,132,700 shares

3. Dividends

None to be reported.

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 shares in 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.

(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 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Cash and deposits	2,947,059	4,821,355
Cash and cash equivalents	2,947,059	4,821,355

2. Details of significant non-cash transactions

Exercise of share acquisition rights for bonds with convertible bond type share acquisition rights

	(Unit: thousands of yen)	
	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Amount of increase in capital stock due to the exercise of share acquisition rights	225,000	—
Amount of increase in legal capital surplus due to the exercise of share acquisition rights	225,000	—
Amount of decrease in corporate bonds due to the exercise of share acquisition rights	450,000	—

(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 2017 (as of December 31, 2017)

(Unit: thousands of yen)

	Carrying value on the balance sheet	Fair value	Differences
(1) Cash and deposits	2,947,059	2,947,059	—
(2) Accounts receivable—trade	489,874	489,874	—
(3) Advances paid	18,760	18,760	—
Assets, total	3,455,694	3,455,694	—
(1) Accounts payable—trade	604,382	604,382	—
(2) Accounts payable—other	330,867	330,867	—
(3) Income taxes payable	54,813	54,813	—
Liabilities, total	990,062	990,062	—
Derivative transactions, total (*)	15,844	15,844	—

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

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.

(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 2017 (as of December 31, 2017)	FY 2018 (as of December 31, 2018)
Lease and guarantee deposits	85,799	71,378

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 2017 (as of December 31, 2017)

(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	2,946,982	—	—	—
Accounts receivable–trade	489,874	—	—	—
Advances paid	18,760	—	—	—
Total	3,455,617	—	—	—

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	—	—	—

(Derivative transactions)

1. Derivative transactions to which hedge accounting is not applied

Currency-related transactions

FY 2017 (as of December 31, 2017)

(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	1,366,477	—	15,844	15,844
Total		1,366,477	—	15,844	15,844

(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 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.

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 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Provision for retirement benefits at beginning of period	1,396	1,392
Retirement benefit expenses	147	325
Paid amount of retirement benefits	(151)	(436)
Provision for retirement benefits at end of period	1,392	1,281

(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 2017 (as of December 31, 2017)	FY 2018 (as of December 31, 2018)
Retirement benefit obligations under non-contributory plan	1,392	1,281
Net defined benefit liability or asset on the balance sheet	1,392	1,281
Provision for retirement benefits	1,392	1,281
Net defined benefit liability or asset on the balance sheet	1,392	1,281

(3) Retirement benefit expenses

Retirement benefit expenses calculated under the simplified method FY 2017: 147 thousand yen
FY 2018: 325 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, 2017 and 2018 were 1,836 thousand yen and 1,942 thousand yen, respectively.

(Stock options)

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

(Unit: thousands of yen)

	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Selling, general and administrative expenses	121,205	122,944

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

(Unit: thousands of yen)

	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Gain on reversal of share acquisition rights	14,077	9,826

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

(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 72,000 shares	Common stock 12,500 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 361,000 shares	Common stock 326,500 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 153,000 shares	Common stock 32,000 shares
Grant date	March 31, 2010	October 15, 2010
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; 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 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 192,000 shares	Common stock 195,000 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 362,500 shares	Common stock 430,700 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 116,000 shares	Common stock 124,000 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 252,000 shares	Common stock 330,000 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 *(5).	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 204,200 shares	Common stock 312,000 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 *(5).	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 236,500 shares	Common stock 395,000 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 *(5).	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 280,000 shares	Common stock 451,200 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 *(5).	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 305,000 shares	Common stock 464,800 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 *(5).	Same as on the left
Exercise period	From March 30, 2021 to March 29, 2028	From March 30, 2021 to March 29, 2028

*(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

The following information is based on stock options that were available in the fiscal year ended December 31, 2018. The number of stock options are calculated to the number of shares.

(a) Number of stock options

(Unit: number of shares)

	The 14th Warrant	The 16th Warrant	The 17th Warrant	The 19th Warrant
Grant date	October 1, 2008	October 1, 2008	March 18, 2009	March 18, 2009
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	28,000	70,000	4,000	2,500
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	28,000	70,000	—	—
At the end of the year	—	—	4,000	2,500

(Unit: number of shares)

	The 20th Warrant	The 21st Warrant	The 22nd Warrant	The 23rd Warrant
Grant date	March 31, 2010	March 31, 2010	March 31, 2010	October 15, 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	344,500	141,500	153,000	10,000
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	—	8,000	—	—
At the end of the year	344,500	133,500	153,000	10,000

(Unit: number of shares)

	The 24th Warrant	The 25th Warrant	The 26th Warrant	The 27th Warrant
Grant date	March 31, 2011	March 31, 2011	May 2, 2012	May 2, 2012
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	192,000	89,000	362,500	212,200
Vested	—	—	—	—
Exercised	—	—	—	—
Expired	—	5,500	—	16,900
At the end of the year	192,000	83,500	362,500	195,300

(Unit: number of shares)

	The 30th Warrant	The 31st Warrant	The 32nd Warrant	The 33rd Warrant
Grant date	May 29, 2013	May 29, 2013	April 30, 2014	April 30, 2014
Non-vested shares:				
At the beginning of the year	21,250	10,925	—	—
Granted	—	—	—	—
Expired	—	200	—	—
Vested	21,250	10,725	—	—
At the end of the year	—	—	—	—
Vested shares:				
At the beginning of the year	94,750	47,975	252,000	136,600
Vested	21,250	10,725	—	—
Exercised	—	—	183,000	41,500
Expired	—	4,700	—	7,000
At the end of the year	116,000	54,000	69,000	88,100

(Unit: number of shares)

	The 35th Warrant	The 36th Warrant	The 37th Warrant	The 38th Warrant
Grant date	April 10, 2015	April 10, 2015	April 14, 2016	April 14, 2016
Non-vested shares:				
At the beginning of the year	173,300	153,500	203,500	268,100
Granted	—	—	—	—
Expired	—	—	—	49,900
Vested	173,300	153,500	16,500	23,500
At the end of the year	—	—	187,000	194,700
Vested shares:				
At the beginning of the year	30,900	29,500	33,000	15,000
Vested	173,300	153,500	16,500	23,500
Exercised	148,000	41,000	—	—
Expired	—	7,000	—	—
At the end of the year	56,200	135,000	49,500	38,500

(Unit: number of shares)

	The 40th Warrant	The 41st Warrant	The 43rd Warrant	The 44th Warrant
Grant date	April 24, 2017	April 24, 2017	April 26, 2018	April 26, 2018
Non-vested shares:				
At the beginning of the year	280,000	391,100	—	—
Granted	—	—	305,000	464,800
Expired	—	90,900	—	60,500
Vested	40,000	26,000	—	30,000
At the end of the year	240,000	274,200	305,000	374,300
Vested shares:				
At the beginning of the year	—	—	—	—
Vested	40,000	26,000	—	30,000
Exercised	—	—	—	—
Expired	—	—	—	—
At the end of the year	40,000	26,000	—	30,000

(b) Per share prices

	The 14th Warrant	The 16th Warrant	The 17th Warrant	The 19th Warrant
Grant date	October 1, 2008	October 1, 2008	March 18, 2009	March 18, 2009
Exercise price (yen) (Note 1)	1,169	1,169	1,169	1,169
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	0	0	0	0

	The 20th Warrant	The 21st Warrant	The 22nd Warrant	The 23rd Warrant
Grant date	March 31, 2010	March 31, 2010	March 31, 2010	October 15, 2010
Exercise price (yen) (Note 1)	585	585	585	585
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	0	0	0	0

	The 24th Warrant	The 25th Warrant	The 26th Warrant	The 27th Warrant
Grant date	March 31, 2011	March 31, 2011	May 2, 2012	May 2, 2012
Exercise price (yen) (Note 1)	682	682	555	555
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen) (Note 2)	0	0	(a) 179 (b) 187 (c) 195 (d) 202	(a) 179 (b) 187 (c) 195 (d) 202

	The 30th Warrant	The 31st Warrant	The 32nd Warrant	The 33rd Warrant
Grant date	May 29, 2013	May 29, 2013	April 30, 2014	April 30, 2014
Exercise price (yen) (Note 1)	(Note 1) 799	(Note 1) 799	1	1
Average stock price at the time of exercise (yen)	—	—	185	183
Fair value price at grant date (yen) (Note 2)	(a) 586 (b) 602 (c) 617 (d) 631	(a) 586 (b) 602 (c) 617 (d) 631	229	229

	The 35th Warrant	The 36th Warrant	The 37th Warrant	The 38th Warrant
Grant date	April 10, 2015	April 10, 2015	April 14, 2016	April 14, 2016
Exercise price (yen)	1	1	1	1
Average stock price at the time of exercise (yen)	185	183	—	—
Fair value price at grant date (yen)	306	306	272	272

	The 40th Warrant	The 41st Warrant	The 43rd Warrant	The 44th Warrant
Grant date	April 24, 2017	April 24, 2017	April 26, 2018	April 26, 2018
Exercise price (yen)	1	1	1	1
Average stock price at the time of exercise (yen)	—	—	—	—
Fair value price at grant date (yen)	203	203	198	198

(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 43rd Warrant	The 44th Warrant
Volatility of stock price ^(Note 1)	56.95%	56.95%
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)	(0.12)%	(0.12)%

(Notes) 1. The volatility was calculated based on the actual stock prices from May 23, 2015 to April 24, 2018.

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.

(Deferred tax accounting)

1. Significant components of deferred tax assets and liabilities

	FY 2017 (as of December 31, 2017)	(Unit: thousands of yen) FY 2018 (as of December 31, 2018)
Deferred tax assets:		
Excess depreciation for lump-sum depreciable assets	2,125	2,631
Excess amortization for deferred assets	1,080,219	799,994
Research and development expenses disallowed	735,170	1,286,703
Accounts payable–other disallowed	1,189	1,755
Provision for retirement benefits disallowed	426	392
Enterprise tax payable disallowed	16,329	28,516
Asset retirement obligations disallowed	933	1,188
Share-based compensation expenses disallowed	127,971	130,759
Impairment loss disallowed	3,653	—
Loss on valuation of inventories disallowed	—	37,438
Loss carried forward	2,925,912	3,524,512
Subtotal	4,893,931	5,776,745
Valuation allowance	(4,893,931)	(5,776,745)
Total deferred tax assets	—	—

2. The reconciliation between the effective tax rates reflected in the financial statements and the statutory tax rate is omitted since the Company reported loss before income taxes for the fiscal years ended December 31, 2017 and 2018.

(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 2017 (from January 1, 2017 to December 31, 2017) and FY 2018 (from January 1, 2018 to December 31, 2018)

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

[Related information]

FY 2017 (from January 1, 2017 to December 31, 2017)

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.	3,382,484	Pharmaceutical businesses including the research and development, manufacturing, and marketing of pharmaceutical drugs and other related activities

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

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

FY 2017 (from January 1, 2017 to December 31, 2017)

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

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

None to be reported.

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

FY 2017 (from January 1, 2017 to December 31, 2017) and FY 2018 (from January 1, 2018 to December 31, 2018)

None to be reported.

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

FY 2017 (from January 1, 2017 to December 31, 2017) and FY 2018 (from January 1, 2018 to December 31, 2018)

None to be reported.

(Affiliated party information)

Transactions with affiliated parties

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

FY 2017 (from January 1, 2017 to December 31, 2017)

None to be reported.

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.

(Per share information)

	FY 2017 (from January 1, 2017 to December 31, 2017)		FY 2018 (from January 1, 2018 to December 31, 2018)
Net assets per share	50.00 yen	Net assets per share	53.06 yen
Loss per share	(79.78) yen	Loss per share	(41.38) yen

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

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

	FY 2017 (from January 1, 2017 to December 31, 2017)	FY 2018 (from January 1, 2018 to December 31, 2018)
Loss (thousands of yen)	(3,977,862)	(2,752,533)
Amount not attributable to the shareholders of common stock (thousands of yen)	—	—
Loss attributable to the shareholders of common stock (thousands of yen)	(3,977,862)	(2,752,533)
Average number of shares outstanding during the year (shares)	49,857,917	66,511,113
Description of potential dilutive shares not included in the earning-per-share calculation due to anti-dilution	24 types of share acquisition rights (11,686,800 units) in accordance with the Commercial Code of 1890 Article 280 (20) and (21), and the Companies Act Article 236, 238, and 239.	24 types of share 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.

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

	FY 2017 (as of December 31, 2017)	FY 2018 (as of December 31, 2018)
Net assets (thousands of yen)	3,239,402	4,901,799
Amount to be deducted from net assets (thousands of yen)	536,772	529,897
(Of which, share acquisition rights herein [thousands of yen])	(536,772)	(529,897)
Net assets attributable to the shareholders of common stock (thousands of yen)	2,702,629	4,371,902
Number of shares used in the calculation of net assets per share (shares)	54,049,149	82,398,849

(Significant subsequent events)

None to be reported.

6. Other

(1) Change in officers

None to be reported.

(2) Other

None to be reported.